Evaluation of the Second European and Developing Countries Clinical Trials Partnership Programme (2014-2016)

Experts Group Report

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1. EXECUTIVE SUMMARY

The European and Developing Countries Clinical Trials Partnership (EDCTP) is a highly relevant programme under the European Union (EU). Its mission is to enhance research capacity and develop new or improved medical interventions that target poverty-related infectious diseases in sub-Saharan Africa. The programme aligns with the EU’s aim of strengthening ties with Africa and addressing poverty, improving health and education, and fostering partnerships. These elements of EDCTP are directly linked with the Millennium Development Goals and the Sustainable Development Goals, which are high priorities for the EU.

This report presents an interim evaluation, completed by an independent panel of experts, of the second EDCTP programme (EDCTP2, 2014-2024). The Panel has assessed the first two and one-half years of EDCTP2 (from June 2014 to December 2016), taking into consideration recommendations from evaluations of the first programme (EDCTP1, 2003-2013). The implementation period is short, and the transition from the first to the second programme was delayed. Hence, any evaluation of the EDCTP2 programme's impact and outcomes must be qualified accordingly.

Clinical trial capacity, particularly for neglected infectious and pandemic diseases, is critically important for Africa. EDCTP is viewed as a key player and holds a unique place in the global health landscape with its focus on clinical trials, developing scientists and fostering research networks. This unique program fills a global health void and complements other EU and international global health efforts.

EDCTP2 has five strategic objectives:

1. Medical Interventions – Increase the number of new or improved medical interventions for poverty-related infectious diseases;
2. Collaboration and Capacity Development – Strengthen cooperation with sub-Saharan Africa through capacity building for clinical trials;
3. European Coordination – Better coordinate, align and integrate national programmes targeting poverty-related infectious diseases;
4. External Partnerships – Increase international cooperation with public and private partners to maximize the impact of funding and research addressing poverty-related infectious diseases;
5. EU Cooperation – Increase impact through collaborations with other EU initiatives, especially related to development assistance.

To assess the progress of EDCTP2 in light of these objectives, the Panel focused on five key areas for evaluation: efficiency, relevance, coherence, effectiveness and added value. This approach involved a desk review and interviews with a variety of stakeholders. Guided by the evaluation Terms of Reference, over 120 relevant documents were reviewed by members of the Panel. Forty-three interviews were conducted with a purposefully-selected sample of individuals and groups.
**Efficiency** – The evaluation of efficiency focused on the competency and economy utilized in pursuit of specific and operational objectives, governance and networking goals. Early indicators show EDCTP2 is progressing efficiently and suggest the programme will attain most of its objectives and targets. All parts of the governance structure are in place with administrative costs below forecast for the evaluation period. A number of areas will require particular attention to ensure efficiency as the programme progresses: alignment of the Participating States (PSSs) with the EDCTP Strategic Research Agenda, processes related to Participating States Initiated Activities (PSIAs), the call and review process, timely approval of annual work plans, long-term strategic planning, the role of the Scientific Advisory Committee (SAC), and external communication.

**Relevance and Appropriateness** – The evaluation focused on the continued relevance of EDCTP2 objectives and the extent to which the programme is appropriate to support EU policy objectives. The current process of prioritization of funding based on the state of product development, changing patterns of disease and emerging opportunities will ensure EDCTP remains relevant in the ever-changing global health landscape. The programme must guard against being "spread too thin" as it encompasses more poverty-related infectious diseases. Clearly, the objectives of EDCTP2 align with and support EU policy objectives including: health and well-being for all; cooperation with developing countries, especially in sub-Saharan Africa, to address global health challenges; and the United Nations Sustainable Development Goals 3, 9 and 17.

**Coherence** – EDCTP2 is or has the potential to be coherent with numerous other EU programmes and policies. The Panel identified many complementarities, overlaps and opportunities for synergies with these other programmes. The EDCTP2 Strategic Business Plan clearly emphasizes coherence, coordination and cooperation among European and international partners. However, interviews with stakeholders indicate to the Panel that EDCTP2 has had neither the human resources nor an implemented strategy to fully realize coherence.

**Effectiveness** – Although the Secretariat has only recently become fully staffed, the programme has been effective – and has the potential to be more effective – at addressing EU policy objectives. EDCTP2 has strengthened both public-public and public-private partnerships that address poverty-related infectious diseases. The Panel observed general satisfaction with the programme but sees areas for improvement. Administrative bottlenecks have delayed funding and slowed implementation. The grant application process is somewhat opaque and in need of better feedback mechanisms to applicants. The Panel notes a lack of coordination among institutions within the same country – both European and African – but North-South collaboration is strong.

**Added Value** – The Panel assessed the extent to which EDCTP2 has been able to add value by identifying and exploiting synergies with other global health initiatives and policies at the EU, national and international levels. Stakeholders described the added value of EDCTP2 as largely potential rather than actual. Realizing the added value requires linking the programme not only to national research agendas but also to national agendas for
priority improvements in the economy, including achieving Sustainable Development Goals. A portfolio approach to partnership and funding calls was identified as an essential mechanism to achieve the value-add aspirations of EDCTP2. The strategic intent of synergies warrants further development, and PSs must provide leadership for this effort.

The first two and one-half years of EDCTP2 have produced some notable successes in a number of areas. Highlights include:

- **Membership and governance**
  - 14 African and 14 European PSs, all with representative members on General Assembly (GA) and equal voting rights.
  - Role developed for high level representatives, individuals successfully recruited.

- **Regional Networks**
  - Regional Networks of Excellence identified as a particularly promising model for advancing science collaboration among sub-Saharan African countries and working with government.

- **PSs and PSIAs**
  - More than 40 sub-Saharan African countries involved in 216 PSIAs; 50% involve up to 4 countries, about 10% involve at least 10 countries.

- **Calls for funding and grants awarded**
  - Successfully expanded calls: 13 unique calls produced 60 funded grants.
  - Scientists from almost 30 sub-Saharan African countries were on teams responding to calls.
  - 73% of the 60 funded grants are led by scientists from sub-Saharan Africa.

- **Capacity building**
  - 82 fellowships to sub-Saharan African researchers supported by PSIAs.
  - 26 fellowships approved under EDCTP2.
  - Alumni tracking system being set up.

- **Networking**
  - EDCTP2 Forum brought together stakeholders to facilitate networking and partnership development across sectors.

- **Monitoring and evaluation**
  - M&E team established, strategy developed, and online portal set up in preparation for the first interim evaluation panel.

**Panel Recommendations:**

Although the programme is developing well, there are areas where EDCTP2 can act more effectively and efficiently. The Panel makes the following recommendations:

**Living up to the potential of EDCTP** – EDCTP should become a proactive strategic player and change agent in sub-Saharan Africa. The Panel recommends EDCTP2 develop a
strategic policy plan with a priority to strengthen or catalyse the development of national health research plans of African PSs.

**Strengthening capacity and scientific leadership in Africa** – The Panel views the EDCTP2 regional networks as critical elements of institutional capacity in sub-Saharan Africa. The networks should develop a joint strategic plan with a focus on capacity building in Africa at all stages of scientists’ career development from young investigator to scientific leadership.

**Strengthening coherence and added value of the EDCTP programme** – EDCTP and the European Commission (EC) should jointly explore opportunities where synergies can be leveraged and complementary programmes aligned for greater impact and reach. EDCTP2 should develop and mobilize a mechanism to attain strategic partnerships. Effective implementation will require high-level support from the EC and will benefit from the appointment of a specific coordinator within the EC responsible for coherence among EU initiatives and policies.

**EDCTP visibility and advocacy** – EDCTP2 should build on the programme’s external strategic communication and advocacy efforts. The focus should be on building relationships and dialogue with participating governments, funders and stakeholders. African governments must see the added value of participating in EDCTP, and all PSs must recognize their joint ownership of the programme. The EC must also take a leadership role in supporting greater visibility and advocacy of EDCTP2.

**Improving instruments to advance research in sub-Saharan Africa**

- *Adopting a portfolio approach* – A portfolio approach will permit more strategic use of funding instruments, including competitive calls. This approach will enhance the value-add of EDCTP2 and maximize impact.

- *Grant Funding Reference Group* – EDCTP and the EC should jointly initiate an external review of the funding process, including launch of calls for proposals, peer-review, evaluation and selection. EDCTP2 should create a Grant Funding Reference Group or similar mechanism to periodically review the funding strategy, evaluation process and instruments.

- *Modifying the process of PSIAs* – PSIAs are not currently achieving their strategic purpose as a part of EDCTP2. The Panel recommends EDCTP and the EC jointly modify the entire process around PSIAs to improve efficiency and enhance impact. EDCTP should have an analytic strategy that identifies synergies, gaps and overlaps among PSIAs to extract added value and better integrate PSIAs into the overall EDCTP2 strategy.

**Governance for reaching long-term objectives and sustainability**

- *General Assembly* – EDCTP and the EC should jointly define the responsibilities and expectations for PSs and their GA representatives. GA members must have significant executive and political authority to provide strategic leadership to EDCTP.
• **Scientific Advisory Committee** – By EU decision the role of the SAC is well defined to advise the GA on various matters, both strategic and technical. In practice, the role is less clear and needs to be clarified within EDCTP by emphasising the statutory mandate to advise the GA on matters of science.

• **Strategic Advisory Group** – EDCTP2 should establish a separate, high-level strategic group to advise on matters of policy, coherence and partnership.

• **3-year work plans** – EDCTP and the EC should jointly review and modify the process for submitting and approving annual work plans so that the process is completed prior to the year of operation. The Panel recommends the process be modified to require approval of a plan every three years with milestones to be reviewed annually.

• **Executive Director** – The role of Executive Director should include proactively initiating and implementing strategic work and high-level advocacy in addition to engaging in long-term planning and sustainability issues. A Deputy Executive Director position should be created to support the Executive Director.

EDCTP has made important inroads in strengthening cooperation and partnership between European and sub-Saharan African countries and developing clinical trial capacity and scientific career development in Africa. The second programme was slow to start and challenging to implement given the complexity and breadth of the structure and the bureaucratic processes and requirements of Horizon 2020. The goals of EDCTP are ambitious and require long-term commitment and investment in order to see results. That is the nature of product development, scientific education, and implementation of clinical trials. A significant investment has already been made in the EDCTP programme, yet at 13 years it is still relatively young and only now beginning to bear fruit. In order to realise the value of the European and African investment in EDCTP, a follow-on program will be required.

The Panel recommends that the EU continue to support and fund EDCTP2 and plan its successor initiative. A decision on the future of the EDCTP programme must be made soon to maintain its momentum and to avoid the lull in activities that affected the transition to EDCTP2. The programme is critical to supporting the Sustainable Development Goals, to fostering Europe’s ties with Africa and its commitment to address poverty-related infectious diseases, to creating scientific links between institutions and to helping improve the future for all Africans. But the impact of EDCTP in combating disease will be felt well beyond the African continent as our highly interconnected planet continues to shrink in size bringing the risk of disease ever closer.
2. INTRODUCTION

2.1. Purpose of the evaluation

The purpose of this report is to provide the European Commission with the first interim evaluation of the second European and Developing Countries Clinical Trials Partnership programme (EDCTP2). The main objectives of the evaluation are an assessment of the implementation of EDCTP2 so far, the improvements that have been achieved following prior recommendations for EDCTP1, and what can be expected from EDCTP2 in the remaining time, notably with regard to the desired leverage effects of the initiative.

The Panel were tasked to identify critical issues that need to be addressed and to propose adjustments and recommendations, and to assess how EDCTP2 can best contribute to policy developments.

The evaluation delivers conclusions and key recommendations based on materials provided to the Panel during the review process; interviews conducted by the Panel; and evaluation of programme plans, calls, and actions taken to date within EDCTP2.

EDCTP2 was initiated in 2014 for a period of ten years (2014-2024). This evaluation is limited to the first two and one-half years of the programme, beginning 27/06/2014 - the date the EU Decision on EDCTP2 came into force – until 31/12/2016. The period under evaluation is, in effect, even shorter since the first annual work plan of EDCTP2 (work plan 2014) was only approved by the EC on 15/12/2014. Thus the evaluation is limited in its ability to assess the implementation of EDCTP2 and the potential for its impact.

The Panel assessed the progress of EDCTP2 towards the objectives set out in Decision 556/2014/EU1 and as defined in the Terms of Reference2, taking into account observations and recommendations made in evaluations of the first EDCTP programme (EDCTP1, 2003-2013). This interim evaluation also assesses whether the level of financial contribution from the EDCTP2 PSs is appropriate.

2.2. Scope of the evaluation

The evaluation is an assessment of the plans and implementation activities of the EDCTP2 programme so far; the improvements that have been achieved following prior recommendations for EDCTP1; and an outlook on what can be expected from EDCTP2 in the remaining time, notably with regard to the desired leverage effects of the initiative. Due to the recent start of EDCTP2, officially in December 2014, and a slow transition from

1 EU Decision 556/2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402932108252&uri=OJ:JOL_2014_169_R_0004

2 Terms of Reference for experts of the interim evaluation of the second European and Developing Countries Clinical Trials Partnership programme (EDCTP2); Ref. Ares (2016)4462851 - 17/08/2016 http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3440&NewSearch=1&NewSearch=1
EDCTP1 to EDCTP2, substantial results cannot be expected. It is therefore impossible to draw conclusions on any actual impact of EDCTP2. The evaluation primarily focuses on processes.

The evaluation includes assessments in the following areas:

- the efficiency of the EDCTP2 programme
- the relevance and appropriateness of the EDCTP2 programme
- the coherence of the EDCTP2 programme with other EU policy instruments
- the effectiveness of the EDCTP2 programme and its contribution to EU policy objectives
- the European added value of the EDCTP2 programme
- the national (European and African states) added value of the EDCTP2 programme
- the international added value of the EDCTP2 programme

For all facets of the evaluation, the perspectives and experiences of African and European PSs were sought. The evaluation includes conclusions and recommendations covering policy and operational aspects of EDCTP2 in the context of Horizon 2020 and a potential successor initiative.
3. BACKGROUND TO THE INITIATIVE

3.1. Description of the initiative and its objectives

The First European and Developing Countries Clinical Trials Partnership programme (EDCTP1) was established in 2003 by the EU, 15 European countries3 (13 EU Member States and two Associated States) in response to the global health crisis caused by the three main poverty-related diseases: HIV/AIDS, malaria and tuberculosis. EDCTP1 was funded under the 6th Framework Programme (FP6) as the first initiative established under Article 169 of the Treaty establishing the European Community, currently Article 185 of the Treaty on the Functioning of the European Union (TFEU). Article 185 initiatives are funded by the EU under the Horizon 2020 regulation4 according to the provisions of its Article 26 'Public-public partnerships,' which stresses these initiatives are partnerships between Member States (and Associated States) and the EU that “shall be proposed in cases where there is a need for a dedicated implementation structure and where there is a high level of commitment of the participating countries to integration at scientific, management and financial levels.”

EDCTP1 supported the EU's commitment to achieving the Millennium Development Goals (MDGs) with the aim to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against these diseases. The programme's approach and unique funding model supported clinical research and capacity building activities in an integrated manner through coordination of European and African partners. This approach encouraged the alignment and coordination of European national poverty-related disease research programmes and activities. It also aimed to foster African leadership in clinical research, while improving and upgrading research infrastructure, and strengthening the ethics and regulatory environment for conducting clinical trials in sub-Saharan Africa5.

Following the success of the first programme, EDCTP1, the EU decided in 2014 to extend its commitment to this strategic partnership and increase its financial contribution from EUR 200 million to EUR 683 million for the second programme, EDCTP2. The programme receives funding as part of Societal Challenge Health, Demographic Change, and Wellbeing of Horizon 2020, the current EU Framework Programme for Research and Innovation4.

The general objective of EDCTP2 is to contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-

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3 Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and the United Kingdom and the two Associated States Norway and Switzerland. Belgium has withdrawn from participation in EDCTP2, Finland has joined EDCTP2 and Switzerland is an aspiring PS to EDCTP2.


Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for these diseases, in partnership with sub-Saharan African countries\(^1\).

Due to the burden and prevalence of other poverty-related infectious diseases in sub-Saharan Africa beyond HIV/AIDS, tuberculosis and malaria; the scope of EDCTP2 was extended to include a list of 17 neglected tropical diseases as well as emerging infectious diseases of particular relevance for Africa, such as Ebola and Yellow Fever.

The EDCTP Association\(^6\), under Article 185, is tasked to implement EDCTP2. The EDCTP Association was legally established on 10 April 2014 under Dutch law in the Netherlands, and currently counts 28 countries as full and equal members of the Association: 14 European and 14 African countries. So far, the following 14 African countries have joined the EDCTP Association as members: Burkina Faso, Cameroon, Congo, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda, and Zambia. The EDCTP Association involves the following 14 European countries as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.

The specific objectives of EDCTP2 are described in detail in Annex I of Decision 556/2014/EU\(^1\).

3.2. Baseline

EDCTP1 provided a unique platform for a genuine dialogue with African scientists, and it started to bridge the gap between North and South in building research capacities and in providing learning and working opportunities for young African researchers. This programme produced major achievements, and developed eight improved medical treatments, in particular for newborns, children and pregnant or breastfeeding women suffering from HIV/AIDS or malaria. It resulted in the launch of the first four African Regional Networks of Excellence promoting South-South cooperation on clinical research, and more than 400 African researchers have been trained. It also contributed to establishing the Pan-African Clinical Trials Registry and the African Vaccine Regulators Forum\(^7\).

Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe,
suitable and affordable medical treatments tailored to the specific circumstances of developing countries still do not exist for most poverty-related diseases, and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. It should be underlined that only 10% of global research funding is allocated to the diseases which account for 90% of the world's pathologies. Moreover, European research activities and programmes are still often fragmented and are therefore either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.

In 2009, independent experts adopted the report of the interim evaluation of EDCTP1. Following that report, fundamental issues were taken into consideration for EDCTP2. The scope of EDCTP1 was amended and extended. The independent experts concluded: the capabilities in developing countries for the sound conduct and management of clinical trials should be further developed and strengthened, in particular the role and development of ethical review committees and the corresponding regulatory environment; the coordination, collaboration and integration of European national programmes should be further improved; collaboration with other major public and private partners, including the pharmaceutical industry, and public-private partnerships such as the Product Development Partnerships ('PDPs'), civil society, non-governmental organisations and foundations should be strengthened and extended; clear and transparent rules of governance should be developed; synergies with European external policy actions should be developed specifically with Union development assistance; co-funding rules should be clarified and simplified; and monitoring tools should be strengthened. In addition to the original emphasis of EDCTP on HIV/AIDS, malaria and tuberculosis, EDCTP2 expanded its scope to include neglected infectious diseases (NIDs), diarrhoeal diseases, lower respiratory tract infections and emerging and re-emerging infectious diseases.

The legal structure of EDCTP2 enables countries from Europe and sub-Saharan Africa to become members of the EDCTP governing body. The EDCTP Association reflects EDCTP’s commitment to equal partnership built on joint ownership and leadership. Currently, 14 European countries and 14 African countries are full members of the Association as PSs. The ultimate decision making body of the EDCTP Association is the GA, on which all PSs are represented. Its principal responsibility is to ensure that the statutory objectives of the programme are achieved, and that its resources are properly and efficiently managed.

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4. EVALUATION QUESTIONS

The Panel focused on the following key questions to inform and guide the evaluation and process including the desk review, materials, reports and document examination, and the interview questions and interviews conducted. The Terms of Reference (ToR) for the Panel (see Annex 10.3) capture the detail and subsections for each of the question headings below. These questions were central to every aspect of the panel’s evaluation.

- Assess the efficiency of the EDCTP2 programme
- Assess the relevance and appropriateness of the EDCTP2 programme
- Assess the coherence of the EDCTP2 programme with other EU policy instruments
- Assess the effectiveness of the EDCTP2 programme and its contribution to EU policy objectives
- Assess the added value of the EDCTP2 programme
  - at the European level
  - at the national level
  - at the international and regional level

Based on its analysis of these questions, the Panel has made recommendations for EDCTP2.
5. IMPLEMENTATION STATE OF PLAY

5.1. Preamble

In evaluating the implementation state of play, the Panel relied on a desk review of the Strategic Business Plan⁵ and the approved 2014⁹, 2015¹⁰ and 2016¹¹ annual work plans to determine the vision, mission, goals and targets for EDCTP2. The EDCTP communication strategy¹² and the EDCTP Strategic Research Agenda¹³ were also reviewed for the same purpose. These documents outlined the strategy for implementation and the roles and responsibilities of the different parties. To determine what has been achieved so far, the panel reviewed the PowerPoint presentation of EDCTP2 overview by Dr. Michael Makanga, EDCTP Executive Director¹⁴, and the Input report to the interim evaluation¹⁵. Annual progress reports concerning years 2014¹⁶, 2015¹⁷ and 2016 (draft)¹⁸, the EDCTP evaluation and monitoring strategy, minutes of the GA meetings and of the SAC meetings were also reviewed. Stakeholders’ perceptions of the implementation of the programme were captured both in formal interviews and from the online EDCTP2 public consultation¹⁹. The Draft Evaluation report was sent to members of the GA for comments and subsequently presented to the GA and SAC during the Panel meeting of 20 April 2017.

It is important to note, the current EDCTP Executive Director only took office on January 1, 2016.

¹⁴ PowerPoint presentation of EDCTP2 overview by Dr. Michael Makanga, EDCTP Executive Director, to the Panel on 12 September 2016
¹⁵ EDCTP Input report to the EDCTP2 interim evaluation 2014-2016 (9 March 2016)
¹⁶ EDCTP2 Annual Progress Report 2014
¹⁷ EDCTP2 Annual Progress Report 2015
¹⁸ EDCTP2 Annual Progress Report 2016 (draft)
¹⁹ Analysis of Results from the Public Consultation regarding the Implementation of the Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) between 2014-2016 – (Final report – April 2017)
5.2. Goals of EDCTP2

EDCTP2 is a ten-year programme, running from 2014 to 2024, with a contribution of €683M from the EU through its Horizon 2020 initiative to match the funding (cash/in kind) provided by European PSs. It also plans to raise at least €500M (cash/in kind) from third parties that include public and private partners and at least €30M (cash/in kind) as contribution from PSs from the developing countries with a minimum cash contribution of €200 000. While EDCTP2 has not deviated from the fundamental vision and mission of EDCTP to support high quality collaborative research between Europe and sub-Saharan Africa to improve the health status of people living in sub-Saharan Africa; it has extended the disease portfolio from poverty related infectious disease of mainly HIV, tuberculosis and malaria to now include neglected infectious diseases and emerging and re-emerging infectious diseases affecting sub-Saharan Africa. In this regard, EDCTP2, through this addition, remains responsive to the global health challenge and the Sustainable Development Goals but focusing on SDG3 “to ensure healthy lives and promote well-being for all at all ages”. Based on prior evaluations, it would seem that EDCTP2 has benefited from and acted on recommendations from EDCTP1. Of particular importance is the partnership recommendation that places African countries on equal footing within EDCTP2 as members of the GA. Hence, European and African PSs have co-ownership of the EDCTP2 programme. The Secretariat and the EU play supportive/facilitative roles.

5.3. EDCTP2 Participating States

EDCTP currently has 28 members: 14 European and 14 African countries contributing and participating in its programme (see section 3.1 above). These countries are also known as Participating States (PSs). The PSs fund and implement a broad array of national activities that contribute to the objectives EDCTP2. These activities, also referred to as Participating States’ Initiated Activities (PSIAs), are funded and implemented by one or more PSs. PSIAs are funded and managed by PSs according to national rules, but the implementation follows a set of common principles agreed by all members. The ownership of EDCTP2 by PSs has been demonstrated by appointment of high level government officials to the GA. Most of these officials, however, are not affiliated with the ministries within the PSs that actually coordinate the strategic focus areas of EDCTP2. PSs have not demonstrated an in-country coordinated mechanism that allows for discussion and streamlining of ideas for their respective countries prior to the attendance at the GA. This lack of coordination has hampered the overall cohesiveness and strong ‘ownership’ of the program. This need for

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greater commitment and ownership is further demonstrated by PSs’ inability to meet certain obligations as described later in section 7.4.2.

5.4. Implementing EDCTP2

EDCTP2 has been implemented by the EDCTP Association as part of the European Framework Programme for Research and Innovation, Horizon 2020. The funding of projects is based on annual work plans, which are drawn from the EDCTP2 Strategic Business Plan and the Strategic Research Agenda. These work plans are developed in compliance with the objectives and provisions set out in the EU’s Decision on EDCTP2, following a comprehensive consultative process involving multiple stakeholders. The annual work plans provide information on EU funded calls for proposals, including the challenge, scope and expected impact, as well as supporting information about eligibility requirements and other specific conditions for applying. The annual work plans also contain an overview of PSIAs. Before implementation, the annual EDCTP2 work plans are reviewed by the Scientific Advisory Committee, an independent international panel of experts approved by both the EC and the GA. The EU-funded actions are evaluated, selected and funded in line with the rules for participation of Horizon 2020 following open calls for proposals that are centrally managed by the EDCTP Association.

PSIA reporting and evaluation: PSIAs are activities funded and implemented directly by one or more PSs. These activities are considered to be integral to the implementation of EDCTP2. PSIAs are funded following national evaluation, selection and granting processes that are implemented by one or several PSs in line with common principles agreed between the EDCTP Association, on behalf of the PSs, and the EC.

PSIA review and evaluation: PSIAs represent an important platform for funding EDCTP’s activities as mandated by the Delegation Agreement. Proposed PSIAs are provided as overviews in the annual work plan submitted by the Secretariat to the EC. PSIAs are funded and managed by PSs according to national rules, but the implementation follows a set of common principles agreed by all Association members, in particular the principles of equal treatment, transparency, independent peer review, evaluation and selection. From 2014-2016, 133 PSIAs were submitted for review. Out of the 133 submitted, 92 were eligible for multi-country review, 33 supported PDPs, six provided core funding for the World Health Organisation (WHO) programme for tropical disease research (TDR), and another 2 provided funding for networks (Esther Alliance and INDEPTH). Of the 92 eligible for multi-country review, 21 were missing detailed information about collaborating countries which left only 71 eligible for final review. The formal approval of PSIAs from the EU is still pending as of this report; hence the financial assessment is still outstanding.

21 Amended EDCTP2 Delegation Agreement, May 2016
22 PSIA Workshop Analysis, Vienna, March 2017
The number of PSIAs and the financial details vary greatly by country. Figure 1 illustrates a fundamental problem with the program: the funding and focus of PSIAs significantly benefit the wealthier countries thereby exacerbating existing disparities in capacity among the African PSs. EDCTP2 must develop strategies whereby wealthier PSs have incentives to engage poorer African nations in EDCTP2 activities, thus ensuring better distribution of the benefits of the programme.

Figure 1 - Overview of sub-Saharan countries participating in European PSIAs (N=71)

EDCTP2 calls: Annual work plans are implemented and managed by the EDCTP Association Secretariat. Funds are made available through open calls for proposals, which are evaluated, selected and funded in line with the Horizon 2020 rules. The calls are described in greater detail in section 5.7. Funding for EDCTP Association activities are expected to be in kind or in cash from the PSs. During the 10-year life cycle of EDCTP2 (2014-2024), contributions to the Association are anticipated to be greater than €683 million from the European PSs and €30 million from the African PSs. The EU will provide matching funds of up to €683 million in cash. An additional €500 million is expected to be leveraged by the EDCTP2 working in collaboration with PDP’s, bilateral funding organisations, research institutions and the private sector, which includes philanthropic foundations, charities and pharmaceutical companies. EU and leveraged funding is managed by the Secretariat,
whereas in-kind and cash contributions from the PSs, including PSIAs, are managed by the PSs.

**Communication, advocacy and networking:**

Two high level representatives were appointed in the last quarter of 2016 as part of the EDCTP Secretariat, one in Africa and another in Europe. The representatives operate as good will ambassadors to advocate for EDCTP at high levels within Participating and non-PSs. The goal is to increase EDCTP visibility, awareness, and promote partnerships with other stakeholders.

An alumni tracking mechanism, which was recommended following the evaluation of EDCTP1, has been implemented. The Secretariat will track alumni and allow networking and interaction among EDCTP fellows. The evaluation and success of the alumni in achieving its goal is currently ongoing.

### 5.5. Governance Structure of EDCTP2

EDCTP2’s governance structure consists of a General Assembly (GA), the Board and the Secretariat (see Figure 2). The ultimate decision-making body of the EDCTP Association is the **General Assembly**, which includes representatives from all Participating States. Its principal responsibility is to ensure that the statutory objectives of the programme are achieved, and that its resources are properly and efficiently managed. Observers to the EDCTP GA are representatives of the EC, the African Union and the World Health organisation African region. The **Board** of the EDCTP Association is appointed by the GA from among its members (representatives and their deputies). The Board is responsible for the management of the Association and supervises the Secretariat. The **Secretariat** implements the EDCTP2 programme, manages EDCTP’s day-to-day work and supports the other EDCTP bodies. The Secretariat is led by the Executive Director, Dr. Michael Makanga, and has two offices in The Hague, The Netherlands and in Cape Town, South Africa. The “EDCTP2 Decision” states that a Scientific Advisory Committee shall advise the GA on priorities and strategic needs regarding clinical trials; advise the GA on the content, scope and dimension of the EDCTP2 draft annual work plan; and review the scientific and technical aspects of implementing EDCTP2. EDCTP2 engaged the wider scientific stakeholders in theme-linked meetings and the SAC in developing the Strategic Business Plan (2014-2024). These inputs guide development of detailed annual work plans, which dictate implementation activities for EDCTP2. These annual work plans must be approved by the GA and the EC prior to implementation and prior to issuing funding calls that are part of the work plan.
5.6. Areas of Focus

The EDCTP2 focus remains on accelerating and enhancing product development; funding clinical trials of all phases including pharmacovigilance and effectiveness studies; strengthening capacities in sub-Saharan Africa through trainings/mentoring, and infrastructure development; creating an enabling environment for research and clinical trials through strengthening of the ethical, regulatory and legal frameworks in sub-Saharan Africa; and building extensive partnerships between Europe and sub-Saharan Africa, and with the international scientific world that includes North-North, North-South, and South-South partnerships.

Essentially EDCTP2 operates and implements its work plan through open calls for proposals that are independently reviewed by experts; and PSIAs which are funded following national evaluation by each of the PSs.

5.7. Calls for Grant Proposals

The EDCTP2 calls for proposals have been supported through three distinct types of Horizon 2020 actions: Research & Innovation Actions (RIA), Coordination & Support Actions (CSA), and Training & Mobility Actions (TMA). RIAs refer to multicentre clinical
trials conducted by research consortia involving both European and African research teams (see Table 1 below). They include integrated capacity development and networking elements. CSAs provide support for activities expected to strengthen the enabling environment for conducting clinical trials and clinical research. These activities include ethical review and regulatory capacity. Finally, fellowships focusing on career development of individual researchers or research team members are funded within the TMAs. The three funding instruments address the main objectives of EDCTP2. EDCTP2 has implemented the appointment of independent experts for the evaluation of proposals.

The first three calls of EDCTP2 were launched in December 2014. In 2015, a total of 11 calls for proposals were ongoing: 3 calls of the 2014 Work Plan and 8 calls of the 2015 Work Plan. In 2016 all pending activities from the 2015 Work Plan were implemented and 9 calls for proposals were launched including 4 RIA, 2 CSA and 3 TMA calls. A total of 20 calls for proposals have been launched so far under EDCTP2. These activities have increased the total grants awarded to a cumulative figure of 60 projects (13 under RIA, 21 under CSA, and 26 under TMA. For details see annex 2 and 4 of the Input report to the interim evaluation\(^\text{13}\)). The total number of grants signed was 24 by 31/12/2016.

**Table 1 - Overview of calls launched and granted between 2014 and 2016**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of calls launched</th>
<th>Total calls launched</th>
<th>Number of grants awarded and signed ((*)) by 31/12/2016</th>
<th>Total grants selected for funding</th>
<th>Total grants signed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RIA</td>
<td>CSA</td>
<td>TMA</td>
<td>RIA</td>
<td>CSA</td>
</tr>
<tr>
<td>2014</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>2015</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>8</td>
<td>7 (4*)</td>
</tr>
<tr>
<td>2016</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>9</td>
<td>Evaluation ongoing</td>
</tr>
<tr>
<td>Cumulative period</td>
<td>7</td>
<td>6</td>
<td>7</td>
<td>20</td>
<td>13 (4*)</td>
</tr>
</tbody>
</table>

The calls are opened to both PSs and other countries that do not belong to EDCTP. While opening the calls to more countries will increase competition and might improve the science, it is potentially counterproductive as states may have no incentive to contribute as PSs. For example, 60 countries have benefited from EDCTP2 grants yet there are only 28 PSs in the programme (see Figure 3). Kenya, which is not a PS, has benefited significantly from the EDCTP funds.
Calls for proposals have experienced significant delays due to the lengthy process for approval of the annual work plans (see Table 2). The 2014 Work Plan took 9 months to be approved by the EC. The annual work plans for 2015 and 2016 took 17 and 9 months respectively, though the 2015 Work Plan was unusual in that it was initially submitted together with the 2014 Work Plan and then later resubmitted with the 2015 PSIAs.

**Table 2 – Timelines to approve EDCTP2 Annual Work Plans**

<table>
<thead>
<tr>
<th>EDCTP2 WP 2014</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>26 March 2014</td>
<td>Submission of the first draft biannual EDCTP2 Work Plan 2014-2015 by the EDCTP</td>
</tr>
<tr>
<td>15 April 2014</td>
<td>EC reply to EDCTP to adapt WP 2014-2015 to the requirements of EDCTP2 Decision, H2020 Rules for Participation and EDCTP2 Delegation Agreement</td>
</tr>
<tr>
<td>25 April 2014</td>
<td>Revised version of the WP 2014-2015 submitted by EDCTP</td>
</tr>
<tr>
<td>28 May 2014</td>
<td>Revised version of the WP 2014-2015 submitted by EDCTP</td>
</tr>
<tr>
<td>8 June 2014</td>
<td>Revised version of the WP 2014-2015 submitted by EDCTP</td>
</tr>
<tr>
<td>3 July 2014</td>
<td>Revised version of the WP 2014-2015 submitted by EDCTP</td>
</tr>
<tr>
<td>13 August 2014</td>
<td>Revised version of the WP 2014-2015 submitted by EDCTP</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8 - 9 September 2014</td>
<td>Peer review evaluation meeting of the EDCTP2 Work Plan 2014-2015</td>
</tr>
<tr>
<td>18 September 2014</td>
<td>Evaluation Summary Report sent to EDCTP by the EC</td>
</tr>
<tr>
<td>6 October 2014</td>
<td>EDCTP new version of the EDCTP2 WP 2014-2015</td>
</tr>
<tr>
<td>31 October 2014</td>
<td>Launching the EC inter-service consultation for approval of WP 2014</td>
</tr>
<tr>
<td>19 December 2014</td>
<td>Commission Approval of EDCTP2 WP 2014</td>
</tr>
<tr>
<td></td>
<td>Total duration: 9 months</td>
</tr>
</tbody>
</table>

**EDCTP2 WP 2015**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 March 2014</td>
<td>Submission of the first draft biannual EDCTP2 Work Plan 2014-2015 by EDCTP</td>
</tr>
<tr>
<td>8 April 2015</td>
<td>Submission of the Annual EDCTP2 WP 2015 to EC by EDCTP</td>
</tr>
<tr>
<td>26 June 2015</td>
<td>EC reply to EDCTP to adapt WP 2015 to the requirements of EDCTP2 Decision, H2020 Rules for Participation and to EDCTP2 Delegation Agreement</td>
</tr>
<tr>
<td>3 September 2015</td>
<td>Commission approval EDCTP2 WP 2015</td>
</tr>
<tr>
<td></td>
<td>Total duration: 17 months</td>
</tr>
</tbody>
</table>

**EDCTP2 WP 2016**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 September 2015</td>
<td>Submission of the first draft Annual EDCTP2 WP 2016 by EDCTP</td>
</tr>
<tr>
<td>29 September 2015</td>
<td>EC reply to EDCTP to adapt WP 2016 to the requirements of EDCTP2 Decision, H2020 Rules for Participation and to the EDCTP2 Delegation Agreement</td>
</tr>
<tr>
<td>9 October 2015</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>3-4 November 2015</td>
<td>Peer review evaluation meeting of EDCTP2 Work Plan 2016</td>
</tr>
<tr>
<td>11 November 2015</td>
<td>Evaluation Summary Report sent to EDCTP</td>
</tr>
<tr>
<td>2 December 2015</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>23 December 2015</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>8 January 2016</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>26 January 2016</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>1 March 2016</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>10 May 2016</td>
<td>Revised version of the WP 2016 submitted to EC by EDCTP</td>
</tr>
<tr>
<td>8 June 2016</td>
<td>Commission approval EDCTP2 WP 2016</td>
</tr>
<tr>
<td></td>
<td>Total duration: 9 months</td>
</tr>
</tbody>
</table>

5.8. Monitoring and Evaluation

Internal monitoring and evaluation of the ongoing implementation of EDCTP2 is carried out by the Secretariat using key performance indicators (KPI). KPI indicators include both short term outputs like the number of supported clinical trials and the number of medical
interventions that have progressed from one phase to another: medium term outcomes like the number of publications from EDCTP2 supported projects and long term impacts like the number of new medical interventions, the number of improved policies or guidelines, and the number of patent applications or patents. Formal reports and recommendations are prepared and submitted to the Secretariat. As part of monitoring and tracking the progress of EDCTP2 Alumni, a tender evaluation is currently underway for the development of an Alumni platform that will not only track, but also enable networking among EDCTP Alumni. Examples of key reports include reports on PSIAs and the Bibliometric analysis (2015)\textsuperscript{23}.

In addition, every three years the EC assembles panels of external experts to evaluate the progress of EDCTP2 and its impact on health policies, capacity strengthening, and partnerships and synergy with other like-minded organizations. The EC aims for a balanced composition of experts on the panels, taking into account factors such as expertise, regional provenance, and gender balance.

6. METHODS/ PROCESS FOLLOWED

6.1. Orientation of Evaluation Panel Members and Distribution of Work

In addition to the information included in the ToR, an orientation to the EDCTP2 programme was provided for Panel members during initial meetings with the EC services in charge of EDCTP2, with the EDCTP Secretariat and EDCTP Executive Director, and via the Panel's attendance at the biannual meeting EDCTP Forum of researchers and other stakeholders that took place in Lusaka in November 2016. The ToR of the evaluation assignment was used as a basis for the initial outline of the work. Each Panel member was assigned responsibility for leading the evaluation questions related to one of the main evaluation tasks outlined in the ToR: efficiency, effectiveness, coherence, relevance and value-add.

6.2. Several evaluation principles guided the Panel’s work

- This is a formative rather than a summative evaluation and therefore primarily involves a process evaluation. Findings are expected to inform and help shape EDCTP2 programme development and implementation.
- The evaluation approach will deliberatively and selectively engage a variety of stakeholders; some follow up with these stakeholders will be required to share and discuss evaluation findings.
- Some findings will provide a baseline assessment for subsequent summative evaluation(s) of EDCTP2, given the early implementation stage of the programme.

6.3. Evaluation Design

An iterative evaluation process was used to retrospectively examine EDCTP2, and its state of implementation. The Panel used mixed methods data collection including a desk review of documents and individual and group interviews. A draft methods document was prepared to guide the work, following the initial meeting of the Panel. Data analysis strategies for interviews were detailed following in-depth interviews in Lusaka.

The panel met by teleconference or in person on the following dates:

- 12 September 2016 - in Brussels (Belgium)
- 06 October 2016 - teleconference
- 04-10 November 2016 - in Lusaka (Zambia)
- 19 December 2016 - teleconference
- 09-10 January 2017 – in Brussels (Belgium)
- 10 February 2017 - teleconference
09 March 2017 - teleconference
• 23 March 2017 - teleconference
• 27 March 2017 – teleconference
• 19-21 April 2017 - in Brussels (Belgium)
• 05 June 2017 - teleconference

Ethics
Written consent was obtained from all those invited to be interviewed, using standard EU procedures. Consent was requested for digitally recording interviews, keeping written notes of interviews and using anonymized quotes so that the Panel could appropriately use them for reference while proceeding with the interim evaluation.

6.4. Sampling and Data Collection

6.4.1. Desk Review of Documents
Pertinent documents were identified with the assistance of the EC services and from the EDCTP Secretariat. Major data sources identified included internal and external EDCTP and EDCTP2 documents (e.g. minutes of meetings, previous evaluation reports, annual progress reports; pertinent strategic, operational and policy documents, etc). A full list of documents reviewed is provided in Annex 10.5.

An initial list of relevant documents (minimum of five documents) was identified by each Panel expert (Panel lead) assigned to lead a preliminary desk review of an Evaluation question. The Evaluation questions and extraction criteria for each desk review were informed by the ToR. In the case of the “coherence” Evaluation question, external websites and reports were identified based on the specific programme, policy or organization being assessed for coherence with EDCTP2. The preliminary desk review was completed by each Panel lead and a draft written summary prepared. Results were discussed and compared during a full day, face-to-face meeting. This desk review helped inform priority interview questions and probes to be used for targeted stakeholder interviews. It also guided the selection of individuals and organizations who/those were to be interviewed and additional documents and websites that needed to be reviewed. In some instances, interviewees also identified documents requiring review; these were examined in subsequent rounds of the document desk review.

Websites and organization/initiative publications and reports were the major source of information for the evaluation questions on coherence. Agencies identified in the Evaluation ToR were the primary focus of the coherence evaluation. In addition, major international PRD funding agencies were evaluated for coherence with EDCTP2.
6.4.2. Interviews

An initial sampling frame of organizations and interviewees was constructed based on evaluation questions in the ToR, and input of EC officials and the EDCTP Executive Director. Purposeful and convenience sampling was used, given the aims of maximum variation sampling. We aimed to elicit a diversity of viewpoints among interviewees with varying types and levels of involvement with and/or interactions with EDCTP. Purposeful sampling meant that the Panel targeted specific organizations and in some cases individuals, who had the necessary background to answer the Panel’s questions. Panel members were purposeful in the selection of a range of experiences and organizations already involved with or with the potential to link to EDCTP2 objectives (e.g. governmental, non-governmental and private sector organizations). The Panel also aimed to include participants from a variety of countries, to achieve balance in European and African countries, and with respect to the latter, those with stronger and weaker research capacity, as well as EDCTP Participating and non-Participating States. The Panel sought gender balance among interviewees. A list of interviewees and their distribution by type of stakeholder, continent and gender are included in Annex 10.2.

Convenience sampling was used to identify particular respondents from an organization or country/region, who were available for face-to-face interviews in Lusaka (i.e. they were on site). Examples of the latter included the sampling of fellows who had been supported by EDCTP2, and the sampling of members of the SAC. Snowball sampling techniques were also used, wherein additional interviewees who could add depth or diversity to the Panel’s data were identified during interviews. This snowball technique was used to identify additional stakeholders mentioned during interviews, in a meeting with members of the GA and during informal discussions with participants at the Lusaka meeting. Eligibility criteria were consent to participate, and able to conduct an interview in English.

Since a number of interviewees had been involved in EDCTP2 in several different roles, the perspective that each interviewee was asked to take for the interview was made explicit during the interview. Interviewees were asked to reflect on their personal experience with EDCTP2 and/or the experience of their organization. For instance, some participants had been grant recipients, led a research centre, supervised graduate students/fellows, and were on either the SAC or the GA. In some cases the Panel asked them to address more than one of these roles and/or more than one organizational perspective. For some interviewees, and in particular for participants interviewed by Skype or over the phone, interview schedules were shared in advance of the interview.

Generally, all members of the evaluation team were present for the face-to-face interviews conducted in Lusaka (November, 2016) and Brussels (January, 2017). For each of these interviews, one evaluation team member was assigned to lead the interview and a second member captured the interviewee’s response. These responsibilities were rotated, with consideration given to areas of in-depth expertise of team members and their assigned Evaluation questions. The individual who kept notes from the interview was responsible for providing an oral summary during debriefs on the interviews. The note-taker prepared a brief written summary of the interview, highlighting key points. All of these summaries were consolidated into a single document.
Phone/Skype interviews were conducted by one or two team members, who also kept notes from the interview and provided a brief written summary as stated above. All team members were debriefed on these interviews during team conference calls. Debriefing provided an opportunity to ensure that key points were identified, consistencies and discrepancies with other interviews identified, and additional areas for questioning and/or additional potential interviewees determined.

**6.5. Data Analysis**

**6.5.1. Document Review**

There were two phases of document analyses. The preliminary review provided an orientation to the initiative and informed the background documentation. Each Panel lead developed an extraction form and extraction process that captured information pertinent to their Evaluation questions. Summary data were shared at the EDCTP2 meeting in Lusaka. During a fulsome discussion of this data, emerging themes/observations were identified and consistencies and discrepancies across documents were noted. This was used as a basis for identifying interview questions and for identifying stakeholders for interviews. Additional documents to be reviewed were also identified.

In the case of the Evaluation question on coherence, websites and organization/initiative reports and publications were reviewed. These provided a primary source of data for the analysis. Data extracted for each of the agencies included in the coherence review included a programme summary (major initiatives, goals, action plans and policy priorities), and relevant programmes and policies that were deemed to have potential synergies with EDCTP2. A comparative summary was prepared that lined up EDCTP2 strategic objectives with each agencies aims and programmes. This was then used to identify potential collaborative opportunities.

Subsequent reviews of documents were undertaken to validate or refute interview data and to help with the interpretation of interview data. Each Panel lead reviewed those documents pertinent to the focus of their Evaluation question.

A number of key documents were made available to us once interviews were well underway. Examples included the interim evaluation document, the Bibliometric analysis (2017)²⁴, the communications strategy¹² and the public consultation report¹⁹.

With respect to EDCTP2 work plans, strategic documents, and statutes, we examined those that had been formally approved within the evaluation period (up until the end of Dec 31, 2016).

**6.5.2. Interviews**

²⁴ Bibliometric analysis of publications on poverty-related and neglected infectious diseases (NIDs) published between 2003 and 2015
All notes from interviews that had been completed by February 24th were reviewed by one team member and several points per interview highlighted. These were categorized by Evaluation question. Categories used for quotes were reviewed by the entire team and some adjustments were made. In some instances, quotes were pertinent to more than one Evaluation question. This process helped to further refine the pertinent scope and operational definitions for each Evaluation question. These definitions are provided in the preamble of the Evaluation question findings (Section 7). In addition, the Panel used this initial review of all quotes to determine if there were other categories not captured by the Evaluation questions outlined in the ToR.

Additionally, the consolidated interview document containing highlights of all interviews was reviewed independently by each member of the team, and content pertinent to their Evaluation question identified. These pertinent responses were then coded and a summary of these preliminary results prepared by each Panel lead prior to the Panel's January meeting. The preliminary coding structure developed for each Evaluation question was shared during a face-to-face meeting of Panel members. The raw interview notes were consulted to confirm the coding structure and to identify supporting quotes. As described in the next section, some comparisons were made across selected stakeholder groups. Inductive and deductive content analytical approaches were used. Notes from interviews were read and reread and in some instances the more complete transcript was reviewed. Final coding frameworks were developed from the interview data.

Gaps in data (as per the ToR) were identified and the team determined whether the gap represented the stage of implementation of EDCTP2 (and thus it was considered premature to collect data) or the data were missing and additional interviews needed to be completed or documents reviewed/re-reviewed.

### 6.5.3. Evaluation Question-Specific Analyses of Interview Data

Some of the analytical approaches were specific to the evaluation task under study, e.g.:

- **Efficiency**: All interview responses were reviewed and analysed with respect to issues related to programme efficiency.
- **Relevance**: All interview responses were grouped into the following categories: high representatives, industry, members of GA and SAC (past and present), grantees, coordinators and others. Similarities and differences across these groups were identified.
- **Coherence**: Notes from all interviews were reviewed to determine if there were any comments on coherence specific to the EU organizations that were part of this Evaluation question.
- **Effectiveness**: Points of divergence in respondents’ responses were highlighted as analysis was completed. No specific comparisons were made across different types of respondents.
• Added-value: An initial coding framework was used to develop a matrix comparing responses of EDCTP2 and other funding organizations; and responses of participants sharing perspectives of European PSs, African PSs, EU and international organizations. Interview data were inserted into the matrix to help identify patterns of responses and to facilitate comparisons across different stakeholder groups.

6.5.4. Limitations – robustness of findings

As per our ToR, this evaluation did not include a review of impacts from EDCTP1. However, it is important to note that our three year window of evaluation coincides with the significant transition period that took place between the completion of EDCTP1 and the launch of EDCTP2.

Our findings are based on a substantial number of documents, websites, and extensive interviews. Nonetheless, there are certain limitations.

The list of agencies sampled for the website searches and document review is not exhaustive. For instance, we did not develop a list of agencies (PDPs) that PSs are funding through their PSIAs as the basis for selecting agencies for the coherence questions. Rather, our focus was on agencies listed in the ToR and international agencies working in this arena.

Several key documents were provided to the evaluation team late in the process (January and February, 2017). This meant that the Panel were unable to use interviews as a means to follow up some of the Panel’s reflections from these documents.

For many of the non-EDCTP2 organizations, the Panel interviewed only one individual from each of these organizations. A wider set of stakeholders from each of these organizations might have provided a larger and different mix of viewpoints.

We purposefully sampled interviewees from English-, French- and Portuguese-speaking participating countries. However, interviews were only conducted in English. This was not the first language of many interviewees. Although our impression was that no interviewees had significant difficulties expressing themselves in English, having to respond to our questions in English may have constrained some of their responses. No one refused an interview due to language.

We initially targeted individuals who came to the Lusaka meeting in November, 2016, for interviews. This was a selective rather than a representative group of individuals involved in EDCTP2.

We did not examine other infrastructure investments (e.g. BSL4 laboratories) funded through Horizon 2020 and FP7 that might be considered prerequisite investments for capacity building efforts and clinical trials.

The Panel draft report was presented to the GA and to the SAC in a meeting in Brussels on 21 April 2017 to check the robustness to the findings and to increase the feasibility of the Panel recommendations.
7. ANSWERS TO THE EVALUATION QUESTIONS

The implementation of EDCTP2 was assessed as outlined in the ToR for the interim evaluation\(^2\) and described in Section 2.2 (Scope of the evaluation). An extensive list of evaluation criteria was provided in the ToR (see Section 10.4 below, Mandate of the interim evaluation). Guided by the ToR, the Panel assessed the programme by addressing five Evaluation questions: Efficiency, Relevance and appropriateness, Coherence with other EU policy instruments, Effectiveness and contribution to EU policy objectives, and Added value. The ToR specified questions related to the implementation of previous evaluations. The answers to the Evaluation questions are presented in Section 7. Each subsection ends with a brief summary.

One hundred and twenty internal and external documents were retrieved and reviewed, and content from numerous websites was considered. Forty-six stakeholders were interviewed; the majority of interviews were conducted face-to-face. A larger proportion of interviewees were men than women (63% versus 37%, respectively). Twenty interviewees (43.5%) were from Africa, twenty-four interviewees (52.2%) from Europe and two from the USA (4.3%). Although some interviewees had multiple roles, we asked them to respond primarily from the perspective of one of these roles. These primary roles are shown in the summary table of interviewees in annex 10.2 below. Nine (19.6%) came from other funding organizations, industry or international organizations. Eight (17.4%) were from the EDCTP Secretariat, ten (21.7%) from the GA and four (8.7%) from the SAC. A small number of interviewees (one or two per institution) were stakeholders from national authorities, external partners (e.g. private-public, product development), or other organizations. Although only three individuals were interviewed in their primary role as grantees, a number of other individuals had received or were currently receiving funding from EDCTP.

The Panel was also asked to provide recommendations related to implementation of the programme with respect to the original objectives as well as to its legal and administrative framework, and what can be learnt with respect to the overall socio-economic impact of the EDCTP2 programme. Aspects of these topics which are not covered in this section are addressed in Discussion and Conclusions (Section 8). Finally, the Panel was asked to provide recommendations for the remaining time of the EDCTP2 programme. The Panel’s recommendations are stated in Section 9.

7.1. Efficiency of the EDCTP2 programme

The evaluation questions related to the efficiency of EDCTP2 focus on how competently and economically the activities have been executed. It is about performing tasks in an optimal way, e.g. with respect to time or resources. Efficiency does, however, not give any deeper understanding of how valuable and useful the tasks are for reaching the objectives. This aspect is covered under the headings of Relevance and, especially, Effectiveness.
The evaluation of efficiency is supported by specific objectives and performance indicators stated in the formal documentation concerning the EDCTP2 Decision and the Delegation Agreement and which are listed below. The indicators relate to a series of very specific targets that EDCTP2 is projected to have reached at the end of its 10-year duration (2014-2024). As the First Interim Evaluation covers just over two years (December 2014-2016), it is not to be expected that the targets have been reached. Rather, the objective at this point in time is to evaluate the progression towards the set objectives and targets. Consequently, a certain measure may serve as proxy for a more formally defined target or indicator. For example, if the programme is to deliver a new medical intervention or a new guideline this will require that clinical trials are initiated. This in turn necessitates funding from EDCTP2. Thus, allocating funds to a clinical trial suggests – as a proxy – that the final target may be reached.

The evaluation of programme efficiency is primarily based on reviewing the Input report to the interim evaluation. Additional information was obtained during the interviews conducted by the Panel, and via direct questions to the EDCTP Secretariat.

### 7.1.1. Progression towards objectives and reaching set targets

**Table 3 - Progression of EDCTP2 towards objectives and reaching set targets**

<table>
<thead>
<tr>
<th>Target</th>
<th>Progression</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>An increased number of new or improved medical interventions:</strong></td>
<td></td>
</tr>
<tr>
<td><em>Delivered at least one new medical intervention by the end of the programme</em></td>
<td>10 EDCTP2 grants signed and 3 EDCTP grant proposals approved, each including at least one clinical trial testing new or improved medical interventions. 15 PSIAs addressing this target.</td>
</tr>
<tr>
<td><em>Issued approx. 30 guidelines for improved or extended use of existing medical interventions</em></td>
<td>33 PSIAs relevant to reaching this target.</td>
</tr>
<tr>
<td><em>Progressed the clinical development of approx. 20 candidate medical interventions</em></td>
<td>10 PSIAs relevant to reaching this target.</td>
</tr>
<tr>
<td><em>Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant legislation</em></td>
<td>3 EDCTP2 grants signed, each including at least one planned clinical trial coordinated by a sub-Saharan African institution. 20 PSIAs supporting clinical trials coordinated by sub-Saharan African institutions.</td>
</tr>
</tbody>
</table>

*Support clinical trials on new or improved medical interventions:*
- **Increase the number of supported clinical trials to at least 150 (EDCTP1: 88)**

| 10 EDCTP2 grants signed and 3 EDCTP grant proposals approved, each including at least one clinical trial testing new or improved medical interventions. 40 PSIAs supporting clinical trials. |

- **Sustain or increase the proportion of EDCTP2-funded clinical trials with African leadership**

| 3 EDCTP2 grants signed, each including at least one planned clinical trial coordinated by a sub-Saharan African institution. 20 PSIAs supporting clinical trials coordinated by sub-Saharan African institutions. |

- **Increase the number of published peer-reviewed scientific articles to three times that of EDCTP1 (EDCTP1 > 700)**

| 1 article published based on results obtained in an EDCTP2 funded project. (N.B. None of the EDCTP2 projects have yet been reported; listed here is an article within the framework of an EDCTP2-funded IMPACT grant shared with EDCTP by a grantee.) 260 articles originate from work conducted within PSIAs (N.B. PSIA articles cover a period that included EDCTP1). |

**Support research capacity-building activities:**

- **Increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to >400**

| 3 EDCTP fellowship grants signed and 23 fellowship grants approved for funding. 82 fellowships to sub-Saharan African researchers supported by PSIAs. |

- **Increase the number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa to >74**

| 6 CSA calls launched. CSA calls have resulted in 21 projects (excl. 2 calls where evaluation is still ongoing). |

**Ensure efficiency of the implementation of the EDCTP2 programme:**

- **Administrative costs are below 6% of the EDCTP2 budget.**

Yes, administrative costs are well below the 6-percent limit (approx. 3.2% for the evaluation period, yet it is projected that the full 6% will be spent during the EDCTP2 period).

*numbers are taken from the Input report to the interim evaluation\(^{15}\)

**Support research capacity-building activities – Sustain or increase the participation of sub-Saharan African countries in the EDCTP2 programme**
African participation in EDCTP2 can be either at a national level as one of the PSs and member of the GA, or as a research performer responding to EDCTP2 calls and receiving funding for clinical trials (Research & Innovation Actions, RIAs), capacity building and enabling activities (Coordination & Support Actions, CSAs), or career development (Training & Mobility Actions, TMAs).

At the national level one of the most important changes with EDCTP2 was that all PSs are full and equal members. As all full members are represented in the GA, this has obviously strengthened sub-Saharan African involvement in running the programme. There are at present 14 sub-Saharan African countries participating in EDCTP2. These countries also participated in EDCTP1. However, EDCTP has received an expression of interest from three additional sub-Saharan African countries to become members.

During the entire reporting period, 20 calls for proposals have been launched (7 RIAs, 6 CSAs and 7 TMAs). Evaluation is still ongoing for the 2016 calls, but the 2014-2015 calls have resulted in a total of 60 projects (out of which 24 grant agreements have been signed). Including the 36 grants pending signed grant agreements, the percentage of projects with a lead participant from sub-Saharan Africa is 73%. The EDCTP2 calls are open to all sub-Saharan African countries and thus involve several nations that are presently not members of the EDCTP Association and consequently not represented in the GA. Almost 30 sub-Saharan African countries participated in the projects. When excluding the 26 TMA grants, which primarily have lead participants from sub-Saharan Africa, the percentage of RIA and CSA grants with sub-Saharan African leadership is 56%. In 10 of the projects (approx. 29%), the United Kingdom is the lead country. South Africa and Uganda are lead countries in 3 projects each.

More than 40 sub-Saharan African countries have been involved in the 216 PSIAs that have been initiated under EDCTP during the period 2014 to 2016. Approximately one fourth of PSIAs involve a single nation and 50% involve up to 4 countries. Approximately 10% of PSIAs include participants from at least 10 countries. The number of sub-Saharan African countries involved in PSIAs demonstrates broad participation across Africa.

**Develop a research agenda for EDCTP2**

- **At least 50 % of the public investment by Participating States are integrated, aligned or coordinated through the EDCTP2 programme.**

The Strategic Business Plan\(^5\) and the Strategic Research Agenda\(^13\) outline an ambitious programme to which PSs can align their national programmes or investment. Besides PSIAs that are managed and funded by the PSs themselves, and are expected to strengthen the EDCTP programme, there is so far not much evidence of any significant Participating State investments being integrated, aligned or coordinated through the EDCTP programme. Rather, observations made during the interviews suggest that integration is weak.
Establish cooperation and launch joint actions with other funders

- **Increase the contributions received from developing countries to at least €30M**

The EDCTP reports that during 2014-2016 the 28 PSs contributed approximately €318M to EDCTP2. Out of this amount, the African PSs contributed approximately €900 000. The total cash contributions received from the PSs amounted to almost €32M with no contribution from African PSs.

- **Obtain additional contributions, either public or private, of at least €500M**

During 2014-2016, EDCTP received more than €4.5M in contributions from third party organisations, with the largest amount coming from WHO/TDR. Out of this amount approximately 30% were cash contributions. In 2016, €8.7M was leveraged from the MRC/DFID/Wellcome Trust Joint Global Health Trials scheme for joint funding of clinical trials as part of one of the 2015 EDCTP calls. Also in 2016, discussions with Switzerland (aspirant member in the EDCTP Association) resulted in earmarked funding from the Swiss government to Swiss researchers/organisations participating in EDCTP2 calls. Based on activities in 2016, the estimated third party contributions in 2017 should exceed at least €4M. EDCTP works actively to attract additional third party contributions. If EDCTP2 continues to attract contributions at the same pace they will fall far short of reaching the €500M. To reach the target of €500M, the intensity of these efforts must increase significantly. The strategic value of the €500M target, compared to many other more relevant targets, should be discussed.

Establish cooperation and launch joint actions with other development assistance initiatives to increase the impact of the results of EDCTP-funded activities

This is assessed under section 7.5, Added value of the EDCTP2 programme.

7.1.2. Governance structure of EDCTP2

*Is the governance structure of the initiative working efficiently and in line with the provisions laid down in Annex III of Decision 556/2014/EU?*

The structure of the legal entity, the EDCTP Association, was fully implemented in 2015. All parts of the governance structure are in place and appear to be in line with the above-mentioned provisions. However, according to Annex III of the EDCTP Decision¹, the Secretariat should “increase the visibility of the EDCTP2 programme through advocacy and communication”. The Panel notes that EDCTP has developed an ambitious and well-formulated communication plan¹². The plan is somewhat imprecise regarding the implementation of the activities, which may relate to comments expressed by several stakeholders that EDCTP2 is not visible enough. The function of the SAC is very much in accordance with the tasks stated in Annex III, which are focused on scientific prioritization, implementation, technical aspects, annual work plans etc. However, this seems to be contradicted by the view expressed by EDCTP in, for example, the Input report to the interim evaluation¹⁵, which states that the SAC “is responsible for the development of the
strategic planning of the programme”. Although the processes related to scientific matters are appropriately handled by the SAC, the information obtained from EDCTP documents and from answers by several interviewees did not suggest that the SAC contributed significantly to the strategic planning of EDCTP as a whole. The overall responsibility for the long-term strategic planning lies with the GA (which shall “ensure that all necessary activities are undertaken to achieve the objectives of the EDCTP2 programme”) but the processes appear to be neither well-defined nor efficient.

**Is the governance and implementation structure cost-effective?**

The administrative costs for 2014-2016 amount to approximately €6.8M out of an approved total budget of €214M from the EC. This corresponds to 3.2% and thus significantly less than the 6% of the EU's financial contribution that can be used to cover administrative costs according to the amended delegation agreement. The EDCTP Secretariat projects that the administrative costs will reach 6% for the entire time period of EDCTP2. It is not necessarily an end in itself to maintain very low administrative costs, especially during the start-up phase of a programme. The evaluation indicates that additional investments, for example in communication activities, would be cost-effective.

**Have the management aspects been properly addressed?**

The start-up of EDCTP2 was somewhat slow, but largely the EDCTP2 management appears to be ambitious, professional and well-functioning. However, the evaluation (document review and interviews) points to three serious management-related issues in need of significant focus. First, the exceptionally slow processes related to the annual work plans cause serious budgetary problems that delay the implementation of EDCTP2 activities (see Table 2 in section 5.7 and discussion below). Second, a number of interviewees raised concerns regarding the EDCTP2 grant application process, e.g. it being too slow and awkward. This view is confirmed by the recent public consultation report. The EDCTP2's proposal evaluation and selection processes received a relatively high share of negative feedback. Concern was also expressed among the interviewees regarding the low approval rates. Third, the reporting of PSIAs is viewed by several stakeholders as unnecessarily laborious and complicated. The added value of the PSIA reporting is doubtful as the reports appear primarily to serve as an input to the accounting related to in-kind contribution. There appears to be no further analysis of the outcome of PSIAs with respect to the EDCTP2 objectives. The Panel recognises that some of these processes are not entirely the responsibility of EDCTP alone but include also the EC and the PSs.

The Panel further notes that the management, as represented by the EDCTP Secretariat, has a skewed gender distribution. Although more than half of the staff listed as part of the Secretariat are females (23 of 40), all six senior positions (Executive Director, High Representatives and three Directors) are held by men.
Are effective monitoring and supervision arrangements in place?

Procedures for monitoring and supervision are being established by EDCTP.

7.1.3. The EDCTP2 programme as an instrument to foster activities of a transnational nature within Europe and between Europe and sub-Saharan Africa

Are the EDCTP2 programme and its activities cost-effective? Were the costs involved justified, given the changes/effects which have been achieved?

The Panel consider it premature to address the issue of the EDCTP2 achievements. It is, however, strongly recommended that the processes for addressing this specific issue (e.g. defining appropriate performance indicators that would capture effectiveness) are initiated as soon as possible in order to facilitate future evaluations (interim evaluation and final evaluation).

Did the delegation agreement and the annual work plans support an efficient implementation of the activities of the EDCTP2 programme?

It is the Panel’s understanding that EDCTP2 has appropriately addressed the requirements stated in the Delegation Agreement. This includes implementing several action points as described in Annex 1 of the Delegation Agreement. However, the processes related to the annual work plans have not supported an efficient implementation of EDCTP2. The processes required for the annual work plans to be approved by the EC have been extremely slow (see Table 2 in section 5.7). As the approval by the EC is required before any funds are released, this has significantly delayed parts of the EDCTP2 programme and worked against an efficient implementation. For example, the 2014 Work Plan was approved only on 19 December 2014. The subsequent work plan, describing planned activities in 2015, was approved by the EC on 3 September and then by the GA on 5 October 2015, i.e. more than nine months into the year of operation. Although there was a slight improvement in the following year, the 2016 Work Plan was still not approved by the EC until 8 June - almost six months into the programme.

What were the principal achievements and shortcomings of the EDCTP2 programme when it came to the implementation of certain activities (e.g. joint calls) or the progression towards certain objectives (e.g. strengthened cooperation with sub-Saharan African countries, extended international cooperation with other public and private partners, regional organisations and other initiatives)?

Achievements and shortcomings of EDCTP2 are addressed in Section 7.4, Effectiveness of the programme.
What were the intended or unintended impacts of the simplification measures, which were introduced in the context of Horizon 2020, on the administrative efforts for participating actors, i.e. both end-users/beneficiaries of the EDCTP2 programme and the EDCTP2 implementation structure (the EDCTP Association)?

The impact of the programme is addressed in Section 7.4, Effectiveness of the programme.

7.1.4. Summary

Many of operational objectives and the indicators for efficiency set out in the documents underlying the initiation of EDCTP2 are defined with respect to what is expected to be achieved by 2024. It is thus obviously premature to evaluate the exact numbers only two years into the programme. This is especially true for an indicator such as number of published papers where the result is only to be expected years after the actual activity. However, it is still possible to evaluate the progression towards the objectives. The second programme had a slow start but overall EDCTP2 is doing very well. At this time point there is no reason to doubt that EDCTP2 will be able reach most of the programme objectives and targets. Nonetheless, there are a number of areas in which EDCTP (including the PSs and the EC) will have to focus specifically in order to ensure more efficient progression. These areas include, for example, the alignment of the PSs to the EDCTP Strategic Research Agenda, processes related to PSIAs, the call and review processes, approval of annual work plans, long-term strategic planning, and external communication.
7.2. Relevance and appropriateness of the EDCTP2 programme

The answers to the evaluation questions related to the relevance and appropriateness of the EDCTP2 programme presented in this section have been drawn from the understanding of the WHO global health report and challenges\(^25\), the WHO report on Global Burden of Disease\(^26\), the EDCTP2 Strategic Business Plan\(^5\) and annual work plans\(^9,10,11\), the Input report to the interim evaluation\(^15\), and from the responses of interviewees.

The focus of EDCTP2 on poverty-related diseases (PRDs) makes it an important instrument for countries to reach their Sustainable Development Goals. Infectious diseases, childhood illnesses, and maternal causes of death account for as much as 70% of the burden of disease in sub-Saharan Africa, disproportionately affecting the most vulnerable. The Millennium Development Goals four to six (MDG 4-6) explicitly focuses on controlling the key infectious diseases identified as HIV/AIDS, malaria, tuberculosis and measles. In the same vein, the more recent Sustainable Development Goal\(^20\) 3 (SDG3) target is to “Ensure healthy lives and promote well-being for all at all ages”. Target SDG3.3 aims, by 2030, to “end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases”. The vision of EDCTP2 is to reduce the individual, social and economic burden of poverty-related diseases in developing countries. Sub-Saharan Africa is on target in terms of relevance in addressing the global health challenges especially in Africa today. Through its focus on capacity building and international networking, EDCTP2 enhances infrastructure, human resources, and the ethical and regulatory frameworks of institutions in sub-Saharan Africa to reduce this disease burden through the conduct of research and clinical trials at international standards. This focus is key to establishing and sustaining African investigators and leadership. EDCTP2 disease portfolio continues to remain relevant through its process of prioritization that is informed by the state of product development, changing patterns of diseases, and emerging opportunities. For example, EDCTP2 is addressing antimicrobial resistance using infrastructure, trained personnel, and community trust to effect behavioural changes that minimize the rampant abuse of microbial agents in sub-Saharan Africa.

7.2.1. To what extent are the original objectives of the EDCTP2 programme still relevant?

As stated in the preamble above, the general objective of EDCTP2 is to contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for these diseases,

\(^{25}\) http://www.who.int/whr/2003/chapter1/en/

\(^{26}\) http://www.who.int/pmnch/media/news/2012/who_burdenofdisease/en/
in partnership with sub-Saharan African countries. In the EDCTP2 programme, “poverty-related diseases (PRDs)” include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola and Yellow Fever. The fact that EDCTP2 is focused on contributing to the SDG3 targets for 2030 is a clear indication of the relevance of the disease profile outlined for EDCTP2. In addition EDCTP2 operates through networks, partnerships and collaboration with government agencies of the different countries and the global partners targeting the same goals in sub-Saharan Africa, which is critical in addressing global health challenges. Over and over again interviewees expressed the incredible need the EDCTP2 programme meets, and how it is unique in its wholesomeness in addressing the disease burden and challenges in sub-Saharan Africa. For example:

“EDCTP has been extremely useful in capacity building, especially in ethics and regulatory structures”

“The accomplishments of EDCTP have been fantastic. Much would not have been accomplished without EDCTP – the recent work on Ebola is a great example.”

7.2.2. To what extent are stakeholders satisfied with the objectives, implementation and governance of the EDCTP2 program?

From the interim evaluation of the EDCTP2 report and comments made by the interviewees, this panel can comment on the extent to which stakeholders are satisfied with the objectives and governance of EDCTP2. However it may be premature to comment on the implementation at this stage other than to provide some preliminary snap shots.

There is general satisfaction with the objectives of EDCTP2 by the stakeholders, although the impression is more could be achieved with greater strategic and long-term planning in addition to better coordination, partnerships and collaboration. As one of the interviewees expressed it:

“EDCTP is on the right track. They should however look critically at what proposals they are funding. Look at the regulatory and stewardship role and come up with proposals that assist in the development of whatever the need - be it research or capacity building.”

One area of concern that was expressed by a number of interviewees from both European and African countries was whether by extending the portfolio of diseases to include an additional 17 NIDs, EDCTP2 has made its coverage too broad. One of the stakeholders expressed this opinion as:
“...the focus in EDCTP1 has been lost in EDCTP2 by broadening the areas of research to NIDs. This is not to say that NIDs are not important for the African continent but EDCTP cannot do everything if they want to remain nimble, efficient, and impactful”.

This concern was also exemplified by the first results from EDCTP2 calls for proposals (annex 2) where 20 calls produced 184 fundable proposals of which 60 projects were funded - a good success rate of 33%. However, 566 initial stage applications were eligible and invited to the second round, which yielded 244 eligible full proposals. Of the 244 full proposals, 60 (25%) were funded which is still within normative funding rates of other international funding agencies but it is lower than rates of about 50% of full proposals that were funded for EDCTP1.

One area that received more critical comments and recommendations for improvement was the governance structure of EDCTP2. The governance structure\(^1\) consists of: (1) the General Assembly (GA), the decision making body with representatives from all PSs; (2) the Management Board, comprising members of the GA with responsibilities for the management of the EDCTP Association and the supervision of the Secretariat; (3) the Secretariat and Executive Director, responsible for the implementation of the activities of EDCTP2 and the day to day work of EDCTP; and (4) the SAC, responsible for providing advice on scientific and strategy matters (see section 5.5, Figure 2). In addition, two recently appointed High Representatives will support advocacy for EDCTP2 at the highest level. Although these structures implement activities within their respective roles, a weakness became increasingly obvious to the Panel and was reiterated at different points of engagement: how do these governance structures interact to ensure a coherent strategic direction for EDCTP2? It was not clear to the Panel who is, or should be, providing the strategic direction for the organization. Neither was the role of the EC well-defined in this context, although it was occasionally implied that the strategic direction is left to the EC. Substantial effort is put into the development of the business plan and annual work plans, but it is not clear which body strategically plans for partnerships and synergies to ensure maximum overall impact of the programme. How does the governance structure prioritize its activities in the face of the changing state of product development, disease patterns, and emerging opportunities?

7.2.3. To what extent is the EDCTP2 programme appropriate to support the realization of EU policy objectives?

Chief among these policy objectives are the following: improving the lifelong health and well-being of all; strengthening cooperation with sub-Saharan African countries and with third countries to address global health challenges; and contributing to the achievement of the United Nations’ Sustainable Development Goals.

7.2.3.1. Improving the lifelong health and well-being of all, and contributing to the achievement of the United Nations’ Sustainable Development Goals.
As pointed out above, the goal of the EDCTP2 activities is to reduce the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for these diseases, in partnership with sub-Saharan African countries. This adequately addresses the EU policy objective of improving the lifelong health and well-being of all. EDCTP2 activities also contribute to the achievement of the United Nations’ SDGs, which in turn align with EU policy objectives. Specifically, EDCTP2 is directed to the following SDGs\(^{20}\) (at paragraph 54):

### Goal 3. Ensure healthy lives and promote well-being for all at all ages

3.3 By 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases

### Goal 9. Build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation

9.5 Enhance scientific research, upgrade the technological capacities of industrial sectors in all countries, in particular developing countries, including by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending

### Goal 17. Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development

17.6 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, in particular at the United Nations level, and through a global technology facilitation mechanism

17.7 Promote the development, transfer, dissemination and diffusion of environmentally sound technologies to developing countries on favourable terms, including on concessional and preferential terms, as mutually agreed

17.8 Fully operationalize the technology bank and science, technology and innovation capacity-building mechanism for least developed countries by 2017 and enhance the use of enabling technology, in particular information and communications technology

17.9 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
17.14 Enhance policy coherence for sustainable development

17.15 Respect each country's policy space and leadership to establish and implement policies for poverty eradication and sustainable development

17.16 Enhance the Global Partnership for Sustainable Development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the Sustainable Development Goals in all countries, in particular developing countries

17.17 Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships

Nevertheless, the Global Burden of Disease Study - while showing some reductions in mortality due to infectious diseases, maternal and child health, and nutrition - warned that non-communicable diseases, such as cancer and heart disease, are becoming the dominant causes of death and disability worldwide. In this regard, the current EDCTP2 mandate does not address non-communicable diseases that are gaining importance globally.

7.2.3.2. Strengthening cooperation with sub-Saharan African countries and with third countries to address global health challenges

Strengthening cooperation with sub-Saharan African countries is achieved through EDCTP2’s efforts to build capacity for the conduct of clinical trials in compliance with fundamental ethical principles and relevant EU and international regulatory standards. These activities are outlined in the Strategic Business Plan and involve three key activity areas: 1) infrastructure development that involves upgrades of clinical and laboratory facilities to support high quality clinical research; 2) the development of local expertise and scientific leadership through human capacity development including research training, fellowships, mentoring, and early career development; and 3) the development of the regulatory and ethical frameworks to create the enabling environment for the conduct of clinical trials and research using the highest possible international standards. Networking between the north and south, the south and the south, and partnerships with external partners have further strengthened the capacity building in sub-Saharan African countries, improving cross-fertilization of ideas between researchers and institutions while minimizing duplication.

Comments from interviewees' shows that this activity could be strengthened in certain areas as exemplified below:

Table 4 - Comments from interviewees to strengthen cooperation with sub-Saharan African countries and with third countries

<table>
<thead>
<tr>
<th>Suggested improvements</th>
<th>Quotes</th>
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<tr>
<td>A more even distribution of capacity building activities across sub-Saharan African countries rather than the current concentration in eastern and southern Africa with limited activities in central and western Africa</td>
<td>“There should be more research in west Africa and more harmonization across regions – English and French”</td>
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<tr>
<td>There is also a need to selectively target young African scientists and introduce new technologies to sub-Saharan African countries to guarantee sustainability and a future for sub-Saharan Africa</td>
<td>“Governance should also be streamlined to open up new opportunities for young scientists to contribute. EDCTP2 is becoming a club of ‘old boys’ and may not be benefiting from the new innovations and smart young minds” “Retaining talent is important to avoid brain drain. EDCTP should collaborate with academia and governments. Opportunities must exist within the countries. Industry is willing to contribute with our expertise (applying science in the development of drugs etc). A fellowship programme with EDCTP has been discussed but a year is not enough”</td>
</tr>
<tr>
<td>It might be necessary to carve out roles that are commensurate with the level of expertise and development in sub-Saharan African countries</td>
<td>“Networks are expanded due to needed expertise for example CANTAM – to gain HIV and TB expertise Zambia now part of the network and also the UK as well” “South Africa should have a different role. The bulk of our investments are there because of the capacity being there. The first step is to retain the talent in Africa and in the short term this also includes South Africa. But there should be a plan for South Africa to become a catalyst, to form hubs in Africa, create hubs of innovation” “There should be a way to motivate SA to take up tasks that are appropriate for such a country which is obviously not LMIC and is in a transition state to being a developed nation” “It is becoming more and more difficult to justify all the funds going to SA so need to look at that again and maybe would require changing the rules” “Perhaps South Africa should become a hub. Important not to punish them”</td>
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<tr>
<td>More effort should be put into partnerships especially external partnerships that</td>
<td>“There is presently not much pharma industry in Africa but that could change. Should involve all African countries and not just a few - make the pond big enough to get the best”</td>
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</table>
would lead to product development and pharmacovigilance talents”
“South Africa should have a different role. The bulk of our investments are there because of the capacity being there. The first step is to retain the talent in Africa and in the short term this also includes South Africa. But there should be a plan for South Africa to become a catalyst, to form hubs in Africa, create hubs of innovation”

7.2.4. Summary

There is no doubt that EDCTP2 objectives to reduce the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, have relevance in contributing to UN’s SDGs 3, 9 and 17. The current process of prioritization based on state of product development, changing patterns of diseases, and emerging opportunities is key to ensuring that EDCTP2 stays relevant in this world of ever-changing global health challenges. Even as non-communicable diseases are gaining prominence in global health, EDCTP2 is struggling to keep up with the expansion of its original mandate of poverty related diseases to include neglected infectious diseases as evidenced by the lower grant approval rates in EDCTP2 compared to EDCTP1. This delicate balance between responding to the health challenges caused by the expanded list of infectious diseases and the need to streamline and stay focused is a challenge for EDCTP2.

A number of sub-Saharan African countries have benefited from capacity building by EDCTP2 involving infrastructure upgrading; human resource development through training and mentoring; strengthening of ethical and regulatory frameworks to support clinical trials; and product development, networking, and key partnerships. Additional effort is required to ensure that partnerships and collaborations are streamlined to match capacities and peculiarities of participating institutions in sub-Saharan Africa. There seems to be a need for more involvement of young African scientists and new technologies, as well as more partnerships that can advance sub-Saharan Africa in the areas of pharmacovigilance and product development.

One area of weakness may be the governance structure of EDCTP2. While a structure with the potential for success has been described and put in place, more focus and responsibility should be directed towards strategy. To remain relevant, EDCTP2 should create a committee with responsibility for providing strategic direction to the programme but also with flexibility to promptly take advantage of emerging opportunities.
7.3. Coherence of the EDCTP2 programme with other EU policy instruments

Coherence of the EDCTP2 programme was assessed with regard to several EU funded programmes and policy instruments. Taking these initiatives into consideration, the panel evaluated the unique opportunity for coherence and synergy across programmes, policies and activities. In addition to EU programmes, the panel evaluated potential for coherence and synergy with global health funders such as the Bill & Melinda Gates Foundation, the National Institutes of Health, and the Wellcome Trust. At the international level the Sustainable Development Goals (SDGs) encourage and support coherence and alignment of activities through increased global partnerships across programmes and sectors in SDG 17. The panel evaluated opportunities for interconnectedness, alignment, efficiency, and coordinated programming as part of the coherence evaluation.

EU programmes and policies reviewed by the panel include the following:

- the EU-Africa Strategic Partnership including the Joint Africa-EU Strategy and Roadmap (2014-2017) and the EU-Africa High Level Policy Dialogue on Science, Technology and Innovation;
- the EU’s vision of a competitive “Global Europe”;
- the EU’s development cooperation policy and actions, in particular the “European Consensus on Development”;
- “The Agenda for Change”;
- the EU Role in Global Health;
- the European Research Area and the Horizon 2020 programme;
- the second Innovative Medicines Initiative programme (IMI2);

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34 http://ec.europa.eu/research/era/partnership_en.htm
35 https://www.imi.europa.eu
the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)\(^{36}\);
the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)\(^{37}\);
the Global Alliance on Chronic Diseases (GACD)\(^{38}\);
the EU’s Chemical, Biological, Radiological and Nuclear Risk Mitigation Centers of Excellence initiative (EU CBRN-CoE)\(^{39}\)

EDCTP2 coherence was also assessed and evaluated against other global initiatives to which the EU contributes, including the Global Fund to Fight AIDS, Tuberculosis and Malaria\(^{40}\) and the Global Vaccine Alliance (GAVI)\(^{41}\). In addition, EDCTP2 was assessed for coherence with other EU and global initiatives for complementarity, potential for synergy, and areas of overlap.

A desk review of each of the organizations listed above, and others, was completed to assess coherence across these initiatives. In addition to reviewing documents describing these programmes and policies, a thorough review of EDCTP2 was conducted. The main EDCTP2 related documents reviewed for this analysis include: the Strategic Business Plan\(^{5}\), the annual work plans – 2014\(^{9}\), 2015\(^{10}\) and 2016\(^{11}\), the EDCTP2 Decision\(^{1}\), Annual Report of the SAC\(^{42}\), the Bibliometric analysis (2017)\(^{24}\), EDCTP2 progress reports\(^{16,17,18}\) and funding calls, EDCTP2 newsletters and other documents. In person and telephonic interviews were conducted with EDCTP stakeholders representing the EC and several of the programmes and policy instruments including, the EDCTP GA, the EDCTP Secretariat, SAC, COE, and team, EDCTP grantees, representatives from African and European PSs, funders and potential co-funders.

Coherence is a common theme running through EU programmes and EDCTP2 documents, plans and reports. The EC clearly recognizes the importance of coherence, and prioritizes it across EU funded programmes and EU policy instruments. The Strategic Business Plan 2014–2024\(^{43}\) presents the five specific objectives of EDCTP2 along with outcomes and

\(^{36}\) [http://www.jpiamr.eu](http://www.jpiamr.eu)

\(^{37}\) [https://www.glopid-r.org](https://www.glopid-r.org)

\(^{38}\) [http://www.gacd.org](http://www.gacd.org)

\(^{39}\) [http://www.cbrn-coe.eu](http://www.cbrn-coe.eu)

\(^{40}\) [https://www.theglobalfund.org/en/](https://www.theglobalfund.org/en/)

\(^{41}\) [http://www.gavi.org](http://www.gavi.org)

\(^{42}\) 2016 Annual Report of the Scientific Advisory Committee (September, 2016)

\(^{43}\) EDCTP Strategic Business Plan for 2014-2024, concise version,

targets (see pg. 16). In addition to medical interventions, and collaboration and capacity development, there are three objectives that clearly relate to coherence:

**European coordination** – To better coordinate, align and, where appropriate, integrate national programmes to increase the impact and cost-effectiveness of European investments in health research on poverty-related infectious diseases;

**External partnerships** – To work with a broad range of public and private partners to maximize the impact of research, to attract additional investments, and to fully explore the opportunities for high-quality clinical research offered by EDCTP2’s integrated approach; and

**EU cooperation** – To increase impact through collaborations with other EU initiatives, particularly those related to development assistance.

The Strategic Business Plan 2014-2024 states on page 17:

### EUROPEAN UNION CONTEXT OF EDCTP

EDCTP was established by the EU in 2003. It was the first initiative based on Article 185 of the Treaty on the Functioning of the EU (ex-Art. 169), which allows the EU’s participation in research programmes undertaken by EU and Associated Member States.

The EU is a major contributor to international health aid and research. Several policy statements and collaborative agreements have laid out the EU’s position in this area. In 2010 the Commission Communication and Council Conclusions on the role of Europe in global health established a conceptual framework, with emphasis on strengthening national health systems, maternal health, and the fight against HIV, TB and malaria.

The 2007 EU Programme for Action and its 2009 Progress Report highlighted the key role of EDCTP in its own right and as a model for other programmes aiming at coordinated international collaboration. This aspect of EDCTP has also been emphasised in multiple policy declarations, programmes and reports. The Africa–EU Strategic Partnership, emanating from the 2007 Lisbon Declaration and re-emphasised in the Europe 2020 Strategy, identifies EDCTP as an important body in its first Action Plan for implementation of this Strategic Partnership.

The EDCTP programme contributes to the European Commission flagship initiative ‘Innovation Union’ as the programme will enhance the effectiveness, visibility and coherence of global health research in Europe. It offers a shared approach to clinical research of poverty-related infectious diseases and has the potential to contribute to a European Research Area, as envisaged for EU’s international science and technology cooperation programmes. Further, at their Berlin meeting in 2015, the G7 Ministers of Science expressed their resolve to support the fight against “poverty-related infectious diseases and neglected tropical diseases”, with EDCTP recognised as one of the mechanisms to be built upon.
EDCTP2 has a clear intent, with great potential, to capitalize on coherence and synergy across many programmes and initiatives. The Panel's review and interviews have reinforced the Panel's understanding of this potential, but a strategy, plan and actions have not yet been implemented around leveraging the potential for coherence.

The opportunity and importance of EDCTP2 implementing a strategy and plan of action to capitalize on programme and policy synergies and alignment came across in the Panel's desk review and also through interviews. The EDCTP new high level representatives emphasized the importance of EDCTP2 to, “bring projects together; construct portfolios across sectors; bring partners together... in this jungle of partners; the EDCTP portfolio must be better linked to the partners”. An interviewee from another EU funded programme said, “love to see where there is more communication and better coordination and information on what EDCTP does that is in line with the African Union framework; EDCTP and other funders in Africa are stand-alone funding streams and trying to address the African disease burden. It would have been good if the funding streams talked to each other and harmonized ways of addressing funding so that they do not duplicate effort and funding.... And there is more coordination.”

EDCTP is not recognized as an ‘out in front player’ in the global landscape for capacity building or funding. Major funders such as the Bill & Melinda Gates Foundation, Fogarty (NIH), TDR, and Wellcome Trust see EDCTP as an organization with great potential, yet they all find it challenging to coordinate their programme funding with EDCTP2 due to the bureaucracy, lack of funding flexibility, lack of a portfolio funding approach, and a slow decision making process. These points were reiterated by several of the interviewees.

Additional points and recommendations from interviewees include:

– “Funding decisions need to be driven by good science, and not politics.”
– “EDCTP should have a pipeline responsive approach to project funding – this is not happening so EDCTP is not filling the needed gaps.”
– “Why is EDCTP working in a silo – EDCTP should link with Wellcome Trust, NIH, DFID, BMGF and others”. People and leaders want to come together and coordinate funding – “EDCTP could coordinate with other big funders and organizations capable of executing ... need to connect the dots.”
– “A portfolio mechanism across other initiatives could be established – this would be very helpful.”
– “The EDCTP Secretariat could hold meetings with other funders to evaluate various portfolios and identify opportunities for collaboration – the meeting would need to be structured for decision making outcomes,” (meetings have taken place in the past but they were not structured to make decisions and take action).

The desk review identified numerous potential synergies and areas of overlap between EDCTP2 and the other EU programmes and policy instruments. Table 5 summarizes where these potential synergies exist between each objective of EDCTP2 and the various programmes that were part of the review. A detailed analysis of each programme and how it relates to EDCTP2 can be found in Annex 10.5.
**Table 5 - Potential Synergies between EDCTP2 Objectives and Other European Programmes & Policies**

<table>
<thead>
<tr>
<th>EDCTP2</th>
<th>ASP</th>
<th>E2020</th>
<th>ECD</th>
<th>AFC</th>
<th>EUGH</th>
<th>ERA</th>
<th>H2020</th>
<th>IMI2</th>
<th>JPIAMR</th>
<th>GloPID-R</th>
<th>GACD</th>
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**EDCTP2 Strategic Objectives:**
- **SO1** - Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones.
- **SO2** - Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation.
- **SO3** - Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments.
- **SO4** - Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments.
- **SO5** - Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance.

**ASP** – EU-Africa Strategic Partnership  
**E2020** – Europe 2020  
**ECD** – European Consensus on Development  
**AFC** – Agenda for Change  
**EUGH** – EU Role in Global Health  
**ERA** – European Research Area  
**H2020** – Horizon 2020  
**IMI2** – Second Innovative Medicines Initiative  
**JPIAMR** – Joint Programming Initiative on Antimicrobial Resistance  
**GloPID-R** – Global Research Collaboration for Infectious Disease Preparedness  
**GACD** – Global Alliance for Chronic Diseases  
**CBRN** – Chemical, Biological, Radiological and Nuclear Risk Mitigation Centers of Excellence initiative  
**GF** – Global Fund to Fight AIDS, Tuberculosis and Malaria  
**Gavi** – Global Alliance for Vaccines and Immunisation
7.3.1. Summary

The Panel’s desk review included extensive analysis of other EU programmes and policies. Numerous opportunities for synergies with EDCTP2 were identified as outlined in Annex 10.5. The Panel’s interviews indicate EDCTP has not had the human resources, strategy in place, or capacity to act on these opportunities to fully realize coherence and links across programmes, funders, and EU policy. The recently published Strategic Business Plan 2014–2024 is encouraging, as coherence is emphasized and coordination and cooperation across European and international partners is identified as a priority.

There is a great deal of work that needs to occur in order for EDCTP2 to achieve its ambitious objective of coherence across EU programmes. This will require support from the EC at a high level to encourage cooperation and collaboration with other EU programmes. Leaders of EU funded programmes should be incentivized and encouraged to proactively identify and collaborate on joint programmes, coordinated alignment and communication to raise awareness of the European initiatives to address PRDs in Africa. The EC would benefit by having a high level strategy across programmes and policies to facilitate alignment, coordination and collaboration where opportunities exist. This approach would be more effective if a specific coordinator were responsible for coherence among EU initiatives and policies.
7.4. Effectiveness of the EDCTP2 programme and its contribution to EU policy objectives

This review documents the effectiveness of EDCTP2 contributions towards the EU policy objectives. The EU, in the development policy Agenda for Change, outlined the need to reduce poverty in a rapidly changing world. The focus includes good governance, human rights and democracy; and takes into account inclusive sustainable development and the UN’s Sustainable Development Goals. Attainment of these goals is expected to be accompanied by differentiated development partnerships and improved coherence and coordination among EU Member States, in addition to greater ownership and reciprocal engagement with partner countries and mutual accountability.

The EDCTP2 programme has contributed to the general policy objectives of the EU, and in particular the Horizon 2020 objectives. The Horizon 2020 Regulation\(^4\) in the preamble (11) states that Horizon 2020 has a focus on three main areas: excellence in research, fostering industrial leadership and tackling societal challenges. This is done within a framework that includes all types of research ranging all the way from the bench to the market.

7.4.1. Overall goals of strengthening public–public partnerships for PRD including neglected ones

The EDCTP2 programme has contributed to the strengthening of public-public partnerships in the field of poverty-related diseases (PRD), including neglected ones but in a somewhat serendipitous manner. This has been achieved in part by the expansion of the portfolio of poverty related diseases that are under the EDCTP2 calls for funding. In tackling the PRD, EDCTP2 is addressing societal challenges. However, the calls do not specify the nature of partnerships that are eligible except for the guidance provided on the type and number of participating countries. For example in the Research and Innovation Action (RIA), the requirement is for at least two participating entities established in EU Member States and one low or middle-income country in sub-Saharan Africa. The calls do not specify that public-public strengthening is a requirement\(^4\). EDCTP2 has leveraged partnerships with other public organizations like the UK MRC to fund specific projects for improving the grants management process. EDCTP2 has also partnered with the World Health Organization in developing internship opportunities.

Despite the fact that EDCTP2 began only a little over 2 years ago and the Secretariat has not been fully operational (e.g. the High level representatives were recently appointed), the programme has still been effective - and has the potential to be more effective – at addressing the objectives of Horizon 2020.

EDCTP2 has already made several calls, while some calls are still unfunded and under review or the contracting process is still underway. EDCTP2 has been able to expand the portfolio of what is to be funded. There have been calls to support the improvement of research regulation - calls which would also build capacity for pharmaceutical regulation. The regulatory calls have targeted strengthening the public regulatory functions, but have not specifically targeted public- public partnerships. In making calls for capacity building there has been opportunity for the development of centers of excellence which also provide opportunities for networking and development of collaborations- both North-South and South-South.

While one of the core goals of EDCTP2 is the delivery of products that will respond to the public health concerns prioritized in Horizon 2020, it is too early for actualization of this goal. However, the goal of public-public strengthening may need to have further specification in the calls or refinement if it is to be achieved as a targeted output.

7.4.2. Operational Goals and compliance with Horizon 2020 regulation and Financial commitments

The EDCTP2 programme has complied - but not fully - with the criteria laid down in Article 26 of the Horizon 2020 Regulation. The objectives of the programme are clearly defined, and PSs have indicated clear financial commitments. There has also been complementarity of the activities, which are in line with the target of poverty related diseases. The objectives of EDCTP2 are defined in the EU Decision concerning EDCTP2 (Annex 1) and in the Strategic Business Plan (section 3.4). They are in keeping with the objectives of Horizon 2020 as well as the objectives set out in other EU policies and programmes.

However, the majority of the African PSs and a number of the Europeans PSs have not met their financial commitments. The commitments are documented as both direct financial support and funding through PSIA. It is not clear that there has been value added by the contribution of PSIA even though in some cases the amounts documented from European PSs have been significant (see Input report to the interim evaluation, pages 39-40). The indicative financial commitments of the PSs, in cash or in kind, are clearly indicated in the Strategic Business Plan (section 7.3), and if honoured would be an appropriate pooling of resources to foster transnational research and innovation. However in reality, the funding has not kept pace with the indicated levels, and matching funds from PSs, in kind or in cash, have been delayed (Input report to the interim evaluation, page 20-22, Tables 9-11). One European PS has not made any contributions in the past two years of the programme and only one African PS has submitted the cost incurred as a PSIA.

7.4.3. Scientific and Managerial functions

The staffing structures were finally achieved towards the end of the second year of the programme. The High Representatives for Africa and Europe, Director South-South Cooperation, Programme Portfolio Manager, Legal Officer, M&E Officer, Networking and Project Officer positions have been filled. Of note, the high representatives were appointed
during the last quarter of 2016. At the time of the face-to-face interviews of the Panel in Lusaka during the 8th EDCTP Forum, they had not as yet actively engaged in their roles.

EDCTP developed and published a communication strategy, developed a new brand manual, and developed various standardized and quality controlled materials for external communication. The impact of these developments however has not yet been felt among the stakeholders. Inadequate communication and lack of information - particularly after proposals were not funded - was a recurring theme among stakeholders; “The problem is that we do not really understand how they [EDCTP] finance and how they decide who should get funded as they do not communicate well after applications. Sometimes you get it sometimes you do not. Not very clear on evaluation criteria.” Other stakeholders also expressed concern about feedback after proposals were not funded and thought there were opportunities for useful feedback that may be helpful for future funding calls: “[EDCTP] Can better communication happen after the calls for which no one is not or is successful? Is it budget that stops funding? Was it a late submission? Feedback on proposals submitted would be useful.” Concerns were expressed about the overall communication on content of EDCTP2 and its current activities: “What one would have ‘loved’ to see more is a situation in where there is more communication and better coordination and information on what EDCTP does.” Stakeholders also commented on possibly improving “framing” the way in which information about the programme is provided, i.e. presenting information differently for different groups: “EDCTP communication to the world could be better;” “Building a castle, not shaping a stone”.

There are demonstrable ongoing improvements to the EDCTP2 grants online system catering both to the centrally managed projects and PSIAs. In order to address the ongoing concern for good financial management practices and capacity, an EDCTP audit committee has been established, which is expected to improve accountability and transparency. In addition, the table below lists the operational goals that have been achieved. However, not all these achievements have been clear to stakeholders who in interviews sometimes expressed concerns about the attainment of some of these operational goals.

**Table 6 - Achievements of Scientific and Operational Goals**

<table>
<thead>
<tr>
<th>Goal</th>
<th>Achievement</th>
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<tbody>
<tr>
<td>Monitoring and evaluation</td>
<td>M&amp;E team established, strategy developed, and online portal set up in preparation for the first interim evaluation panel</td>
</tr>
<tr>
<td>Science, strategy and planning</td>
<td>The Strategic Business Plan and the annual work plans derived from it were completed for the first two years of the programme implementation</td>
</tr>
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</table>
Implementation of work plan activities

For each year of the programme, this has been delayed because of the delays in approval of the work plan and consequently implementation.

Outreach and advocacy activities conducted to increase EDCTP visibility

Undertaken to increase visibility and foster partnerships with private sector and possible third party funding.

EDCTP Strategic Business Plan

Completed and published.

EDCTP Annual Strategic Research Agenda for 2017

Completed, pending approval.

Standard Operating Procedures, and Procurement Policy

Policy documents and SOP’S required by the delegation agreement updated and adopted.

The Strategic Business Plan⁵ takes into account the Horizon 2020 strategic planning in its development and operation. The Strategic Business Plan and the Strategic Research Agenda¹³ are utilized for development of annual work plans by the Secretariat. The scope of the calls, research innovation, capacity building and networking initiatives demonstrate there is general alignment between the annual works plans and the strategic goals.

7.4.4. Programme achievements and challenges

One principal achievement of EDCTP2 is the membership that has been established among partner countries. Having the African PSs at the decision-making table has galvanized interest and participation at the GA. There are, however, shortcomings linked to this participation. This view was expressed by many of the stakeholders both from African and European PSs. The theme of the concern was that many countries, both African and European, do not send decision makers to the GA. The GA membership is frequently made-up of scientists as the Governments assume they are best placed to engage with the GA and EDCTP2. However, nominated scientists from specific institutions may not have the mechanisms by which to engage in broader in-country consultations that would allow their views to be more representative of the larger scientific communities. Both European and African participants indicated that either lack of seniority or being in a position external to government prevented some GA representatives from articulating their countries’ positions or making decisions and commitments on behalf of their governments. This issue was identified as a particular challenge for representatives from African PSs who are often scientists and do not have the decision making power that can commit their Government to action. Solutions were suggested such as: “EDCTP needs to be involved at higher level in African nations, WHO would be a very good channel to engage African Governments. WHO
has a very important voice – when it comes through WHO, governments listen. At least 2 times per year, WHO brings all African Ministers of Health together.”

The predominant pattern of non-governmental GA representatives was also identified as a factor that has made it difficult to get African governments fully committed. The need for a more proactive approach to engaging African Governments was articulated: “EDCTP needs ‘champions’ to go to government and present ‘opportunity’. This person needs to be someone that has a ‘relationship’ with the government. He should go back and ‘report’ to the government”. A need was expressed to approach the African Governments in a manner that would enable them to appreciate the value of their engagement: “EDCTP has not branded or marketed its message in a way that is appealing to the African governments.”

Another concern expressed in interviews was that many African countries are not prioritizing research. A national research plan has not been formalized in many African countries. Many competing interests and other concerns distract from research priorities. Countries lack effective advocacy for research and EDCTP2. Quite simply, the case is not being made for research investment. Of note, the appointment of high-level representatives to EDCTP2 was completed in the third quarter of 2016. The high representatives had therefore not been available to engage the governments and policy makers in countries (both European and African), which may have lessened the potential for greater strategic advancement and engagement of more African PSs. The inadequate engagement/ lack of ownership of EDCTP2 by African PSs was a recurring theme among different stakeholders and was reflected in the absence of strong funding commitments, both in cash and in kind; only three African PSs have reported PSIAs between 2014 - 2016.

While regional African bodies expressed an interest and willingness to support EDCTP engagement with African governments, there seemed to be insufficient advocacy and direct discussion with the African bodies that can support /advocate EDCTP2 activities and better engage PSs, e.g. African Union (AU), World Health Organisation (WHO), African Academy of Sciences (AAS) and Alliance for Accelerating Excellence in Science in Africa (AESA), and New Partnership for Africa's Development (NEPAD).

**What level of scientific, managerial and financial integration has been achieved? How does the level of integration of the EDCTP2 programme compared to the EDCTP1 programme?**

A detailed comparison of the integration of EDCTP1 and 2 was not undertaken. EDCTP1 and EDCTP2 are two distinct programs. EDCTP1 functioned under the EU 6th Framework Programme (FP6), while EDCTP2 functions under the Horizon 2020 programme. During EDCTP1 the African countries did not have the same level of engagement as the European countries, as they were only observers on the GA. EDCTP2 provides a stronger framework for active engagement and effective partnership of the African PSs, since as full members, they have decision-making power at the GA. This arrangement provides an opportunity for
more inclusivity and integration. The overall goals of EDCTP2 are more comprehensive with regards to PRD and are aligned with the overall goals of Horizon 2020.

While financial and managerial integration is in process, different stakeholders raised concerns that the regulations of Horizon 2020 have made the timely and efficient achievement of the goals of EDCTP2 challenging. The process of approval in the first two years of the programme has taken a long time. As a result, the Secretariat has not had sufficient time to implement the work plans even once approved. The process of yearly work plans, and the delays in the approval process and the review mechanisms result in limited implementation time, especially when the work plan is approved 8 months into the working year (see above, Table 2 in section 5.7).

EDCTP2 has been unable to fully integrate with Horizon 2020, in particular the lack of access to existing tools like Horizon 2020 Participant Identification Code (PIC). The PIC provides a required mechanism for certification of the legality of an organization and identifies its legally authorized representative, a step mandatory before funding. This situation has reduced the efficiency of funding disbursement. Another bottleneck, which is beyond the Secretariat’s control, is the requirement for ethical approval of projects. This process is dependent on review by ethics committee(s) in institutions and counties shortlisted for funding and is a critical requirement before obtaining the funds.

While the two offices in Cape Town and in The Hague seem to be integrated and have regular communication and some travel from between them, communication and clarity of roles were cited as areas where improvement would lead to greater cohesiveness and productivity.

Certain regulations make the process of funding capacity building – which is a corner stone of the EDCTP programmes – challenging (e.g. tuition fees are not an allowable cost, so a stipend can be paid to a scholar but tuition cannot be paid to the institution).

7.4.5. Socio-economic impact

Through the portfolio of funded grants, EDCTP2 is supporting scientific collaborations on PRDs research, both within Europe, in Africa, as well as between the two continents. The EDCTP2 calls (due to their eligibility criterion) require participation that results in North-South, South-South and North-North partnerships. Both sub-Saharan African research institutions and European institutions perform joint activities in the process of implementing the research programmes. While the involvement of various participating institutions and countries is apparent, it is too early to evaluate the socio economic impact of the programme in these first 2 years.

In responding to the PRD, the EDCTP2 programme contributes to the EU policy objectives, which have a focus on three main areas: excellence in research, fostering industrial leadership and tackling societal challenges. Once there has been sufficient implementation time, evaluation should be able to determine the impact with regards to contribution to Horizon 2020 goals and EU policy objectives. Annex 11 of the Input report to the interim evaluation, “Key expectations of results of grants funded between 2014 and 2016”,...
suggests they are on track to demonstrate outcomes including strengthened institutions, shortened treatment outcomes of PRD and point of care and other diagnostics for target diseases.

### 7.4.6. Leverage opportunities for public/private investments

EDCTP2 has successfully leveraged opportunities to collaborate with private/public institutions to increase investments. These opportunities build on key areas of strategy that benefit EDCTP2 stakeholders. In the period under evaluation, these efforts have yielded in cash and in kind contributions to the EDCTP2 programme, including joint calls for both research innovation and training opportunities. Some examples are provided below that demonstrate the diversity of partners engaged:

- In order to strengthen financial and project management, EDCTP2 has invested in the development of a tool to support good financial and grant management practices. In further building this core competency and skill, EDCTP2 worked with MRC-UK, the Wellcome Trust and other funders to support development of a web-based Financial Management Assessment Tool (FMAT).
- In building private/public partnerships, in 2015-2016, Janssen provided in-kind contributions to EDCTP2 through Secretariat support via staff secondment equal to €205 500 (see table 24 of the Input report to the interim evaluation\(^\text{15}\)).
- Leveraged funding in 2016 included the largest such contribution of €8.7M from the MRC/DFID/Wellcome Trust Joint Global Health Trials scheme for joint funding of clinical trials as part of the 2015 Call for Proposals “Improved treatment and clinical management of poverty-related diseases”.
- Discussions held in 2015 and 2016 between EDCTP and the Leprosy Research Initiative (LRI) yielded €400 000 for EDCTP2-funded projects on leprosy research. As a result of this leveraging, this co-funding will be available for successful applicants in the 2017 Call for Proposals “Targeting control and elimination of NIDs through clinical trials” (see Input report to the interim evaluation\(^\text{15}\), Section 3.2.4.3).
- Lusophone countries have benefitted from leveraged funds with the Gulbenkian Foundation which committed to support building research regulatory capacities in Lusophone countries for the call put out in 2016. From 2017, the Foundation will support students and fellows from Lusophone countries participating in EDCTP2 programmes.
- Outreach for funding support has not been limited to EDCTP2 PSs, but has also included aspiring states like Switzerland which earmarked funding for Swiss institutions that participated in and were successful EDCTP2 calls for funding.
• Beyond research and capacity building, sponsorship from both the private and public sectors raised € 477,745 to support the 7th and 8th EDCTP Forums.

7.4.7. Operational objectives; Stakeholder satisfaction with implementation

In previous sections, the operational, managerial and scientific programme objectives are discussed. While stakeholders expressed general satisfaction with the overall EDCTP2 programme, there were concerns among stakeholders across the north and south on the delays in implementation. Specific concerns were over the administrative structures at the governance levels, which were considered to be slow and result in delays in implementation of the program: “There is very little strategy behind PSIAs. The initial step was to make them open [to improve transparency]. Second step is to encourage collaboration across all countries. However, PSIAs are not the instrument needed to reach overall goals”. The introduction of the Horizon 2020 administrative structures was to simplify matters and allow maximum efficiency and effectiveness. However the unintended outcome seems to have been an even slower process: “Flexible funding is needed, currently only EU funds are flexible; other flexible funds need to be mobilized. PSIAs are not the source of this flexible funding due to restrictions on how funding within PSIAs can be used.” The Horizon 2020 regulations require adherence to certain legal requirements, like verification of legal status of institutions to be funded. The EDCTP Secretariat reports that one challenge is lack of access to the Horizon 2020 contact information and database. In order to comply with legislative and programmatic requirements, the creation of a new database for EDCTP2 also slowed down the process (see the Input report to the interim evaluation, page 11, section on Grant agreement preparation).

The end-users/beneficiaries of the EDCTP2 programme in interviews indicated that the administrative structures at the governance levels have been slow and resulted in a much slower initiation of the programme and delays in implementation: “The programme is not fit for purpose - the time it takes to go through various stages causes delays and makes it challenging to keep on time. The processes are long and they will always lag behind.” They also expressed a recurring theme among different stakeholders of a need for better visibility, as there is insufficient political connection to policy makers so dissemination of information on research and its benefits may not be as robust as required.

Stakeholders expressed a lack of coordination internally within countries of various research partners and institutions, and also a lack of coordination among PSs within Europe and similarly among African PSs. The need for better and more concerted coordination efforts within and across the EU and African Nations was also expressed as important.

Another area of concern was the actual mechanism for funding. While PSIAs allow for individual country initiated programmes to contribute to the funding pool, they were not ‘strategic’ for the overall goals of the

Concerns on the funding model: “The current model of short term funding may not be the most effective and a consideration may be given for portfolio funding for greater effect”.
programme and did not allow for flexibility of funding to programme areas: “The current model of short term funding may not be the most effective and a consideration may be given for portfolio funding for greater effect”.

There was also some concern about the levels of funding and the process of applying for grants and feedback once the applications were in. The concerns ranged from cumbersome repetitive processes for the application, to feedback that was not useful for the applicants for revising grants if they wanted to reapply. In some cases, these concerns made the applicant question the quality of the review and if the reviewers had really taken time to read the applications. There was some discouragement over the perceived lower rate of funding, i.e. the ratio of the applications to the final number of funded proposals, especially given that the calls were broad and inclusive. Given the amount of time/effort and sometimes financial muscle needed for large joint grant applications, some stakeholders felt that a two-tier process for grants - with financial support for actually applying for the large grants (for activities such as joint planning meetings with international partners) - may be preferable. Thus, the first stage would restrict those putting in the major effort to a smaller number of potential grantees thereby reducing the burden for both the Secretariat and the grant applicants. Others felt the applicants-to-awards ratio could be improved by more focussed calls in which the scope of work/area of interest is more limited. Some concerns were raised that the overall levels of funding may be insufficient: “The senior scholarship funding – the title is prestigious but the funding is very little -the up side is that it is good for training but there is no funding for the senior scholar, it is not adequate.”

There was a concern that apart from capacity building grants, in practice there were no grants for middle career scientists seeking growth, especially those who had already been successfully trained using this same mechanism. In fact, trainees have not been tracked after they complete their training period so their subsequent productivity has not been captured, which would provide the clearest measure of the success of training efforts and subsequent opportunities. This issue is being addressed by the process now underway to evaluate a tender to develop a tracking system for Alumni (see the Input report to the interim evaluation\(^5\), section 2.2.2.3 page 14).

One pointed concern arose in the first year of implementation when the submission date for one specific call for proposals was changed twice and significant changes were made to the content of the funding call. Scientists reported that these changes resulted in wasted time and effort for those responding to the call.

A recurring theme was the lack of a clear definition of scientific leadership. This concern highlights the need for evaluation matrices to measure success of EDCTP2 in order to clearly gauge effective leadership. Scientific leadership was to be defined as “global scientific leadership” and not only scientific leadership in the African context. The same global parameters that would define scientific rigor and leadership would need to apply.

Funding was provided on the ‘best science’ model - which to some extent disadvantaged the countries that still needed greater capacity building. Some expressed a need for more
There was optimism that the overall goals of EDCTP2 would be achieved because of their unique niche; “They (EDCTP2) will achieve their goals as they are meeting a need, which the country cannot fund on its own”.

EDCTP2 remains relevant in addressing public health concerns of the region as indicated by stakeholders: “Bringing in neglected diseases in EDCTP2 was very good. Also capacity building is important.” Beyond funding for research in the specified disease areas, several interviewees considered the capacity building aspect of EDCTP2, such as support for research regulatory capacity, to be a very valuable contribution: “EDCTP has been extremely useful in capacity building, especially in ethics and regulatory structures.” There was optimism that the overall goals of EDCTP2 would be achieved because of their unique niche; “They (EDCTP2) will achieve their goals as they are meeting a need, which the country cannot fund on its own”.

7.4.8. Socio-economic impact

The socio-economic impact of EDCTP2 with regard to scientific, financial and managerial integration is exemplified by the response to the Ebola outbreak, which happened early in the implementation of EDCTP2. As indicated during the interviews: “Much of what was accomplished would not have been accomplished [in reference to the Ebola response] without the concerted efforts of EDCTP2.” With regard to the Ebola response, EDCTP2 contributed directly to the goals of Horizon 2020 and EU policy by improving well-being/health and engaging in a collaborative European/African partnership.

Given the limited duration of the programme, the overall socio-economic impact of EDCTP2 was not widely discussed, but a few stakeholders who are actively engaged in EDCTP2 made recommendations for maximizing its impact. A “change in mentality” towards true partnership between EU and sub-Saharan countries - instead of donor-recipient attitudes - was voiced as a means to enable more meaningful engagement of the African countries and instil greater ownership of the programme, commitment to funding and utilization of outputs: “There is a need for the development of true partnerships in order to realize the overall socio-economic impact. EDCTP should move out of the current donor-recipient attitude and should all be on the same level in true partnership.”

Stakeholders suggested EDCTP2 take a broader, long-term view of “portfolio” funding to emphasize targets from “start to end.” Systematic funding should target products that can be processed through the pipeline from phase 1 to phase 4: “Long term planning/portfolio
development may be important to achieve the pipeline of development of products that can enable achieving the goals for the programme – product development for drugs or vaccines to tackle the target public health concerns.” To evaluate this type of impact comprehensively, more implementation time would be required with greater downstream documentation.

7.4.9. Operational objectives: Networks and Partnerships

The regional networks were mainly interrogated via the face-to-face interviews. Stakeholders felt networks could be further strengthened both between countries and within. Further interactions among the networks from various regions should be fostered. However, lack of funding for the actual coordination of the networks was identified as a challenge to fostering regional collaboration and networking.

While it is early in the implementation of EDCTP2, opportunities exist for engagement between stakeholders that would enhance the programme, allow for more collaboration and build stronger links among partners who are working in the same region. Examples provided by interviewees suggested that engagement with the pharmaceutical industry could encourage investment in product development areas of interest to industry. Links with the African Academy of Sciences (AAS) or the Alliance for Accelerating Excellence in Science in Africa (AESA), which is housed within the AAS, may provide opportunities for further leveraging of funds and networking.

Additional opportunities exist to foster new relationships as illustrated by one interviewee who works across several countries in the region: “Further engagement with NEPAD would also raise visibility within the African Union and encourage more African countries to participate. NEPAD would provide an opportunity for leveraging on the good will and opportunities for engagement with AU member states.”

7.4.10. Integration of the strategic planning within Horizon 2020

As described in section 7.4.3 and 7.4.4, EDCTP2 is implemented within the framework of Horizon 2020 and the societal challenge of health, demographic change and well-being. The strategic planning process and approvals of yearly work plans are conducted according to the regulations of Horizon 2020. Being part of the EU was cited as a real advantage; EU engagement and support is useful and high-level engagement with the EU parliament is described as a strength of the programme. Other stakeholders, however, cited challenges with the integration of the planning process causing delays in implementation of work plans and problems funding and implementing capacity building programmes, “The unique goal of EDCTP2 was in the 3 focus areas, infrastructure, excellence in science and capacity building – is this being lost – being swallowed up in Horizon 2020 rules?”; “Very legalistic. Does not take into account the special niche of EDCTP2.” The key differences between EDCTP1 and EDCTP2 are the frameworks and the rules and regulations under which they
are implemented. EDCTP2 under Horizon 2020 has noted some challenges in the implementation of the programme because the goals of EDCTP2 include capacity building and infrastructure development. The Horizon 2020 regulations do not easily align with the payment for example of tuition fees or the direct costs of infrastructure development: “For infrastructure – Horizon 2020 does not provide equipment (purchase) – will they be able to make it happen?” “Horizon 2020 has constraints on how calls can be done.” These challenges of implementation and regulation were noted as a key difference between EDCTP1 and EDCTP2. EU funding to EDCTP2 is organised through a delegation agreement between the EC and the EDCTP Association that is necessarily required to operate within Horizon 2020 rules. However, the nature of the Horizon 2020 regulations have created some bottlenecks for implementation; “EDCTP2 and 1 are different – EDCTP2 has a delegation agreement between EU and Africa, which requires they operate within Horizon 2020 rules – this creates a bottleneck”.

7.4.11. CHALLENGES

7.4.11.1. Administrative bottlenecks

The Input report to the interim evaluation\(^{15}\) noted that EDCTP2 has had administrative challenges in meeting its performance targets: (1) EDCTP2 had to establish its own system to comply with Horizon 2020 procedures, which includes verifying identities of the legal entities and legal representatives, especially participants in Africa who have a limited track record of Horizon 2020 funding; (2) several iterations between EDCTP and the Coordinator are required to fulfil acceptable ethical considerations during review; (3) the annual work plan review process and timeline for approval create ongoing administrative bottlenecks.

7.4.11.2. Administrative burden of EDCTP2 reporting

The administrative processes around PSIAs are perceived as complex and laborious (interview data). The workload is not in line with the usefulness or strategic impact of the PSIA instrument in its present form. Moreover, it is questionable whether PSIAs, as practiced, are an efficient or effective instrument to reach the objectives of EDCTP2.

7.4.11.3. Participating State representation in the GA

The GA is responsible for both deciding the long-term strategic direction of EDCTP2 and maintaining the commitment and active participation of PSs. Although the professional and scientific expertise of the Participating State representatives in the GA is robust and the GA is viewed as a well-functioning structure, several stakeholders argued that its composition does not provide adequate strategic expertise and political insights required to take EDCTP2 further. In face-to-face interviews with stakeholders, it emerged that the current make-up of the African PSs on the GA is largely scientists, most of whom do not have the mandate to make decisions on behalf of their governments. Furthermore, it is unclear how
much access they have to their governments to provide the appropriate feedback on the discussions that occur at the GA.

7.4.11.4. Function of the Scientific Advisory Committee

Although the EDCTP2 Decision\(^1\) (Annex III) designates a well-defined role for the SAC to provide scientific and technical expertise to the GA, its practical function within EDCTP appears less distinct. For example, some SAC members argued that the SAC has an overall strategic role within the EDCTP structure whereas others viewed their task as providing scientific advice. The confusion is probably due to an unclear definition of the role of the SAC in articulating the overarching strategic direction of EDCTP. The SAC appears to interact primarily with the Secretariat and much less extensively with the GA and/or the Executive Board. The different terminologies ("scientific advisory committee" or "scientific strategic committee") used for this body in different documents, presentations, and interviews adds to the confusion.

7.4.11.5. Secretariat function

Central to the function of the EDCTP is the approval of the annual work plans by the EC. Until the annual work plan is approved, no calls can be launched and no commitments made in principle. The Panel heard of one clear case where the consequence of not waiting for the final approval was the unfortunate withdrawal of one call barely a week before applications were due for submission. It is remarkable that the EC and GA approved the EDCTP2 2014 Work Plan only in January 2015 for work that should be implemented in 2014. Similarly, the 2015 Work Plan was approved by the EC and the GA in October 2015, i.e. more than nine months into the year of operation. The process seemed to have improved slightly for the 2016 Work Plan that was approved by the EC and GA in June 2016 (six months into the annual programme period).

7.4.11.6. Grant application process

A number of stakeholders interviewed as part of the evaluation expressed concerns regarding the processes related to the grant application procedures, e.g. it being too long, cumbersome and repetitive. Similarly, the Public consultation report\(^19\) indicates that EDCTP2’s proposal evaluation and selection processes "received the lowest proportion of positive feedback as well as the highest share of negative feedback.” Although the response rate to the EDCTP2 public consultation was quite low, the observation is noteworthy as it relates to a fundamental process by which EDCTP2 implements its goals. There is also a concern among the stakeholders that too many full stage proposals are being invited. This is partly a consequence of the broader disease profile, and limited funds. Some were concerned that the large proportion of failed proposals may lead to a loss of EDCTP2 credibility. Even more disconcerting was a stakeholder statement that "we do not really
understand how they [EDCTP] finance and how they decide who should get funded as they do not communicate well after applications.”

7.4.12. Summary
EDCTP2 goals appropriately support the realization of EU policy objectives, which include the lifelong health and well-being of all, and the strengthening of cooperation with sub-Saharan African countries to address global health challenges. EDCTP2 is an important player in responding not only to PRD but also to capacity building for research. The programme also contributes to the achievement of the United Nations’ Sustainable Development Goals. EDCTP2 contributes directly to Sustainable Goal 3 and supports many of the other SDGs indirectly. The operationalization has followed the Horizon 2020 regulations and has benefitted from the input of the EU.

EDCTP2 in responding to diseases of poverty is on track to contribute to the EU policy goals of lifelong well-being among all. While there has been progress in strengthening cooperation between sub-Saharan African countries and EU countries, more work is needed. The stakeholders are somewhat satisfied with the objectives and the implementation, but implementation has been slower than some anticipated. Governance structures are considered adequate, but the processes linked to governance and administrative implementation are viewed as somewhat cumbersome and causing delays in the execution of desirable work programmes.

There was a notable lack of coordination among institutions within the same country for both sub-Saharan African and European countries. Similarly, for both Europe and Africa, there was inadequate coordination among PSs represented at the GA. The South-South and North-North collaboration needs further strengthening but the North-South collaboration is on track with appropriate engagement of PSs in the implementation of research. The implementation of the overall programme has been slower than would have been expected but it has achieved some of the key operational goals.
7.5. Added value of the EDCTP2 programme

This section summarizes findings from interviews and documents regarding the added value of the EDCTP2 programme. The value-add of EDCTP2 concerns what has been achieved and what could be achieved over and above similar levels of funding and similar types of activities undertaken by individual European and African states and/or by individual funders.

The Strategic Business Plan 2014-2024\(^4\) sets out a number of parameters for evaluating the value-add of EDCTP2. For instance, it describes the long-term impact expected through better coordination and alignment within Europe, with the EU, and with external partners. It further emphasizes the breadth of partnerships needed (with both public and private partners) “to maximise the impact of research, attract additional investment, and to fully exploit the opportunities for high-quality clinical research offered by EDCTP’s integrated approach.” In this business plan, networking activities are described as meeting several objectives (page 30):

- “Fostering productive relationships between European and African individuals and institutions.
- Concentrating efforts, promoting efficiency and avoiding duplication by aligning European and African funders, institutions and authorities.
- Attracting investment from partners in the private, public and charitable sectors.”

This document also emphasizes the need to broker sustainable partnerships and overcome networking challenges experienced previously. The latter are summarized as follows:

“collaborations between European and African scientists and institutions have generally been developed on an ad hoc basis, with little strategic planning, leading to fragmentation and duplication of efforts” (page 30).

Three of five key impact targets in the Strategic Business Plan 2014-2024 (page 35) focus on the value-add of collaborative efforts and partnerships:

1. greater coordination and alignment of national research efforts to maximise the impact of European investments in global health research;

2. partnerships with public and private organisations (both for-profit and non-profit) to ensure that additional use is made of the clinical research capacity established in sub-Saharan Africa to accelerate the evaluation of new medical interventions, and

3. through partnerships with development agencies and related organisations, EDCTP will contribute to sustainable delivery of validated medical interventions through strengthened healthcare systems
To assess value-added and to address the questions identified in the ToR, the perspectives of those from European and African countries, the EU and international organizations were sought. Enablers of and challenges in achieving value-add of the EDCTP2 programme were probed, with consideration given to the groundwork already laid by the EDCTP1 programme. The primary source of data for this section was interviews. However, a number of documents were also used to inform the types of questions the Panel asked interviewees and to augment and validate interviewee responses. The main documents that informed the results in this section were the Input report to the interim evaluation\textsuperscript{15}, the Bibliometric analysis (2015\textsuperscript{23} and 2017\textsuperscript{24}), annual progress report (for 2015\textsuperscript{17} and 2016\textsuperscript{18}), the Strategic Business Plan 2014-2024\textsuperscript{13}, several EDCTP2 funding calls and the Strategic Research Agenda\textsuperscript{13}. The findings section begins with themes that emerged from interviews and then addresses each of the questions outlined in the ToR for this evaluation.

Results

7.5.1. Themes arising from interviews

Data from interviews yielded five themes. Each theme is briefly described below and then elaborated, where pertinent, in response to evaluation questions outlined in the ToR.

7.5.1.1. Support for value-added through partnerships

Strong support for the value-add that could be achieved through partnerships consistently came through in interviews. However, partnership approaches were described as being focused primarily on individual funding calls; lacking overall strategic direction; being nascent in their development; and, in the case of the EU, lacking a coalescence of leadership from European PSs. It was noted that new approaches to partnering would be required to achieve higher level and longer-term goals of EDCTP2.

Many interviewees indicated their strong support for the principle(s) of North-South partnership and strong and diverse external partnerships to strengthen the value-add of EDCTP2. The joint leadership of African and European PS representatives on the GA was repeatedly described as an important design feature of EDCPT2 that was critical to realize the overall value-add of the programme.

7.5.1.2. Getting to value-added – potential rather than realized

Successes in the areas of capacity-building, regulatory and ethics work were most often identified as exemplars of value-add achieved through both phases of EDCTP. South-South networking, and in particular, that supported through the Regional Networks of Excellence funding was identified as an important success. There were targeted suggestions regarding the further realization of value-add among European PSs, within the EU and among African PSs.
Many descriptions of external partnerships emphasized what potential existed rather than what had already been realized. External partnerships described, most often involved aligning interests and leveraging funds for specific funding calls. Meetings between EDCTP2 staff and collaborative partners, while consistently viewed as constructive were described by some as process rather than decision-oriented.

A few interviewees (primarily senior officials of the EU, other research funding organizations or industry), described their concrete vision of EDCTP2 as a game-changer. Examples of such descriptions included: “EDCTP2 is a crystallization point”, “EDCTP2 needs to fund a global health strategy and link with SDGs to advance SDGs”, “We would like to do more with EDCTP2, but they are not out in front”, “EDCTP2 could build regulatory capacity for manufacturing”, “There is a need to strengthen science diplomacy and build this into the political agenda at a high level”, and “We must convey the message [to African governments] that EDCTP’s goals and missions are important for the survival and economy of Africa; this is the challenge for EDCTP2 and the rest of us”. However, discussions by the GA and SAC were described as being focused on funding calls. As one European participant described “When it comes to questions like how EDCTP2 could be a game-changer, not much happens”.

7.5.1.3. Impediments and barriers to achieving value-added networking and partnerships

Interviewees identified a number of significant impediments to more fully achieving the value added of networking and partnerships. These included: (a) the heavy administrative burden for EDCTP2 and Participating State staff (e.g. reporting on PSIAs, preparing funding calls), (b) inflexible rules and processes of Horizon 2020, (c) a governing body for EDCTP2 that tends to have process-oriented rather than strategic-oriented discussions and related approaches to decision-making and (d) the lack of a strategic advisory group focused on partnerships.

Strategic leadership from European PSs was described as weak. EC officials emphasized that they often had to take on a leadership role they thought PSs should be assuming. These views were reflected in comments such as: “Coordination among [Participating] States must happen”, “EDCTP2 needs a lot of push from the Commission”, and “[European Participating] States don’t talk to each other to take advantage of [EDCTP2] opportunities”.

There were a number of barriers and bottlenecks to pursuing strategic partnerships raised by EDCTP2 programme staff and the Secretariat. In particular, the administrative load was identified as heavy and inadequately resourced. The programme lacks flexible funds, such as contingency funds, that may be needed to quickly advance an opportunity for collaboration with another funding agency. It was the Panel’s impression that a primary focus on funding calls was the basis for identifying these barriers. Roles of the Secretariat and other partners in initiating and developing synergies also warrant consideration given competing priorities and the time-consuming imperative of getting funding calls ready in a timely fashion. Some of the existing and potential partners interviewed described the
priority-setting approaches they already had in place and implied that these might be utilized by EDCTP2. However, one member of the GA was concerned that such collaboration could adversely affect the branding of EDCTP2.

Other research funders described the challenges of coordination among funders and a lack of incentives to do so. Among these challenges were different mandates and organizational cultures and the time required for these coordination activities. However, there were a number of significant consequences of an uncoordinated research approach identified by respondents from the public and private sector. Among these were underpowered trials, data from studies that could not be used in meta-analyses, stalled leadership, a failure to include “young minds” from the African content and Europe to “leap frog” scientific achievements, and a failure to move beyond current models of funding. Deliberate, strategic coordination among funders and other partners (e.g. industry) were thus identified as an imperative.

### 7.5.1.4. The way forward

Two main areas for development emerged in interviews: (1) strengthening ties with African governments and regional organizations; and (2) adopting a portfolio approach for EDCTP2 investments.

Several African interviewees spoke about their experiences of working with Ministry partners, either in their role as designated representatives on the GA, and/or as scientists who were aiming to advance clinical trials research in their respective countries. GA members who represented their countries described the challenges of engaging policymakers, given “inconsistent accountability and communication mechanisms” between some GA members and their governments. They identified the need to link EDCTP2 to government planning and budgets, noting that this was essential to obtain the €200 000 cash contribution from African member states. A GA member noted that it was easier to link EDCTP2 work plans to policy-making when national research work plans were in place. Ghana was identified as a country where a five year research plan has recently been adopted by the government. This plan prioritizes malaria, TB and HIV research. One interviewee noted that without national research plans, the “pull factor” for the uptake of research was weak. Networks of Excellence investigators reiterated some of these concerns, as they highlighted factors that would help clinical trials research flourish in their countries of focus.

Regional organizations that already have formal structures and mechanisms to link with government on matters of research were described as potential brokers for the work of EDCTP2. For instance, the West African Health Organisation (WAHO) was identified as an organization that could facilitate the recruitment of new members states (e.g. Nigeria), while the African Academy of Sciences was identified as an organization that could help make the case for national research plans.

A senior member of an African funding organization observed that some African governments do not see R&D as essential to economic growth. This individual thought it
was important for EDCTP and other partners to emphasize this critical message and then to show how EDCTP2 could advance an R&D strategy. Along the same lines, others identified that EDCTP2 can provide a means for African and European governments to meet SDG obligations.

A portfolio approach, where several products within the pipeline are being tested, was identified as a preferred and/or essential approach to achieve the value-add aspirations of EDCTP2. This point was made by a considerable number of respondents including senior officials of the EC, EDCTP Secretariat employees, members of the GA and representatives of public and private organizations. However, some difficulties in adopting a portfolio approach were identified. The most commonly-described challenges concerned the legal structure and restrictions of Horizon 2020 and the lack of flexible funds and contingency funds for EDCTP2, which impeded timely and flexible negotiations with other partners on potential joint funding initiatives.

Several prerequisites and conditions for extending the value-add of EDCTP2 were identified. Recurring suggestions were:

- To support and link with other organizations and structures and coordinate with other partners undertaking related work (e.g. regional networks, WHO, WAHO, African Academy of Sciences etc.)
- To encourage European PSs to join efforts to provide strategic leadership for EDCTP2 in order to facilitate greater alignment with other EU programmes
- To develop strategic priorities and performance indicators (process and outcome) for achieving the value-added potential of EDCTP2
- To rethink relationships with industry, and
- To rethink the role of South Africa within EDCTP2.

### 7.5.1.5. Potential indicators to assess value-added

A number of interviewees directly or indirectly identified indicators that might be used to assess the value-added of EDCTP2 activities. Several indicators proposed are already identified in EDCTP2 documents such as the Strategic Business Plan 2014-2024. Some are new indicators that may warrant consideration by the GA. Examples of the latter, from interviews, are listed below.

**Output Level Indicators:**

- Extent to which EDCTP2 brings projects together
- Extent to which EDCTP2 portfolio is linked to that of partners
- Different entry points to partners and partnerships are being explored

**Outcome Level Indicators:**
Regional collaborations (African and European) reflect well planned and executed activities that build on complementary strengths of collaborators.

Sustainable funding mechanisms are being identified and fostered.

EDCTP2 acting as a catalyst for partnership development.

Governance mechanisms in place for decision-making with partners and resolution of conflicts.

Accountability and communication mechanisms in place for GA members to receive inputs from and report back to their countries.

In general, these indicators concern the intermediate goal of developing a strategic approach to enable sustainable partnerships.

An important observation made most succinctly by one African interviewee, but alluded to by others, was that “African leaders need to see that EDCTP2 goals are important to the survival and economy of Africa”. This requires linking the initiative not only to national research agendas (which for many African member countries were described as either not yet in place or having little or no accompanying national budget) but also to national priority agendas for improvements in the economy, and achieving SDG targets.

7.5.1.6. Findings related to the specific evaluation questions

7.5.1.6.1. Assess the European added value of the EDCTP2 programme

What is the additional value resulting from the implementation of the EDCTP2 programme compared to what would have been achieved by individual Member States acting independently at international, national and/or regional levels?

The GA provides an important mechanism for joint discussions and planning. The co-leadership provided by European and African PSs was repeatedly identified as critical to success. However, uneven leadership and gaps in joint leadership among European PSs were identified as weaknesses by a number of participants. One interviewee stated that EU countries want EDCTP2 funding to go back into their own research sites, suggesting that disincentives to collaboration were also in play.

While PSIAs were intended to provide a mechanism for synergistic activities among European PSs, various interviewees indicated that they had not served this purpose (see further discussion about PSIAs below).

To what extent is the EDCTP2 programme able to identify and exploit synergies with other EU policies, e.g. health, development cooperation and external affairs policies, in particular EU relations with African countries and regions?

Interviewees described some efforts and successes to identify and exploit synergies with other EU policy directions. However, these primarily involved efforts to reflect such
policies (e.g. development cooperation) within funding calls and/or to identify opportunities for joint funding.

The Strategic Research Agenda prioritizes diseases and scientific foci for funding calls. However, it contains no explicit strategic direction with respect to collaborative partnerships that would purposefully exploit synergies with other EU policies.

While the PSIA mechanism (discussed in more detail below) was intended to help exploit these synergies and the GA put in place working groups to foster this effort, interviewees consistently noted that PSIs have not proven to be a mechanism to harness potential synergies.

*To what extent does the EDCTP2 programme increase the EU’s contribution to and visibility in the fight against poverty-related diseases?*

Several senior officials indicated that EDCTP2 was beginning to improve EU’s contribution to and visibility in the fight against poverty-related diseases. They also made specific suggestions for enhancements. While there have been some improvements in communication materials from EDCTP2, this was identified as an area requiring further attention; this material could serve as a vehicle to make this link more apparent. There were also other high profile EU initiatives identified such as the Joint Programming Initiative on Antimicrobial Resistance, wherein links and connections might help bolster EDCTP2. More deliberate and explicit links to the Sustainable Development Goals were also identified as a future focus. One participant was concerned that EDCTP2 branding might be diluted if EDCTP2 were to be linked to other major funding initiatives. Although this concern was not expressed by others, it does suggest the need for a deliberate and strategic approach.

A consideration in demonstrating how EDCTP2 is contributing to the fight against poverty-related diseases will be to show its coherence with other programmes funded through Horizon 2020. For instance, one interviewee noted the strong complementarity of EDCTP2, with its focus on clinical trials and the Innovative Medicines Initiative (IMI), with its focus on poverty-related diseases.

*To what extent does the EDCTP2 programme increase the EU’s contribution to reaching the Sustainable Development Goals?*

A few interviewees were asked about the link between EDCTP2 and the SDGs. Responses were more generic than specific. It was suggested that the EDCTP2 programme has potential to advance progress on some Sustainable Development Goals and that this needed to be communicated to PSs and the EC. However, a review of EDCTP2 annual work plans and communication documents did not include any sections highlighting the link between SDGs and EDCTP2.
A couple of interviewees, when prompted, suggested that if EDCTP2 were to incorporate some indicators required for SDG reporting, this might provide a win-win situation to assist governments with mandatory reporting on SDGs. It would also help to raise the visibility of EDCTP2 as this type of reporting could help bring it into the agenda of G7 and G20 meetings.

### 7.5.1.6.2. Assess the national added value of the EDCTP2 programme

**To what extent is the EDCTP2 programme able to identify and exploit synergies with other European national and/or regional policies and initiatives, including health, development cooperation and external affairs policies and initiatives?**

A detailed examination of potential synergies between EDCTP2 and other EU programmes and policy instruments was conducted by the Panel (see Annex 10.5). To gauge the extent to which these synergies are being realized in practice, the Panel sought the input of interviewees who provided perspectives of the EU and of several European countries and agencies.

While the PSIA mechanism seems to have been developed with the intent of building synergies, there is little evidence that synergies are being realized through this mechanism. One interviewee stated this very clearly “PSIAs are just a collection of what countries are doing; there is very little strategy behind them”. This participant went on to say that “PSIAs are not the instrument needed to reach the overall goals of EDCTP2”. It seems that the PSIA funding would have been disbursed irrespective of EDCTP2. The Panel could not find any examples of new directions for such funds that arose due to EDCTP2. It’s possible that this reflects relatively early days for EDCTP2 programming, but mechanisms for joint planning, to identify and develop opportunities for the realignment of PSIA funding were not suggested. Furthermore, the PSIA mechanism was described as bringing a heavy administrative burden to the countries involved, in part, because the reporting required to complete the annual forms does not fit with the sources of data readily available from pertinent agencies in European countries.

A number of individuals from European PSs commented on the national value-add of the EDCTP2 programme. The UK identified the link to their development aid investment in research as a synergy. Germany was identified as a country where within-country coordination had improved. Sweden described the Ebola initiative of EDCTP2 as an example of an initiative that linked with their development agenda. In contrast, Belgium withdrew as a PS in the transition from EDCTP1 to EDCTP2, citing the apparent disconnect between EDCTP2 and the national priorities of Belgium as one of their concerns. Furthermore, Belgium indicated that their researchers remained eligible for EDCTP2 funding, thereby minimizing the impact of their withdrawal.

Several senior officials applauded the efforts of several European countries to provide leadership for EDCTP2, but expressed aspirations for these countries to develop joint
strategic leadership within the EU that would extend beyond trying to increase the amount of funding obtained by scientists in their own countries.

### 7.5.1.6.3. Assess the international added value of the EDCTP2 programme

To what extent is the EDCTP2 programme able to identify and exploit synergies with other international, regional and national policies and initiatives, including health, development cooperation and external affairs policies or with regard to Africa?

Those directly involved in EDCTP2 as well as other stakeholders from a variety of organizations identified in the evaluation ToR, offered reflections on potential international synergies and how these might be exploited or developed. Outreach to international stakeholders (private and public) that has been undertaken by EDCTP2 Secretariat and staff is summarized in the Input report to the interim evaluation. This shows a diversity of organizations that have been contacted, some with longer-standing involvement initiated in the earlier phase of EDCTP.

In discussing outreach, members of the GA and others, indicated that the strategic intent of pursuing and developing synergies warranted further discussion and development. There were numerous suggestions of partnerships that might be explored. Several organizations were identified as important new targets for outreach. Examples included the African Academy of Sciences, Regional WHO offices and organizations at the interface of policy and research such as WAHO. One EDCTP2 interviewee referred to the “jungle of partners” potentially pertinent to EDCTP2. This intricate web of partners is reflected in numerous documents reviewed for this evaluation including PSIAs, bibliometric analyses, annual progress reports and the World Report on research funding. These include research funders and foundations, development aid organizations, and those working in the private or academic sector.

There are early indications of how some international partnerships are being leveraged but three things stood out from interviews. First, the primary focus appears to be identifying joint funding opportunities (both in terms of collaborations being sought and how this is being translated into action) that can be used to augment funding calls - there are several examples of successful initiatives (see Section 7.4, Effectiveness). Second, there is openness to collaboration among the international partners the Panel interviewed. A wider set of options for partnerships were identified and considered important (i.e. options other than joint funding mechanisms). There was recognition that the longer-term planning mechanisms EDCTP2 required for prioritizing and building strategic and sustainable partnerships are not yet in place. A portfolio approach was frequently identified as an approach required for value-added collaboration. Third, a number of interviewees stated that there are good relationships between EDCTP2 and various partners (potential and actual). They mentioned various exploratory meetings that have already taken place, (these are also documented in annual progress reports and the Input to the interim
evaluation\textsuperscript{15}). However, one interviewee described these meetings as process- rather than decision-oriented and this perspective was affirmed by other inputs to this evaluation.

Although a number of international partnerships had materialized or were under discussion, the Panel did not see evidence of a process for prioritizing international strategic partnerships. The Panel did not locate a description of strategic foci for these partnerships, and the Panel did not hear a common view as to what governance body was responsible for developing this strategic approach or an articulation of what this strategic approach might involve. Interviewees did identify a number of areas for strategic development that clearly require strong partnerships and suggested that moving in this direction required solid leadership and would help to advance the value-added intent of EDCTP2. Some areas for strategic development with partners were identified including developing young African leaders, mobilizing the talent pool of African scientists, furthering and harnessing successes including research capacity that has been built in African countries, and work on ethics and regulatory frameworks. South Africa was identified as a critical player in the development of strategic partnerships for EDCTP2, but several interviewees thought the South African role needed to be re-evaluated and reconsidered.

In terms of scientific output, the value-add of joint funding for scientific partnerships is clearly demonstrated in the Bibliometric analysis\textsuperscript{24}. This analysis highlights the stronger scientific outputs (publications and their citation) that have been achieved through European-African partnerships rather than by European or African scientists alone. In all four categories of diseases presented in the analysis (HIV/AIDS, TB, Malaria, and Neglected infectious diseases), publications involving European-African co-authors were more highly cited and had higher ARC scores than publications written only by European or only by African authors (See Table 1, p. 24). While these data are for the first phase of EDCTP, they do point to the value-added of collaborative scientific work involving European and African researchers.

\textbf{How does the EDCTP2 programme compare with similar types of public-public partnerships?}

Interviewees indicated that in comparison with joint programming initiatives, EDCTP2 has reached much further, is a more mature organization, and has made some significant headway on ethics and regulations. These are important areas where added-value has been achieved and there are lessons to be learned from the approach taken.

Nevertheless, most successful public-public partnerships have a broad joint vision, clear joint objectives, a portfolio strategy and a long term partnership plan that bridges the complementary mandates and visions of the partner organizations. This is the strategic area of development for public-public partnerships that requires further work by EDCTP2.

\textbf{To what extent is the EDCTP2 programme able to identify and exploit synergies with other international programmes or initiatives? [e.g. the Global Fund to Fight AIDS,}
Although there were a number of options for potential synergistic work identified by the Panel (Annex 10.5) during interviews, only a few of these synergies seemed to be actively targeted and/or under development. Senior officials interviewed from a number of international funding agencies, indicated that EDCTP2 had a low profile and noted the lack of strategic discussions to plan, align and coordinate activities among funders. They identified a number of barriers to effective coordination but appeared to support the need to overcome them.

The value-added achieved to date is most notable among African countries, particularly through the funding of Regional Networks of Excellence. One of these networks, described their impressive and expanding links with countries, industry and other partners, but noted that these efforts will require additional funding support if they are to fully succeed. Leads and researchers from these regional networks indicated that a rethink of funding models for the networks was needed in order to advance the next phase of their work.

The Bibliometric analysis (2015)\textsuperscript{23} points to some more nuanced considerations of partnerships that might be important for discussions going forward. In particular, the lower citations rates for African countries wanting to join EDCTP2 suggests that there is strong potential to further develop capacity and that targeted approaches are needed for weaker institutions. This was a point also made by a number of African scientists, and in particular those who had experience with the EDCTP\textsubscript{1}-funded Networks. The dominance of several academic institutions both in Europe and South Africa raises critical questions about how to measure success for other institutions and how to assess the quality of network links between those institutions with weaker and stronger research capacity. This point was also raised by some African participants, who expressed some concerns about the dominant role of stronger African institutions that could more successfully compete for funding calls, and thereby inadvertently undermine capacity and leadership development in weaker institutions. The Network model was seen as a mechanism that deliberately addressed this challenge and used strategies to bridge the complementarity of stronger and weaker institutions.

\textit{To what extent is the EDCTP2 programme able to identify and exploit synergies with the efforts of other public and private research funders, including with pharmaceutical industry?}

Several interviewees identified gaps in the exploration of additional synergies for the programme. When asked, interviewees described strong potential for a number of synergies with public research funders and with the pharmaceutical industry. Several interviewees discussed the need to sort out how products can fit into the clinical trials pipeline, how to expand the range of products in that pipeline, and how to mobilize joint efforts to get the funding needed for late phase trials.
While communication regarding EDCTP2 activities in annual work plans was identified as a strength, proactively creating forums for discussions of other synergies or using existing governmental or private sector forums (e.g. WHO regional meetings, WAHO forum) to identify and exploit synergies were described as more nascent, yet promising activities.

The Bibliometric analysis (2015)\textsuperscript{23} identifies the ranking of EDCTP against other funders, as the source of funding for research reported from European and African regions. The consistent pattern to emerge is that EDCTP is ranked 10th or 12th as the source of funding. This does not suggest any under-performance by EDCTP. Rather it indicates that EDCTP is a relatively new programme compared to other longer-standing funders in this area (e.g. NIH), and that EDCTP has a smaller budget than some of the other funders (particularly if one takes into account cumulative funding amounts over years). Nonetheless, it also points to the importance of seeking partnerships with these international funders and finding a way to join up efforts. While interviewees from some of these organizations indicated that they would welcome discussions regarding synergies with EDCTP2, it seemed that many of these discussions were at early stages, had been somewhat ad hoc and lacked tangible ongoing direction. Interviewees also described the importance of synergistic efforts that complemented joint funding calls and realized the larger aims of reducing poverty-related communicable diseases. While the interim evaluation report indicates that a number of high level meetings with other funders have taken place, it is short on any details regarding the outcomes of these specific meetings, intentions to further discussions, and the formulation of long-term, win-win, strategic partnership plans.

7.5.2. Summary

There was substantial congruence in views among European, African and international interviewees. The value-add of EDCTP2 was largely described as potential rather than actual. Realizing the actual value-add is going to require new approaches to strategic partnerships planning. It must be vision-led with a view to sustainable partnerships. It requires a deliberate strategy and will involve new approaches to consultation that go well beyond more traditional stakeholder meetings. It will require an orientation to consultation that extends well beyond discussions about funding calls. Leadership for this effort must come from PSs.

There seems to be a lack of strategic vision regarding the value-add for European countries that are EDCTP2 members, other than providing access to funds for research in low and middle-income countries. PSIAs have not brought European countries together to develop new arenas/initiatives to coordinate efforts.

While there has been outreach to a number of stakeholders and some successes achieved in leveraging funds for several funding calls, a strategic approach to these partnerships can best be described as nascent. A strategy to set priorities for strategic and sustainable partnerships is essentially absent from the Strategic Research Agenda. Furthermore, planning documents do not provide any indication of a planned portfolio approach to be undertaken in tandem with other partners.
Questions outlined in the ToR, asked that the Panel examine value-add from several perspectives. In the Panel’s opinion, the value-add of EDCTP2 can only be achieved through a collective approach, which examines how EDCTP2 operates as a system. Inputs in one component of the system will resonate/impact throughout.

Many suggestions were provided regarding developing a strategic focus. Project documents suggest a blind spot that needs to be examined and might provide foci for discussions of potential collaboration. Specifically, logic models identify medium and longer-term objectives but without any discussion of the mechanisms required to move from one to the next. It is apparent that achieving these mechanisms will require deliberate collaborative efforts. While the value-add impact will be seen in longer-term outcomes, EDCTP2 needs to critically consider how to achieve these – what mechanisms are required and what theory of change can guide collaborative efforts?

While the Strategic Business Plan 2014-2024 describes the central importance of coordination and collaboration in Europe, between Europe and Africa, and with other international partners, this has not been translated into priorities for the three year strategic research plan. The Strategic Research Agenda focuses on funding calls and scientific priorities. The annual work plans focus on planned calls for proposal and PSIAs. Thus, the operationalization of strategic plans for coordination and partnerships is largely undocumented and indicators to assess this progress are largely invisible. This is in sharp contrast to the detailed (and time-consuming) reporting on PSIAs, which yield little information regarding value-added.

The value-add of EDCTP2 can be used to achieve other political goals (e.g. SDGs). This wider set of outcomes should be considered in developing win-win approaches to collaboration.
7.6. Implementation of recommendations from evaluations of the EDCTP1 programme

The Panel should, according to the ToR, evaluate the up-take and implementation of recommendations from evaluations of the EDCTP1 programme. In accordance with the EU funding decision, the EC commissioned external evaluations of the first EDCTP programme, EDCTP1, in 2007\(^45\) and in 2009\(^8\). In 2013, as part of the preparation for a second phase of the EDCTP programme, the EC conducted an impact assessment\(^46\). Finally, in 2014 the EC assigned the Technopolis Group to conduct a comprehensive evaluation of the performance and effectiveness of the EDCTP1 programme from its start in 2003. The Technopolis report\(^47\) was presented in September of 2014. In this section the Panel review the implementation of the recommendations presented in the Independent External Evaluation Report of 2009, the Impact Assessment of 2013 and the Technopolis Performance and Impact Assessment of 2014. Please note that only a selection of the previous recommendations is assessed here. The Panel only assessed recommendations considered still relevant. The assessment of the recommendations is presented using three categories: “Fulfilled”, “Addressed” (but not yet fulfilled), and then “Still valid” when the Panel considered the recommendation to be valid also for the present programme (EDCTP2).


The IEE Panel (Independent External Evaluation Panel) recognized that several of the recommendations presented by the previous evaluation (2007) had not been entirely fulfilled and were thus repeated in their report. Below are some of the 2007 key recommendations and the 2009 recommendations made in view of a second programme (only recommendations determined to be still relevant were assessed).


\(^{46}\) Commission staff working document Impact Assessment on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2013:0253:FIN

**Table 7 - Recommendation of the 2009 Panel**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Fulfilled</th>
<th>Addressed</th>
<th>Still valid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define a clear, convincing and realistic EDCTP strategy with a common shared vision, clearly defined contributions from each partner and equitable sharing of results (2007)</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>COMMENT: A well-defined EDCTP strategy that goes beyond defining and addressing the scientific needs is still missing.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make the General Assembly more political (2007)</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>COMMENT: Several interviewees argued that GA representatives should have a stronger connection to the political level to ensure enhanced national commitment and support.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expand association with major Product Development Public/ Private Partnerships for access to know-how and to provide visibility and avoid unnecessary duplication (2007)</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Simplify and streamline co-funding, from a virtual to an actual common pot, in order to reduce operational complexity and allow African initiation of EDCTP projects (2007)</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>COMMENT: African members can initiate projects. Current processes for co-funding appear to have increased operational complexity rather than reducing it. Many stakeholders wanted simplifications. Cash contributions enable a common pot approach but the amounts are still insignificant.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interested Member States should directly finance an EDCTP “common funding pot” (2007)</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>COMMENT: The “cash contribution” instrument offers the means to provide EDCTP with greater flexibility. However, the number of PSs making cash contributions is small and, with a few exceptions, the amounts are low.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member States should refrain from imposing national criteria, and accept one integrated scientific and ethical evaluation conducted by EDCTP, utilizing a pool of the best experts (2007)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The EDCTP should engage in a profound outreach activity towards Member States who are not substantially contributing to the programme and towards EU countries not yet members of the EDCTP

| GA members must be able to operate with a political and financial mandate from their government and be in a position to effectively coordinate EDCTP with relevant national activities | X X |
| GA members and the EC should actively seek to expand the financial commitments through the use of additional financial resources such as national development funds and EU funds for Africa | X |
| The Chair person of EDCTP GA must have the authority to discuss financial and policy matters with the Commissioner and relevant Ministers | X |
| ... encourages EDCTP to develop more comprehensive indicators for assessing EDCTP’s activities | X X |
| ... the EDCTP GA should develop more specific key performance indicators and monitor, on an annual basis, the EDCTP Key performances | X X |

### 7.6.2. Impact Assessment underlying the decision on EDCTP2 (June 2013)

The Impact Assessment built on the Independent External Evaluation Report (2009) and reiterated several of its conclusions. Under the heading *Lessons learnt from EDCTP* (section 2.3, pages 19-24) the key shortcomings shown in the table below were listed.

<table>
<thead>
<tr>
<th>Table 8 - Impact Assessment Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need for changing the current scope of EDCTP</td>
</tr>
<tr>
<td>Integration of European national programmes should be improved</td>
</tr>
<tr>
<td>Insufficient collaboration with other major funders and pharmaceutical industry</td>
</tr>
<tr>
<td>Stronger links with EU external policy and development assistance</td>
</tr>
<tr>
<td>Co-funding rules should be clarified and simplified</td>
</tr>
</tbody>
</table>
COMMENT: The present evaluation indicates that the PSIA instrument is perceived as neither efficient nor effective.

Monitoring tools need to be strengthened  X  X

7.6.3. Assessment of the performance and impact of EDCTP1 (September 2014)

The performance and effectiveness assessment made by the Technopolis Group covered essentially the entire time period of EDCTP1. A subset of the more distinct recommendations is assessed in the table below.

Table 9 - Recommendations of the 2014 Technopolis Group Assessment

<table>
<thead>
<tr>
<th>Recommendation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Build on the projects that have been funded so far in order to bring them one step further.</td>
<td>X</td>
</tr>
<tr>
<td>The definition of a strategic vision and direction based on portfolio management of the results from EDCTP1 is something that could be strengthened under EDCTP2.</td>
<td>X X</td>
</tr>
<tr>
<td>As the project proposals have been perceived as too detailed and the financial report templates as too complicated by the project participants, it is recommended to add more flexibility to timelines of the projects, budgets and activities and to reconsider the structure and complexity of the information to be provided in the financial templates.</td>
<td>X</td>
</tr>
<tr>
<td>It is further recommended that EDCTP considers the scientific review procedures of other funding organisations to ensure that the best research is funded, and to view how they deal with potential conflicts of interest.</td>
<td>X</td>
</tr>
<tr>
<td>COMMENT: Although the quality of the funded research was not questioned, negative remarks were made on the funding processes.</td>
<td></td>
</tr>
<tr>
<td>There is room for EDCTP to better demonstrate its achievements through a more systematic and integrated monitoring and evaluation system</td>
<td>X X</td>
</tr>
<tr>
<td>To strive for better alignment and integration of research efforts, it is recommended not to fund too many small projects in too many different areas. This implies a focus on projects with a larger budget, based on the portfolio of projects funded, potentially through a brokered approach like the PanACEA consortium.</td>
<td>X X</td>
</tr>
<tr>
<td>It is strongly recommended to continue the support of Strategic Primer Grants as the innovative angle of the programme. Additionally, to allow researchers to further investigate new insights gained during current projects, opportunities could be provided to investigators to request 'add-on' grants.</td>
<td>X</td>
</tr>
<tr>
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</tr>
<tr>
<td>In its second programme, EDCTP could focus on enhancing product development through better involvement and earlier engagement of regulatory groups, Product Development Partnerships (PDPs) and industry partners.</td>
<td>X X</td>
</tr>
<tr>
<td>As a considerable number of sub-Saharan countries have not been involved in the initiated clinical trials, in seventeen of these countries no formal training has taken place. It is worth investigating to what extent students and researchers from these countries could benefit from training opportunities, even if their institutions do not take part in integrated projects or clinical trials.</td>
<td>X X</td>
</tr>
<tr>
<td>Capacity building in Africa requires considerable investments and long-term engagement. EDCTP should therefore build on the capacity that has been developed during its first phase. A situation in which incentives are put in place to retain people for at least a couple of years after the EDCTP projects have finished would be preferable to secure transfer of knowledge they have gained. A post-project grant to conduct another related project could be a good incentive. To avoid distortion of competition, this should not be systematic but based on performance, output and achievements of the other previous projects.</td>
<td>X</td>
</tr>
<tr>
<td>For the second phase of the programme, it is recommended that African scientists continue taking up leadership roles.</td>
<td>X X</td>
</tr>
<tr>
<td>COMMENT: Addressed by the design of EDCTP2 and continuously addressed by EDCTP.</td>
<td></td>
</tr>
<tr>
<td>It will be important for a second programme to try to engage countries in sub-Saharan Africa that did not participate in the first programme, and to fund capacity building activities to develop a basis for clinical research.</td>
<td>X X</td>
</tr>
<tr>
<td>Although EDCTP projects have received considerable contributions from the private sector..., it is considered necessary to expand and structure future engagement with the private sector on a more strategic level. The question 'how to bring pharmaceutical and biotechnology partners on board?' remains open and will have to be addressed.</td>
<td>X X</td>
</tr>
</tbody>
</table>
In the future, measuring in-kind and cash contributions from African countries more systematically could give more credit to the African share and ownership of the partnership. To remain successful, EDCTP needs continuity of investments and this money should not only come from European, but also from African countries.
8. DISCUSSION AND CONCLUSIONS

Section 8 discusses the overall state of play of the programme and the observations made by the Panel during the evaluation. In addition, Section 8 addresses, in the overall context, the progress towards the objectives of the EDCTP2 programme, and how the Panel views the future development of recommendations for the EDCTP2 programme. The resulting recommendations are then presented in Section 9.

8.1. Living up to the potential of EDCTP

EDCTP1 was founded by the EU and 15 European countries in 2003. EDCTP2 builds on the partnership set by EDCTP1, involving African and European nations as equal partners and with the EC playing a critical role. The vision of the second programme (EDCTP2 2014-2024) is to contribute to the reduction of the social and economic burden of poverty-related diseases in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for poverty-related and neglected diseases (see Strategic Business Plan). The vision is not only relevant to both European and African nations but also very ambitious. Now in its fourteenth year, the EDCTP organisation is well-established and recognised as a key player in clinical trials support. Indeed, the outcome and results of EDCTP have, primarily through its funding activities, been effective and valuable. The Panel recognizes the motivational drive and ambition expressed by all EDCTP representatives, as well as the commitment and enthusiasm conveyed by several Participating State representatives. However, the Panel feels strongly that EDCTP2 is not yet living up to its full potential. Although the programme is developing well – and essentially is on par with the formal expectations – there are areas in which EDCTP could act more effectively and efficiently. It is partly about setting the frame of reference. The existing strategic business plan is primarily a science business plan and it lacks articulation of the strategic policy directions of EDCTP. EDCTP has great potential to be a policy instrument of PSs to influence the strategic policy direction. EDCTP should, in order to meet its overall objectives, not only launch competitive calls, but also strengthen cooperation with sub-Saharan African countries. An essential part of this cooperation is building national research programmes in Africa. EDCTP should play an instrumental role in this process. It should be clear that it is an added value to participate in EDCTP2 and this has to be communicated to the PSs – particularly in Africa. To underscore this notion, membership should be a requirement for applying to EDCTP2 calls. However, to further strengthen EDCTP2 it is equally important that the PSs also communicate the added value of the partnership and give EDCTP credit for its achievements. Furthermore, an extended international cooperation with other public and private partners requires further emphasis. While EDCTP2 must continue to fulfil its essential role as a research funder, it has a strategic focus that requires it to work in new collaborative ways that bring the strength of alignment to the goals of EDCTP2.
8.2. Strengthening capacity and scientific leadership in Africa

Differences in scientific capacity and leadership, in both academia and government; and in research funds and opportunities available, frequently surfaced in discussions on African PSs. These differences were the basis for concerns about differential success rates for EDCTP2 calls, the distribution of EDCTP2 funding across PSs, how to support and strengthen leadership among scientists at various stages of their research career, and reducing the brain drain of African scientists.

Retaining talent. One of the most important long-term achievements of EDCTP will be to foster, promote and retain talent in sub-Saharan Africa. EDCTP is clearly one of the key players but needs to find even more efficient and innovative ways to expand and retain talents. For example, EDCTP should design cross-border instruments that consider the entire career track for African investigators, and make use of all available funding tools. While there is opportunity for funding senior investigators and for capacity development of new and young investigators, there may not be adequate attention for mid-career or developing investigators, and they may need reconsideration for merit and for investment. An important task in retaining talent in sub-Saharan Africa will be to address gender equality and gender balance in all aspects of the EDCTP2 programme. This is in line with SDG 5, Gender equality and women’s empowerment, and the EU Development Policy. The work initiated to develop a tracking database (Alumni Platform) of senior fellowship grantees is commendable and should be expanded to include also junior fellows. To facilitate the tracking process, EDCTP should consider requiring all applicants to have an ORCID identifier. It is essential that the database is actively used to follow-up on the careers of the grantees in order to evaluate the impact of the support given by EDCTP and to inform about future funding calls. However, even more important, is building on the alumni network to both enhance South-South interaction and further strengthen African scientific leadership. African scientific leadership is core to the success of EDCTP2 and includes African-led science processes including identifying priority research questions, conceptualizing and implementing research projects and programmes, as well as leading knowledge translation strategies, both traditional (e.g. publications) and innovative (e.g. brokering knowledge exchange relationships and advising on technical committees with government).

Differential capacity of African nations. There are many potential implications for EDCTP programming related to the impressive gains being made by some countries and the slower pace of others. The GA must consider how best to harness the differential capacity of African PSs. South Africa was frequently cited as an example of a country that has demonstrated rapid growth in scientific leadership and is making critical transitions in health science technology, capacity and national funding mechanisms. It is critical to use the comparative advantage of South Africa and other more advanced African PSs for the greater benefit of all African countries and to address the inequities that may be exacerbated in a competitive funding environment. Matters requiring strategic attention
include strengthening South-South relationships among scientists and governments to address poverty-related diseases; furthering capacity-building initiatives that reflect the changing socio-technical environment and supporting both emerging and well-established scientific leadership in the different nations.

**Networks.** A key means for adding value to EDCTP2 is to build on the success of Centres/Networks by expanding their network of partners. The networks should be further strengthened both between countries and within countries to benefit from each other and to seek active engagement with regional structures or networks. Current networks are concentrated in Eastern and Southern Africa. There should be a deliberate effort to extend EDCTP activities in West Africa. In parallel with establishing new regional networks, EDCTP should support existing successful networks through targeted calls. To reach a better distribution of research capacity across Africa, it is essential to create incentives that make stronger countries link up with weaker ones. EDCTP should consider the level of funding of the networks so that it can, in a more flexible way, support activities that foster this new dimension of their work.

### 8.3. Strengthening coherence and added value of the EDCTP programme

The Panel’s assessment of other EU funded programmes and policies as well as other related global programmes suggests that there are unexplored opportunities for programme alignment, joint funding, portfolio management links, and partnership development that EDCTP could explore. A strategic plan focusing on coherence, coordination and leveraging alignment across programmes should thus be developed. This plan should describe partnerships and initiatives that can be implemented in a short period of time in order to speed EDCTP’s efforts towards achieving coherence. Partnerships should be prioritized and formalized across EU initiatives, and links between EDCTP2 activities and goals should be established where alignment exists. Achieving coherence and cooperation across programmes requires active involvement of the EC at the executive and political levels. This will demand priority setting by the GA, strong leadership engagement of partners and PSs, and accompanying directions for strategic communication that supports these efforts. To assess progress, appropriate performance indicators need to be defined.

The GA and Secretariat should align with other public and private entities working in the field of neglected infectious disease clinical development and implementation such as the Bill & Melinda Gates Foundation, the National Institutes of Health, the WHO Global Health Observatory, and others, particularly with other EU and European national/regional-funded organizations. The EDCTP should consider playing a leadership role in coordinating a strategic portfolio approach with clearly defined goals, execution plans, milestones, and timelines.

Annex I of the EDCTP2 Decision states specifically that one of the targets of the programme is to "obtain additional contributions, either public or private, of at least EUR
500,000,000”. So far (2014-2016) EDCTP has acquired only a fraction of this amount. To reach the target of €500M, EDCTP must direct substantial effort to develop processes for fund raising. The Panel questions the strategic value of this specific target, and considers it much more important to focus on the main objectives of the programme.

While EDCTP2 holds strong potential for enhanced value add, the Panel views this as an area of underachievement. Limited EDCTP visibility, inadequate joint strategic coordination and planning mechanisms, and a lack of strategic direction for joint initiatives are contributing factors.

### 8.4. EDCTP visibility and advocacy

Considerable efforts have been made to improve the visibility of EDCTP and to enhance its advocacy functions. The recent appointments of two High Representatives are indicative of these directions. The recent public opinion poll indicates that internal stakeholders are supportive of recent communication efforts. However, external stakeholders identified communication gaps. The general view perceived by the Panel is that EDCTP, building on its strength, expertise, and credibility, could reach much further by adopting a more outward-looking way of working. There is clearly a need for greater visibility of EDCTP.

This is especially true in Africa where EDCTP needs to be engaged at a higher level with the appropriate government ministries in order to achieve its intended impact and long-term goals. More advocacy efforts directed at national and international governmental levels are needed. The High Representatives will play a critical role in EDCTP to address the gaps in communication with key government leaders and influencers in African and European countries. The Panel is not in a position to evaluate the impact or strategy of the High Representatives due to the timing of this review and their recent appointments. Together with the Executive Director and the GA Chair, the High Representatives are expected to play critical roles in increasing visibility of EDCTP and advocacy for EDCTP2. However, the effectiveness of communication with different communities and stakeholders to date, or lack thereof, has impacted buy-in from key stakeholders and other international research funding and capacity building programmes. EDCTP needs to take on a more proactive approach, realizing that communication is not only about sending or delivering a message but also about building relationships and initiating dialogues. The EDCTP should further develop and implement the stated strategic communication plan and utilize the materials developed to keep EDCTP2 “top of mind” in governments for improved efficiency, effectiveness and relevance.

### 8.5. Improving instruments to advance research in sub-Saharan Africa

With a total support from the EU’s Horizon 2020 of up to €683M for 2014-2024, EDCTP2 is one of the most important funders of research and capacity building in sub-Saharan Africa.
The EU funding together with matching contributions from the PSs will provide substantial investments in clinical trials, capacity building, and training that will have significant long-term impact on Africa’s future. In addition to the joint funding required by the EDCTP2 agreement, strategies need to be aligned in order to achieve greater impact. To reach the full potential of the investments, the funding processes must go beyond merely distributing resources to areas of need. A well thought out strategic rationale is required to effectively reach the set objectives and bring added value for the investments made through the many EDCTP2 calls and activities. This includes not only the activities directly handled by EDCTP2 but also the important actions managed and funded by the PSs. All processes related to EDCTP2 funding must be efficient, and perceived as transparent, professional and credible by key stakeholders. Although the Panel recognizes the important achievements of EDCTP2 as a whole, it has identified several areas for improvements, which are captured below. If appropriately addressed, the impact of EDCTP2 will be even greater.

**Portfolio approach.** While rightfully applauded for inclusivity, the broadened scope of EDCTP2 comes with the risk that available resources and activities are spread too thin in order to cover the entire disease spectrum within the EDCTP2 remit. In order to have impact and to work effectively towards the objectives of EDCTP2, more attention and effort must be placed on the process of prioritization. Prioritization should take into account not only the state of product development and the changing patterns of diseases (dynamics of disease burden in sub-Saharan Africa) but also equity, the global funding landscape and emerging opportunities. EDCTP2 should move towards a portfolio approach in order to use funding calls more strategically and with enhanced added value. Indeed, this was a key point raised in many interviews and by a wide range of interviewees, including private and public sectors, and both European and African stakeholders. It has been argued the Horizon 2020 rules, under which EDCTP2 works, do not readily allow EDCTP2 to move in this direction. However, the Panel considers it fully feasible to continue working with competitive calls while still adopting a portfolio approach that would strategically link the investments and different actions with other funders and programmes.

**Grant application process.** A number of stakeholders interviewed as part of the evaluation expressed concern regarding the mechanisms related to the grant application process, e.g. it being too long, cumbersome and repetitive. One further challenge is the large number of full applications with relatively few being funded. The cost in time and administrative efforts for both the scientific community and EDCTP2 in grant proposal preparation and peer review evaluation is not reflected in the number or proportion of funded applications. Given the effort needed for joint large grant applications, some stakeholders suggested using a two-stage process for large grants, and with financial support to the smaller number of applicants invited to the final stage. This would reduce the load for the Secretariat, for grant applicants and for peer reviewers. Similarly, the recent public consultation report described a “high proportion of negative feedback” on EDCTP2 proposal evaluation and selection, and an “elevated number of respondents who complained about the inferior quality of EDCTP2’s grant management and proposal submission processes”. Although the response rate of the public consultation report was low, the
observation is noteworthy as it relates to the most fundamental task of EDCTP2 so far, namely project funding. There is also concern among the stakeholders that too many full stage proposals are invited while very few are expected to be funded, and that the number of failed proposals may lead to a loss of EDCTP2 credibility. This is highlighted by a disconcerting stakeholder statement that “we do not really understand how they [EDCTP2] finance and how they decide who should get funded as they do not communicate well after applications”. It was not within the remit of the Panel to evaluate the application process in detail and the Panel has thus no solid indication of any failings. However, as the grant application process currently is the most important interface with the scientific community it is essential that EDCTP2 considers the critical comments. EDCTP2 needs to further interact with and include international grant review expertise in the processes related to prioritization, evaluation and grant management.

*Participating States’ Initiated Activities (PSIAs).* Apart from the EU funding, the primary resources of EDCTP2 are the resources of national programme activities linked to the EDCTP2 programme. These in-kind activities, known as Participating States’ Initiated Activities (PSIAs), are selected, funded and managed entirely by the European PSs according to national rules. PSIAs constitute significant contributions from the European PSs. This co-funding is conditional to the EU’s co-funding. The in-kind contributions are eligible as co-funding only if the national activity they relate to is explicitly framed within the EDCTP2 joint programme. A substantial amount of effort currently goes into determining whether matching contributions meet the co-funding requirements and whether there is any double counting of contributions. This data is then used to determine the total PSIA matching fund contribution. However, the procedure for selecting the topics of PSIAs and how they are linked to or integrated in the EDCTP2 programme is unclear. Furthermore, this process does not appear to be accomplished jointly with EDCTP2. The Panel’s impression was rather that the framing was done ex-post and that the PSIA reporting was viewed primarily as a way of achieving sufficient in-kind contributions in order to match the EU co-funding. Although a strategic link may be lacking, the PSIA reporting still contains considerable information on the Participating States’ priorities and work in sub-Saharan Africa, which could be harnessed to identify and leverage potential synergistic activities among PSs. Rather than merely listing all the individual PSIA reports as a performance indicator, EDCTP2 should develop an analytic strategy that identifies synergies, gaps and overlaps. This information is fundamental to strategically decide on future calls or joint actions. There is no evidence that PSIAs are creating or being used to create opportunities for synergies within or across European countries. Neither is there evidence that PSIAs are coalescing efforts towards value-add. Yet, PSIA reporting involves a heavy administrative load. It is questionable whether PSIAs, in their current form, are an efficient or effective instrument to reach the objectives of EDCTP2. It should, however, be emphasized that although the Panel does not consider PSIAs sufficiently integrated within the overall EDCTP2 strategy, it emphatically acknowledges the significance of the investments in PSIAs to sub-Saharan Africa. Nevertheless, the underlying strategic aims of PSIAs, as laid out in Article 185, remain critical to the success of EDCTP2. The value-add of
EDCTP2 is to be achieved, in part, through the joint efforts of the EC and PSs. However, at the present time, PSIAs are stand-alone activities of Member States, accompanied by a heavy administrative reporting burden for both the EU and its Member States. Since PSIAs are not currently achieving their strategic purpose the Panel advises the GA to carefully determine whether PSIAs can be used to efficiently and effectively leverage joint activities between PSs and EDCTP2. If not, an alternate planning mechanism is required. Regardless, a more streamlined approach to document co-funding is needed. However, the guiding principle must be that the joint activities are of strategic importance to both EDCTP2 and the PSs. The Panel is seriously concerned about the consequences of the United Kingdom's recent decision to withdraw from the EU (Brexit) as this may influence the commitment of one of the key European PSs. The possible effects and how to proactively address them need to be analysed.

8.6. Governance for reaching long-term objectives and sustainability

The EDCTP2 programme is extensive and ambitious. To successfully reach the objectives and the full potential of the programme, EDCTP2 must further strengthen the governance structure and its processes.

General Assembly. The GA is the key governance structure for EDCTP as it forms the direct link between the executive and political levels within the PSs and the EDCTP organisation. The GA is responsible for both deciding the long-term strategic direction of EDCTP, and ensuring that Participating State commitment and active participation are maintained. Although the professional and scientific expertise of representatives in the GA is more robust in its composition under EDCTP2 than under the first programme, it still has a number of constraints that limit its ability to be strategic in its decision making. Several stakeholders have argued that its composition does not provide sufficient strategic expertise and political insights required to take EDCTP further. The Panel concludes that the expectations on both the PSs and their GA representatives need to be defined. Currently, it is not evident whether GA members should also bring scientific expertise within the EDCTP2 remit. The Panel argues that the scientific expertise should be provided by active input from the SAC whereas the GA representatives should be of significantly higher executive and political level to provide strategic leadership to EDCTP. The PSs may, if necessary, appoint deputy GA representatives to also provide scientific expertise.

Scientific Advisory Committee. The EDCTP2 Decision¹ states that a SAC shall advise the GA on priorities and strategic needs regarding clinical trials, advise the GA on the content, scope and dimension of the EDCTP2 draft annual work plan, and review the scientific and technical aspects of the implementation of the EDCTP2 programme. Although the statutes designate a well-defined role for the SAC to provide the scientific expertise to the GA, its present function within EDCTP appears less distinct. For example, some members argue that the SAC has an overall strategic role within EDCTP whereas others view their task as providing strategic scientific advice. This confusion is probably due to an unclear definition of the overarching strategic needs of EDCTP. The SAC appears to be interacting primarily
with the Secretariat and to a much lesser extent with the GA and/or the Executive Board. The role of the SAC within EDCTP needs to be clarified, emphasising its task to advise the GA on matters of science.

**Strategic Advisory Group.** The interviews conducted during the evaluation suggest that processes for long-term strategic thinking need to be established. EDCTP2 work plans and activities must constantly be aligned with the overall strategic goals of the programme in order to move the policy agenda forward. A more proactive approach to enter into purposefully selected external partnerships would more effectively lead to product development and increase potential impact. Neither the present composition of the GA nor the composition and role of the SAC seem to facilitate strategic governance. Incentives to support and encourage leadership and coordination among PSs, among funders and other external partners need to be considered. Proactive efforts should be taken to prioritize and advance these incentives. The intervention logic model for the EDCTP2 programme, presented in the interim evaluation document, seems to be missing a critical step that might be useful to define. While both medium and long-term outcomes are displayed, the mechanisms (and underlying theory for change) regarding how EDCTP2 will successfully transition from one to the other is not shown. This transition encompasses the segment of activities where collaboration, partnerships, and joint leadership could all play critical roles to achieve longer-term outcomes. The GA should consider establishing a separate, higher level, strategic advisory group to advise on both long-term strategic planning and matters of system/partnership strategy, and in so doing develop a theory of change to move from medium to long-term objectives. This advisory group can help to align efforts of EDCTP with other significant and long-term global funders, prioritize politically-driven goals and directions (e.g. the UN SDGs) and in general attain the value-add of the EDCTP2 programme.

**Secretariat.** Central to the function of EDCTP2 is the approval of the annual work plans by the EC. Until the annual work plan is approved, no calls can be launched and no budgetary commitments made. It is thus remarkable that the EDCTP2 2014 Work Plan was approved by the EC only in December 2014 and then by the GA in January 2015. The subsequent work plan, describing planned activities under the EDCTP2 programme for 2015 was not approved by the EC and the GA until well into the year of operation (in September and October, respectively). There was some further improvement for the 2016 Work Plan, which was approved in June 2016 (but still almost six months into the programme). The Secretariat, responsible for providing and submitting the draft of the annual work plan, and the EC, responsible for approving the work plan, urgently need to streamline and speed-up this process if EDCTP2 is ever to meet its goals in a timely manner. The GA should consider eliminating the annual work plan in favour of a work plan that would be reviewed every three years. EDCTP2 programme milestones could be defined and evaluated on an annual basis in a manner that allows for greater flexibility of funding, timely adjustments and does not disrupt operations and implementation.
Executive Director. Although the supreme body of EDCTP is the GA, the key executive position of EDCTP as a whole is the Executive Director. The role of the Executive Director needs to be clarified and strengthened. The Executive Director should, within a strong and open mandate from the GA, supervise and coordinate the activities of all entities of EDCTP, and proactively initiate and implement strategic work and high-level advocacy. To further strengthen the Executive Director’s role and provide time for more strategic long-term planning and sustainability, EDCTP should consider creating a new position of Deputy Executive Director. In the process of appointing a Deputy Executive Director, the GA must consider gender balance.

8.7. A potential successor initiative

EU Member States and the EC have a strong commitment and history of supporting economic development and partnership with Africa. EDCTP was initiated in 2003 to advance clinical development of products for poverty related diseases, build scientific capacity, and foster partnerships between European and African nations. The structure of EDCTP is complex and its goals are ambitious and challenging.

Like any scientific endeavour that builds on earlier work, EDCTP will require a significant amount of time to fully realize its goals. The initial time and effort required to engage PSs, communicate EDCTP plans to stakeholders and partners, build the foundation of the EDCTP team – its networks, potential partners and grantees – was significant. EDCTP1 was slow and challenging to establish. It needed to adapt and overcome a number of issues, including equal partnership status at the Participating State level. Human and technical capacity takes time to develop, and clinical trials must be developed on top of this capacity.

The EC and PSs have made significant investments in both time and money to create a strong foundation for EDCTP and nurture the programme. Still, more strategic work is needed before the programme will reach its potential and achieve important milestones. If EDCTP is to have an important, lasting impact on scientific capacity and product development through clinical trials, a successor programme must be planned and established. The EDCTP networks have been set up as regional hubs for clinical science, yet they will require more time and support to achieve their intended goals. In addition, EDCTP has invested in the development of scientists and their careers, which will also require more time and nurturing to see lasting results from these investments.

The clinical trial capacity developed through EDCTP will not be limited only to poverty-related infectious diseases. Non-communicable diseases are on the rise in Africa. The skills, clinical trial capacity, partnerships and networks already under development can be leveraged to address these priority diseases as well. Additional opportunities for alignment across other EU and international programmes and instruments should be evaluated with a successor programme in mind.

A successor programme must evaluate not only the evolving disease landscape and the burden of non-communicable diseases but also the funding landscape and political climate. BREXIT will present a funding and political challenge for the EC and for EDCTP.
Simplification of co-funding will need to be a priority for any new programme as the political situation becomes more complex and as countries like South Africa play a different, yet important role in the programme.
9. RECOMMENDATIONS

Overall the panel is optimistic about EDCTP2. There have been some significant achievements that build on the previous EDCTP1. The panel acknowledges the invaluable and unique contribution that the programme has made in sub-Saharan Africa in accordance with the objectives of EDCTP.

Based on the evaluation and as discussed in Section 8, the Panel has unanimously adopted the following recommendations. These recommendations are intended to assist EDCTP2 to maximize its impact in addressing global health challenges. The Panel’s work was limited due to the short time of EDCTP2’s programme execution. With effectively two years of programme work to review, it is a short timeframe for implementation of EDCTP2.

The Participating States (PSs) own EDCTP2 through the GA. Therefore, the recommendations are directed to the GA unless stated otherwise. In addition, the term “Participating States” refers to both African and European Participating States.

Living up to the potential of EDCTP

To reach its full potential and the ambitious goals outlined in the Strategic Business Plan (see page 9), EDCTP should assume a position as a proactive key strategic player and change agent in sub-Saharan Africa. This effort will require a reinvigorated strategic approach not only by EDCTP management but also by the PSs and the EC. The Panel recommends EDCTP develop a strategic policy plan. As a priority, we propose EDCTP catalyse the development and strengthening of national health research plans of African PSs.

A change in ‘mindset’ will be required within EDCTP and at the heart of EDCTP, which is the PSs. The establishment of an effective partnership arrangement among PSs needs to be further developed. Being part of the EDCTP programme must be viewed as an added value. The Panel thus recommends that EDCTP membership should be a requirement for applying to EDCTP calls. EDCTP will need to understand the goals and priorities of PSs and work with them to align EDCTP strategy and programmes. EDCTP should thus actively support the PSs in developing their own national research agendas.

Strengthening capacity and scientific leadership in Africa

The Panel views the networks as a critical element of institutional capacity in sub-Saharan Africa. The strategic role of the EDCTP regional networks should be broadened and clearly defined. The networks should develop a plan that includes a focus on its capacity building activities, with emphasis across the spectrum of scientist career development, and their support of weaker institutions and regions. The capacity for active participation in the EDCTP program varies significantly across sub-Saharan Africa. It is important to ensure a more equitable distribution of EDCTP activities and investments so the benefits of EDCTP impact weaker institutions and regions. A strategy must be developed to incentivise wealthier PSs to engage with less resourceful African nations in all EDCTP activities. To
support the networks in achieving this next phase of their evolution, the level of funding for networks should increase.

EDCTP should adopt a more comprehensive and catalytic funding approach for supporting the career path of young talented African investigators and to build African scientific leadership. Particular attention should be paid to gender balance. EDCTP should assess opportunities in this area to strategically align with other funders and programmes on career development.

**Strengthening coherence and added value of the EDCTP programme**

Based on a thorough analysis of existing programmes and active international funders, EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged and complementary programmes aligned for greater impact and reach. EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships. The EU would benefit by having a high level strategy across programmes and policies to facilitate alignment, coordination and collaboration where opportunities exist. This approach would be most effective with the appointment of a specific coordinator responsible for coherence among EU initiatives and policies.

The strategic value of the EDCTP target to obtain at least €500M in additional public or private contributions is questionable. The EU should, together with the PSs, reconsider this rather high €500M target so that EDCTP can focus on more relevant aspects of partnerships.

**EDCTP visibility and advocacy**

EDCTP should put considerably more focus on external strategic communication and advocacy efforts. The current communication strategy should not only be aimed at delivering information but also become more focused on building relationships and dialogue with Participating States’ governments and European and International funders and stakeholders. Communication functions and strategies must better reflect the fact that EDCTP2 is a programme that PSs own collectively. Currently, this joint ownership, coordination and support of EDCTP are not evident in programmes or in advocacy and communication efforts. This lack of co-leadership weakens the overall potential and effectiveness of EDCTP2.

To determinedly implement the communication strategy, the function of strategic communication and advocacy within EDCTP should be elevated to the highest level of leadership. This role within EDCTP will require considerable networking and coordination across PSs to identify synergies and to achieve better alignment and coordination with PSIs. Closer coordination and planning between the EC leadership and the EDCTP Secretariat and GA will also help to achieve the level of communication and advocacy needed. These coordinated leadership roles will require a mindset change across organizations and individual leaders.
To achieve the advocacy goals of EDCTP2 to execute the communication strategy, clear objectives, tactics, timelines, and milestones to describe how EDCTP will achieve its advocacy goals is needed. Opportunities to align messaging and programmes with PSs should be prioritized for communications and advocacy.

**Improving instruments to advance research in sub-Saharan Africa**

*Adopting a portfolio approach.* EDCTP should take on a portfolio approach in order to use its funding instruments (including competitive calls) more strategically. This would enhance the value-add of EDCTP and maximize impact. EDCTP should adopt a more flexible funding approach that, after careful analysis of the current conditions, would include both broad and more specific calls. The analysis should incorporate considerations of disease burden, the potential for improving health equity and also the global funding landscape.

*Grant Funding Reference Group.* In order to ensure high quality and credibility of the grant application process, EDCTP and the EC should jointly initiate an external review of the processes related to funding, including launch of calls, peer-review, evaluation and selection. EDCTP should consider establishing a Grant Funding Reference Group which could mimic the approach already taken by the EC. For example, inviting Independent Observers to assess the peer review process and its implementation (e.g. 1-2 observers for each call). Alternatively, another mechanism could involve members of the research community obtaining information on how the funding strategy and funding instruments are perceived on a regular basis.

*Modifying the process of PSIAs.* EDCTP and the EC should jointly modify the entire process around PSIAs to improve efficiency and to enhance impact. The aims of PSIAs must be articulated with consideration given to how they can be used to enhance strategic value-add of both EDCTP and the PSs. A more efficient way to bring in the Participating States' engagement in EDCTP, and to effectively obtain the co-funding that is conditional to the EU co-funding, should be developed. EDCTP should initiate a process for in-depth analysis of the outcome of the activities initiated by the PSs in order to identify synergies, gaps and overlaps. PSIAs should be prospectively and strategically integrated with EDCTP programmes and calls in order to minimize gaps. In addition, PSIAs should be strategically integrated among themselves to efficiently maximize their impact.

As PSIAs constitute a significant instrument for demonstrating Participating State commitment as well as for calculating the co-funding level, the EC should jointly with EDCTP analyse the possible effects of the United Kingdom’s decision to withdraw from the EU and develop mitigating strategies.

**Governance for reaching long-term objectives and sustainability**

*General Assembly.* The EC and EDCTP should jointly define the responsibilities and expectations for both the PSs and their GA representatives. The PSs should enhance the executive and political level of GA representatives and ensure that representatives are clear on their responsibility to report back to their respective government agencies that have the mandate to deliver on their governments’ commitment to EDCTP.
Scientific Advisory Committee. EDCTP must further develop the SAC and its critical role of providing strategic scientific advice as stated in the “Decision”.

Strategic Advisory Group. EDCTP should create a separate, high-level strategic group to advise on matters of policy, coherence and partnership to achieve value-add of EDCTP2, to align efforts of EDCTP2 with other significant global funders and with politically driven goals and directions. A strategic policy plan needs to be urgently developed. As a high priority, EDCTP should catalyse the development and strengthening of national health research plans especially for African PSs.

3-year work plans. EDCTP and the EC should jointly and urgently review and modify the process of submitting and approving the annual work plans so that the entire process is completed prior to the year of operation. The process should be changed so that EDCTP submits a 3-year work plan for approval by the EC but with annual milestones that are to be reported and evaluated on an annual basis so that timely adjustments can be made.

Executive Director. EDCTP should further strengthen the position of the Executive Director by emphasizing his/her role to proactively initiate and implement strategic work and high-level advocacy as well as to engage in long-term planning and sustainability issues. To support the Executive Director, EDCTP should create the position of a Deputy Executive Director. The subsequent recruitment and appointment process should reflect the imperative for an improved gender balance at the high-level management.

Financial contribution

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

Recommendations aimed at a potential successor initiative

The Panel strongly recommends that the Member States and the EC support a successor to the EDCTP2. The programme is still highly relevant and appropriate. The Panel is convinced, provided its recommendations are implemented, that EDCTP2 will successfully address its objectives. Furthermore, the EDCTP programme offers great added value to the EU, an added value that goes well beyond a developmental aid perspective. The health issues being addressed by the EDCTP programme are not restricted to developmental countries. Both African and European countries are benefiting from this program as it reduces the risk of poverty-related diseases and contributes to economic development.

A successor initiative should remain focused on essentially the original objectives of EDCTP, and contributing to a realization of the SDGs. However, the Panel emphasizes that
in order to reach the objectives, a strategic approach is required in which competitive calls represent just one of many instruments available to the initiative. The performance indicators must reflect this broader strategy rather than simply focusing on outcomes that are easily counted (e.g. number of published papers or number of clinical trials). Impact is clearly more difficult to measure but if not mentioned specifically, the initiative will lack formal incentives.

Before deciding on a successor, the EC should engage in a serious interaction – at the highest political level – with the PSs and other Member States about the importance and added value of the EDCTP programme. Without a true commitment from the PSs, as described in the Report, a successor initiative will not be successful.

A decision on the future of the EDCTP programme must be made very soon for the programme to continue without losing its momentum. Continuing EDCTP1 into EDCTP2 was a good decision, but the transition was slow and created a serious gap during which activities essentially came to a standstill. Thus, a successor initiative, if so decided, must be planned for Framework Program 9.

It has been discussed whether or not the programme should remain an Article 185 initiative. The Panel argues it is largely irrelevant and most of the issues raised in the Report can be addressed within the present funding instrument.

When setting up a possible successor initiative, the funding instruments must allow a more flexible funding approach. For example, with appropriate oversight and approval, the Secretariat should have the ability to propose strategic funding, in line with the objectives of EDCTP, in order to capitalize on important and potentially impactful initiatives. Furthermore, the Panel argues that in order to reach all the objectives stated in the original decision on EDCTP2, it is not enough simply to launch calls. An effective successor initiative must include much more analysis, strategic work and policy efforts as well as communication activities. The present 6% limit on administrative costs does not allow EDCTP to address these issues to the extent and professional level that the Panel considers necessary as outlined in the present Report. Unless it can be arranged in the EDCTP2 programme, a successor initiative must allow for costs related to these programmatic efforts to be funded.

**EDCTP Response to the Interim Evaluation Report**

The EC should invite the GA to prepare a response focused on strategic considerations to this report. The GA should take action to prioritize the above recommendations.
10. ANNEXES

10.1. List of Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAS</td>
<td>African Academy of Sciences</td>
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<tr>
<td>AESA</td>
<td>Alliance for Accelerating Excellence in Science in Africa</td>
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<tr>
<td>AIDS</td>
<td>Acquired Immuno-Deficiency Syndrome</td>
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<td>ARV</td>
<td>Antiretroviral Treatment</td>
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<td>AU</td>
<td>African Union</td>
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<td>CT</td>
<td>Clinical Trials</td>
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<td>DCCC</td>
<td>Developing Countries Coordinating Committee</td>
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<tr>
<td>EAC</td>
<td>East African Community</td>
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<tr>
<td>EC</td>
<td>European Commission</td>
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<td>ECCAS</td>
<td>Economic Community of Central-African States</td>
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<td>ECOWAS</td>
<td>Economic Community of West African States</td>
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<tr>
<td>EDCTP</td>
<td>European and Developing Countries Clinical Trials Partnership</td>
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<tr>
<td>EDCTP1</td>
<td>First Programme of the EDCTP (2003 – 2013)</td>
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<tr>
<td>EDCTP2</td>
<td>Second Programme of EDCTP (2014 – 2024)</td>
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<tr>
<td>EEIG</td>
<td>European Economic Interest Group</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>EP</td>
<td>European Parliament</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FP6</td>
<td>EU Sixth Framework Programme for RTD (2000-2006)</td>
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<td>FP7</td>
<td>EU Seventh Framework Programme for RTD (2007-2013)</td>
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<tr>
<td>GA</td>
<td>General Assembly</td>
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<tr>
<td>GFATM</td>
<td>Global Fund to Fight Aids, Tuberculosis and Malaria (The Global Fund)</td>
</tr>
<tr>
<td>GCLP</td>
<td>Good Clinical Laboratory Practice</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>IASG</td>
<td>Impact Assessment Steering Group</td>
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<tr>
<td>IEE</td>
<td>Independent External Expert</td>
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<td>IGAD</td>
<td>Intergovernmental Authority on Development</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>Intellectual Property Right</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MEP</td>
<td>Member of the European Parliament</td>
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<td>MS</td>
<td>Member State of the EU</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>MTCT</td>
<td>Mother to Child Transmission</td>
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<td>NCD</td>
<td>Non-communicable Disease</td>
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<td>NEPAD</td>
<td>New Partnership for Africa’s Development</td>
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<td>NID</td>
<td>Neglected Infectious Disease</td>
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<td>NP</td>
<td>National Programme</td>
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<td>NTD</td>
<td>Neglected Tropical Disease</td>
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<td>PB</td>
<td>Partnership Board</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<td>PDP</td>
<td>Product-Development Partnership</td>
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<td>Poverty-related Diseases (HIV/AIDS, Tuberculosis and Malaria)</td>
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<td>Participating State Initiated Activity</td>
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<td>Public Private Partnership</td>
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<td>Research and Development</td>
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<td>RCT</td>
<td>Randomised Clinical Trials</td>
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<td>RTD</td>
<td>Research and Technological Development</td>
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<td>SADC</td>
<td>Southern African Development Community</td>
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<td>SAC</td>
<td>Scientific Advisory Committee</td>
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<td>Sustainable Development Goal</td>
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<td>SSA</td>
<td>sub-Saharan Africa</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<td>UN</td>
<td>United Nations</td>
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<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/Aids</td>
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<tr>
<td>WAHO</td>
<td>West African Health Organisation</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO/AFRO</td>
<td>WHO Regional Office for Africa</td>
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10.2. Interviewees

- Dr Salim ABDULLA, Ifakara Health Institute (Tanzania)
- Dr Muhammed AFOLABI, Medical Research Council Unit (The Gambia)
- Prof. Eleni AKLILLU, Karolinska Institute (Sweden)
- Dr Ebeneser APPIAH-DENKRYA, Ghana Health Service (GHS), (Ghana)
- Mr Abdoulie BARRY, EDCTP (The Netherlands)
- Dr Pauline BEATTIE, EDCTP (The Netherlands)
- Assoc. Prof. Maria Teresa BEJARANO, Swedish International Development Cooperation Agency (Sida), (Sweden)
- Prof. Moses BOCKARIE, EDCTP Africa Office, (South Africa)
- Dr Detlef BÖCKING, Deutsches Zentrum für Luft- und Raumfahrt e.V. (Germany)
- Dr Maryline BONNET, Institute of Research and Development (IRD) and INSERM, (France)
- Dr Gabrielle BREUGELMANS, EDCTP (The Netherlands)
- Prof. Patrice DEBRÉ, Université Pierre et Marie Curie Hôpital Pitié Salpetrière, (France)
- Dr Ruxandra DRAGHIA-AKLI, European Commission (Belgium)
- Ms Margarida FREIRE, Belgian Science Policy Officer (Belgium)
- Dr Roger GLASS, Fogarty International Center and NIH, (USA)
- Prof. Glenda GREY, South African Medical Research Council SAMRC, (South Africa)
- David HUGHES, Novartis PHARMA AG – representing EFPIA, (Switzerland)
- Prof. Pontiano KALEEBU, MRC/UVRI Uganda Research Unit on AIDS(Uganda)
- Prof. Stefan KAUFMANN, Max Planck Institute for Infection Biology (Germany)
- Dr Simon LANGAT, National Commission for Science, Technology and Innovation (NACOSTI), (Kenya)
- Ms Glaudina LOOTS, Health Innovation Department of Science and Technology (South Africa)
- Dr Eusébio MACETE, Health Research Centre of Manhiça, (Mozambique)
- Dr Michael MAKANGA, EDCTP (The Netherlands)
- Dr Mwele Ntuli MALECELA, National Institute for Medical research NIMR (Tanzania)
- Prof Kevin MARSH, African Academy of Science, (Kenya)
- Dr Line MATTHIESSEN, European Commission, (Belgium)
- Dr Pierre MEULIEN, Innovative Medicines Initiative (Belgium)
- Prof. Charles MGO NE, Former EDCTP Executive Director (Tanzania)
- Prof. Jeffrey MPHALELE, South African Medical Research Council, (South Africa)
- Ms Michelle NDERU, EDCTP Africa Office (South Africa)
- Dr Margaret NDO MONDO-SIGONDA, African Union, New Partnership for Africa's Development (NEPAD) Agency AMRH (South Africa)
- Assoc. Prof. Francine NTOMI, WHO Regional office/CANTAM network; Congolese Foundation for Medical Research and University Marien Ngouabi, (Congo)
- Dr Thomas NYIRENDA, EDCTP Africa Office (South Africa)
- Dr Ole OLESSEN, EDCTP Director North-North Networking (The Netherlands)
- Prof. Faith O SIER, KEMRI-Wellcome Trust Research Programme (Kenya)
- Dr Mark PALMER, Medical Research Council, (United Kingdom)
- Prof. John REEDER, Special Programme for Research and Training in Tropical Diseases, (Switzerland)
- Dr Samia SAAD, Bill and Melinda Gates Foundation, (United Kingdom)
- Dr Leonardo Santos SIMÃO, EDCTP - South High Representative (South Africa)
- Dr Sodiomon bienvenu SIRIMA, Centre National de Recherche et de Formation sur le Paludisme, CNRFP (Burkina Faso)
- Prof. Marcel TANNER, EDCTP North High Representative, (The Netherlands)
- Dr Grant THERON, Stellenbosch University (South Africa)
- Dr Mike TURNER, Wellcome Trust (United Kingdom)
- Nicola VIEBIG, European Vaccine Initiative, (Germany)
- Dr Gianpietro VAN DE GOOR, European Commission, (Belgium)
- Dr Richard WALKER, PATH (USA)

<table>
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<td>2</td>
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<tr>
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<tr>
<td>Total</td>
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10.3. **Mandate of the interim evaluation**

The main objectives of the first interim evaluation are an assessment of the implementation of the EDCTP2 programme so far, the improvements that have been achieved following prior recommendations for the EDCTP1 programme, an outlook on what can be expected from the EDCTP2 programme in the remaining time, notably with regard to the desired leverage effects of the initiative.

In order to achieve the objectives, the main purpose of the experts’ work is to:

- Assess the progress towards the objectives of the EDCTP2 programme set out in the Annex I to Decision 556/2014/EU and monitored with the indicators and targets specified in the same Annex I, taking into account observations and recommendations made in evaluations of the EDCTP1 programme;
- Assess the efficiency (including aspects such as implementation, governance and supervision) of the EDCTP2 programme;
- Assess the continued relevance and appropriateness of the EDCTP2 programme in line with Decision 556/2014/EU;
- Assess the coherence with other EU initiatives and actions which are thematically related to the EDCTP2 programme;
- Assess the effectiveness of the EDCTP2 programme and its contribution to the general policy objectives of the EU, and in particular the Horizon 2020 objectives;
- Assess the impact of the EDCTP2 programme in terms of the value added:
  - at the European level,
  - at the national level,
  - at the international and regional level;
- Provide short and longer term recommendations on how the initiative can improve upon its work in the future.

The experts’ work and report should focus on the most recent data made available during the course of the evaluation. It should also assess the extent to which the recommendations in evaluations of the EDCTP1 programme have been taken into account in the EDCTP2 programme.

In order to assess the implementation of the EDCTP2 programme and its activities, as specified in the Annex II to Decision 556/2014/EU, the following non-exhaustive list of evaluation items will guide the experts during their work:

**Assess the efficiency of the EDCTP2 programme**

The assessment of the efficiency of the EDCTP2 programme includes the following three dimensions and corresponding questions:
a) Efficiency in progressing towards the specific and operational objectives of the EDCTP2 programme as well as the indicators set out in Annex I of Decision 556/2014/EU and the corresponding ex-ante impact assessment. The specific and operational objectives of the EDCTP2 programme and the indicators are also detailed under point 13 of these Terms of Reference.

b) Efficiency with respect to the governance structure of the initiative:
   - Is the governance structure of the initiative working efficiently and in line with the provisions laid down in Annex III of Decision 556/2014/EU?
   - Is the governance and implementation structure cost-effective?
   - Have the management aspects been properly addressed?
   - Are effective monitoring and supervision arrangements in place?

c) Efficiency with respect to the EDCTP2 programme as an instrument to foster activities of a transnational nature within Europe and between Europe and sub-Saharan Africa, including
   - Is the EDCTP2 programme and its activities cost-effective? Were the costs involved justified, given the changes/effects which have been achieved?
   - Did the delegation agreement and the annual work plans support an efficient implementation of the activities of the EDCTP2 programme?
   - What were the principal achievements and shortcomings of the EDCTP2 programme when it came to the implementation of certain activities (e.g. joint calls) or the progression towards certain objectives (e.g. strengthened cooperation with sub-Saharan African countries, extended international cooperation with other public and private partners, regional organisations and other initiatives)? e.g. the African Union (AU), AU Commission, and Regional Economic Communities of the AU; the World Health Organisation (WHO) and WHO Regional Office for Africa (WHO AFRO); African Medicines Regulatory Harmonisation (AMHR) programme; Pan-African Congress for Ethics and Bioethics (COPAB).
   - What were the intended or unintended impacts of the simplification measures, which were introduced in the context of Horizon 2020, on the administrative efforts for participating actors, i.e. both end-users/beneficiaries of the EDCTP2 programme and the EDCTP2 implementation structure (the EDCTP Association)?

Assess the relevance and appropriateness of the EDCTP2 programme
   - To what extent are the original objectives of the EDCTP2 programme still relevant?
   - To what extent are stakeholders satisfied with the objectives, implementation and governance of the EDCTP2 programme?
   - To what extent is the EDCTP2 programme appropriate to support the realisation of EU policy objectives? Chief among these policy objectives are the following: improving the lifelong health and well-being of all, strengthening cooperation with
sub-Saharan African countries and with third countries to address global health challenges, and contributing to the achievement of the United Nations' Sustainable Development Goals?

**Assess the coherence of the EDCTP2 programme with other EU policy instruments**

- To what extent is the EDCTP2 programme coherent with other EU initiatives, actions and/or policies which have similar objectives?
  e.g. the EU-Africa Strategic Partnership including the Joint Africa-EU Strategy and Roadmap (2014-2017) and the EU-Africa High Level Policy Dialogue on Science, Technology and Innovation; the EU’s vision of a competitive ‘Global Europe’; the EU’s development cooperation policy and actions (in particular the ‘European Consensus on Development’; 'The Agenda for Change; the EU Role in Global Health’ the European Research Area and the Horizon 2020 programme; the second Innovative Medicines Initiative programme (IMI2); the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR); the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R); the Global Alliance on Chronic Diseases (GACD); the EU’s Chemical, Biological, Radiological and Nuclear Defence Risk Mitigation Centers of Excellence initiative (EU CBRN-CoE).
- To what extent is the EDCTP2 programme coherent with other global initiatives to which the EU also contributes such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Global Vaccine Alliance (GAVI)?
- How does the EDCTP2 programme relate to these other EU and global initiatives, actions and/or policies, for instance with regard to complementarity, synergies, or overlapping?

**Assess the effectiveness of the EDCTP2 programme and its contribution to EU policy objectives**

- To what extent did the EDCTP2 programme contribute to the strengthening of public-public partnerships in the field of poverty-related diseases, including neglected ones?
- To what extent does the EDCTP2 programme comply with the criteria laid down in Article 26 of the Horizon 2020 regulation (Regulation (EU) 1291/2013), more specifically: clear definition of objectives, indicative financial commitments of the Participating States, added value at EU level, critical mass and appropriateness?
  a) Are the objectives clearly defined? Are they relevant to the objectives of Horizon 2020 as well as to the objectives set out in other EU policies and programmes?
  b) Are the indicative financial commitments of the participating countries, in cash or in kind, appropriate for pooling a critical mass of resources to foster transnational research and innovation?
  c) Is the EDCTP2 programme complementary to other EU initiatives, and does its scale and scope provide added value?
• What level of scientific, managerial and financial integration has been achieved? How does the level of integration of the EDCTP2 programme compare to the EDCTP1 programme?

• What is the socio-economic impact of the EDCTP2 programme considering the achieved levels of scientific, financial and managerial integration? How does the socio-economic impact of the EDCTP2 programme contribute to EU policy objectives, including those of Horizon 2020?

• What leverage effects can be identified, especially with respect to public and private investments related to the EDCTP2 programme?

• To what extent have the specific and operational objectives of the EDCTP2 programme been achieved?

• To what extent is the EDCTP2 programme integrated in the strategic planning and implementation of Horizon 2020 within its societal challenge ‘Health, demographic change and well-being’?

Assess the European added value of the EDCTP2 Programme

• What is the additional value resulting from the implementation of the EDCTP2 programme compared to what would have been achieved by individual Member States acting independently at international, national and/or regional levels?

• To what extent is the EDCTP2 programme able to identify and exploit synergies with other EU policies, e.g. health, development cooperation and external affairs policies, in particular EU relations with African countries and regions?

• To what extent does the EDCTP2 programme increase the EU’s contribution to and visibility in the fight against poverty-related diseases?

• To what extent does the EDCTP2 programme increase the EU’s contribution to reaching the sustainable development goals?

Assess the national added value of the EDCTP2 Programme

• To what extent is the EDCTP2 Programme able to identify and exploit synergies with other European national and/or regional policies and initiatives, including health, development cooperation and external affairs policies and initiatives?

Assess the international added value of the EDCTP2 Programme

• To what extent is the EDCTP2 Programme able to identify and exploit synergies with other international, regional and national policies and initiatives, including health, development cooperation and external affairs policies or with regard to Africa? e.g. the International Network of Demographic Research institutions (INDEPTH), the Network of African National Public Health Institutes (IANPHI); le Réseau d’Instituts de Santé Publique en Afrique de l’Ouest (RIPOST); the International Research Ethics Network for Southern Africa (IRENSA); the Alliance for Accelerating Excellence in
Science in Africa (AESA); the African Network for Drugs and Diagnostics Innovation (ANDI).

- How does the EDCTP2 programme compare with similar types of public-public partnerships?
  e.g. the Ambient Assisted Living programme (AAL), the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR).

- To what extent is the EDCTP2 Programme able to identify and exploit synergies with other international programmes or initiatives?
  e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Vaccine Alliance (GAVI); the UN Special Programme for Research and Training in Tropical Diseases (TDR).

- To what extent is the EDCTP2 Programme able to identify and exploit synergies with the efforts of other public and private research funders, including with pharmaceutical industry?

Provide recommendations for the EDCTP2 Programme

- What lessons can be learnt from the implementation of the EDCTP2 programme with respect to its original objectives?
- What lessons can be learnt from the implementation of the EDCTP2 programme with respect to its legal and administrative framework?
- What lessons can be learnt with respect to the up-take and implementation of recommendations from evaluations of the EDCTP1 programme?
- What lessons can be learnt with respect to the overall socio-economic impact of the EDCTP2 programme?
- Which recommendations can be derived for the remaining time of the EDCTP2 programme?

The experts are asked to develop concrete conclusions and recommendations covering policy and operational aspects. They will make two types of recommendations: on one hand recommendations to address policy and operational issues of the EDCTP2 programme in the context of Horizon 2020 and on the other hand recommendations aimed at a potential successor initiative.
10.4. Interim Evaluation Panel

Mats Ulfendahl, Chair, (Sweden) Professor at the Department of Neuroscience, Karolinska Institutet (Stockholm). He obtained his PhD in physiology at Karolinska Institutet in 1989. In 2004 he was appointed professor of experimental audiology and otology (Karolinska Institutet). He was the Director of the Center for Hearing and Communication Research at Karolinska Institutet 2002-2010. For six years (2010-2015), he was the Secretary-General for medicine and health at the Swedish Research Council. Mats Ulfendahl is currently chairing the Swedish Society for Medical Research, and the Delegation for research of the Swedish Society for Medicine. In 2016, he was awarded an honorary doctorate (Odont. Dr. h.c) at the faculty of odontology, Malmö University College, Sweden. Mats Ulfendahl has served on several national and international boards, including the National priority board for highly specialized health care, the Governing Council of International Agency for Research on Cancer (IARC), the High Level Group for Joint Programming (GPC), and he served two terms as chair of the management board of the Joint Programming Initiative on Antimicrobial Resistance. He has been a member of the high-level group Heads of International Research Organizations (HIROs).

Jennifer Dent, Rapporteur, (USA) President, BIO Ventures for Global Health (BVGH). Jennifer joined BVGH in September 2011 and became President in November 2012 when she became a member of the Board of Directors. She has 20+ years of broad-based pharmaceutical and biotechnology experience, including negotiation and structuring of deals, and management of global discovery and commercial alliances. Jennifer began her career as a sales representative in Canada working in a variety of positions for Parke Davis/Pfizer and Genentech. Following the acquisition of Genentech Canada by Roche, Jennifer held a number of senior management positions in marketing, life cycle management, global product strategy, business development, and alliance management at Roche and Genentech in Canada, Switzerland, New Jersey, and South San Francisco. Jennifer co-founded Sound Biotechnology, and prior to that, served as Vice President, Business Development, Marketing, and Sales at CombiMatrix Corporation in Washington. Jennifer graduated from the University of Western Ontario with a BSc, and she received her executive MBA at Western’s Richard Ivey School of Business. +http://www.bvgh.org/Who-We-Are/Board-of-Directors-and-Team.aspx

Nancy Edwards (Canada), RN, BScN, MSc, PhD, FCAHS, Distinguished Professor at the University of Ottawa and Full Professor in the School of Nursing; former Scientific Director, Institute of Population and Public Health, Canadian Institutes of Health Research (July, 2008 to July, 2016); former Director of the Interdisciplinary Population Health PhD Program, University of Ottawa (2015-16). Nancy also holds appointments at the University of West Indies (Jamaica, Mona Campus), Great Lakes University of Kisumu (Kenya) and University of Newcastle (Australia) and has received three honorary degrees. Nancy's clinical and research interests are in the fields of public and population health. She has conducted health services, policy and clinical research both nationally and internationally. Her research has informed the design and evaluation of complex multi-level and multi-strategy community health programmes. Her work in global health has spanned four continents, where she has led both development-oriented and research-focused projects. She has served on numerous advisory committees. Recent examples include the international expert advisory committee for Public Health Research in Horizon 2020; the advisory council for the Canadian Population Health Initiative; and the National Institute for Health
Research, School for Public Health Research advisory board. Nancy co-chaired the Management Committee for the Global Alliance of Chronic Diseases for one term.

**Alash'le Abimiku (Nigeria)** Professor of Medicine Baltimore; and the Executive Director, International Research Center of Excellence at the Institute of Human Virology-Nigeria. Originally from Nigeria, Dr. Abimiku is pivotal to the Institute's success in Nigeria and has remained an international leader in laboratory capacity development in Africa. Dr. Abimiku matriculated from the Ahmadu Bello University, Zaria, Nigeria with a B.S and received her M.Sc. in microbiology and Ph.D. in medical microbiology from the London School of Hygiene and Tropical Medicine, UK. Dr. Abimiku's research career began in basic vaccine research and HIV disease pathogenesis. She was the first to identify the unique nature of the HIV strain prevalent in Nigeria in 1993 as subtype G1 and later documented the adverse consequences of "mixed" feeding of African infant.

**Elizabeth Bukusi (Kenya)** MBChB, M.Med (OBGyN), MPH, PhD, MBE, FAAS, CIP, Co-Director, Research Care and Training Program; Chief Officer, Center for Microbiology Research, KEMRI; Honorary Lecturer, Department of Obstetrics and Gynecology, Aga Khan University, Nairobi; Research Professor, Departments of Global Health and Obstetrics and Gynecology, University of Washington, Volunteer Professor, Department of Obstetrics Geneology and Reproductive Sciences University of California San Francisco, Faculty Centre for Bioethics and Culture, Sind Institute of Urology and Transplantation, Karachi. Since 1995, Dr. Bukusi has served as the Co-Director of the Research Care and Treatment Programme (RCTP). Since 2004, she has been co-PI of the CDC/PEPFAR-funded Kenya-based Family AIDS Care and Education Services (FACES) HIV care and support program. As part of FACES and in collaboration with Dr. Craig Cohen, she developed the Student Training Elective Programme (STEP), which places medical students and residents in FACES clinics. She has over 20 years’ experience conducting research in HIV prevention, care, and treatment among women and men in Kenya. Her research focuses on development of HIV prevention technologies, HIV care and treatment, and ethics in research. Areas of interest: HIV/AIDS prevention, care and treatment; Integration of HIV and family planning care; Integration of HIV care, antenatal care, and prevention of mother-to-child transmission; Microbicides; Clinical research training. Education: University of Nairobi, Medical Doctorate; University of Washington, Master's in Public Health and Doctorate in Epidemiology; University of Cape Town School of Medicine, Research Ethics Training. Centre for Bioethics and Culture, Sind Institute for Urology and Transplantation, Masters in Bioethics.  https://bixbycenter.ucsf.edu/elizabeth-bukusi-mbchb-md-mpm-phd
10.5. Detailed analysis of the EDCTP2 coherence with other EU programmes and policy instruments (Section 7.3)

The desk review identified a number of synergies and areas of overlap between EDCTP2 and other EU programmes and policy instruments. A brief summary of each programme is followed by an analysis of coherence with EDCTP including opportunities for programme partnership, coordination, and alignment.
EU-Africa Strategic Partnership including the Joint Africa-EU Strategy and Roadmap (2014-2017) and the EU-Africa High Level Policy Dialogue on Science, Technology and Innovation

1. Programme Summary

- The formal channel through which the European Union (EU) and Africa work together
- It is based on the Joint Africa-Europe Strategy (JAES) adopted by Heads of State and Government at the second EU-Africa Summit in Lisbon in 2007
- JAES provides:
  - A long-term framework for EU-Africa relations\(^\text{48}\)
  - Political alliance on key issues including: climate change, trade, peace, science, etc.\(^\text{49}\)
  - Roadmap 2014-2017: targets within 5 priority areas of cooperation agreed at the 4th EU-Africa Summit in 2014: 1) Peace and security; 2) Democracy, good governance, and human rights; 3) Human development; 4) Sustainable and inclusive development and growth and continental integration; and 5) Global and emerging issues\(^\text{50}\)

- Goals of the partnership and JAES:
  - Bring Africa and Europe closer together through a long-term vision of economic cooperation and the promotion of sustainable development
  - Change the traditional donor-recipient relationship
  - Facilitate and promote partnerships, with the participation of civil society and the private sector, to deliver direct benefits to African and European citizens
  - Address global common challenges such as climate change, peace and security, etc.
  - Partnership is driven through formal dialogue at various levels: EU-Africa Summits; Ministerial meetings; college-to-college meetings; Joint Annual Forum; regular high level dialogues and expert level meetings

- The current Roadmap 2014 - 2017
  - Current Roadmap was preceded by the First Action Plan (2008-2010) and the Second Action Plan (2011-2013) – which had 9 priority areas of cooperation\(^\text{51}\)
  - Current Priority Area 3: Human development addresses Science, Technology and Innovation (STI)


• The EU and Africa will work towards reinforcing cooperation between research communities and the creation of joint academic research programmes, with a special focus on innovation and the productive sector including research infrastructures.
• They will also develop long-term, jointly funded and managed research and innovation partnerships, in particular in the areas of food and nutrition security and sustainable agriculture.\(^{52}\)
• Financing will come from the European Research and Innovation Programme, Horizon 2020, and other contributions from EU and African stakeholders.

• The EU-Africa High Level Policy Dialogue (HLPD) on Science, Technology and Innovation (STI)
  • Adopted at the 2nd Africa-EU Summit in Tripoli in 2010 as an important element of JAES
  • Platform for regular exchanges on research and innovation policy and aims to formulate and implement long-term cooperation on STI.\(^{53}\)
  • Co-chaired by the European Union (European Commission, DG Research and Innovation) and the African Union (Member State holding chair of the African Ministerial Council on Science and Technology (AMCOST)) and brings together the S&T representatives from the 27 EU Member States and the 55 African countries.\(^{53}\)
  • EDCTP is a flagship of science and technology cooperation between Africa and the EU.\(^{53}\)
  • Criticism: there is a need for the EU-Africa HLPD to focus on a reduced number of common challenges for the STI cooperation to be effective, although there are many common challenges such as climate change, global health, and improved livelihood. The first priority will be the role of STI in promoting food and nutrition security and sustainable agriculture.\(^{53}\)

2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with Africa-EU Strategic Partnership</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>No synergies identified</td>
</tr>
<tr>
<td>SO2: Strengthen cooperation with sub-Saharan</td>
<td>Partnership objectives include:</td>
</tr>
</tbody>
</table>

\(^{52}\) http://www.ist-africa.org/home/default.asp?page=news-doc-by-id&docid=8781

\(^{53}\) http://ec.europa.eu/research/iscp/index.cfm?pg=africa
| African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation | • Promoting top-quality mobility of African and European students, scholars, researchers  
• Supporting the development of centers of excellence in Africa  
• Reinforcing cooperation between research communities  
• Creating joint academic research programmes  
• Developing a long-term, jointly funded research and innovation partnership\(^5^4\) |
<table>
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<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>Africa-EU Strategic Partnership is adopted by EU Member States and incorporated into national strategies and programmes</td>
</tr>
<tr>
<td>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments</td>
<td>JAES works to change the nature of the relationship between Africa and the EU to one based on partnership, egalitarian relationships, shared objectives and mutual benefits and risks(^5^3)</td>
</tr>
<tr>
<td>SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</td>
<td>Implementing instruments of the partnership include other EU initiatives: Horizon 2020, Africa Union Research Grants, AfricaConnect initiative, AU Support Programme, and others(^5^4)</td>
</tr>
</tbody>
</table>

b. Overlapping organizations

- The Africa – EU Strategic Partnership applies to EU Member States and the Africa Union; 14 EU Member States and 14 African countries participate in EDCTP
- The EU Commission and AU Commission develop Partnership initiatives and evaluation metrics
- EDCTP2 is partially co-funded by the EU under the Horizon 2020 framework\(^5^5\)

3. Comparison Summary

- The Africa – EU Partnership identifies EDCTP as an important actor in its first Action Plan for Implementation, especially in the Eight Partnership on Science, Information Society and Space\(^5^6\)


\(^{55}\) [http://www.edctp.org/funding-opportunities/faq-calls/](http://www.edctp.org/funding-opportunities/faq-calls/)

• The Partnership outlines the priorities of Africa – EU relations, with direct attention given to health and STI. The Partnership works to change traditional donor-recipient relationship – clear opportunity for joint initiatives and policy setting

4. Collaboration Opportunities

1. The Africa – EU Strategic Partnership sets the tone and broadly defines the priorities of relations between the European Union and the Africa Union. There are regularly held meetings that readdress goals and initiatives that EDCTP could possibly participate in and influence.

2. The Roadmap 2014 – 2017 will be expiring soon and new targets and approaches will be defined. EDCTP could affect details of the next iteration of the plan.

3. The High Level Policy Dialogue on STI is currently prioritizing food and nutrition security and sustainable agriculture. If/when the focus shifts to another area of interest, EDCTP could advocate for a greater focus on global health, specifically communicable diseases. EDCTP could support the Partnership in advancing its goals for communicable disease product development.
Europe 2020

1. Programme Summary
   - Europe 2020 is the European Union (EU)'s 10-year strategy for a smart, sustainable, and inclusive economy (launched in 2010)
   - Five headline targets have been agreed for the EU to achieve by the end of 2020. These cover
     o employment; climate/energy; education; social inclusion and poverty reduction; and
     o research and development (invest 3% of the EU's GDP in R&D, in particular by improving the conditions for R&D investment by the private sector, and develop a new indicator to track innovation);
   - Each Member State has adopted its own national targets in each of these areas

Programmes/Initiatives
   - Seven flagship initiatives are identified in the Europe 2020 Strategy to boost growth and jobs and build on the progress made under the previous Lisbon Strategy. The 4 most relevant to public health are:
     o Digital agenda for Europe; Agenda for new skills and jobs; European platform against poverty; and
     o Innovation Union – an initiative that has over 30 action points and aims to make Europe a world-class science performer, remove obstacles to innovation, and revolutionize the way public and private sectors work together, notably through Innovation Partnerships

   - Innovation Partnerships bring together public and private actors at EU, national and regional levels to increase R&D efforts; coordinate investments; anticipate and fast-track any necessary regulation and standards; and mobilize “demand” through better coordinated public procurement to ensure any breakthroughs are quickly brought to market
   - The primary programme is the Partnership on active and healthy aging, which aims to add an average of two years of healthy life for everyone in Europe. Other initiatives include youth on the move, a digital agenda for Europe, an industrial policy for the globalization era, etc.
   - The Innovation Union also introduces:
     o Strategic use of public procurement budgets to finance innovation,
     o A comprehensive Innovation Scoreboard based on 25 indicators, and
     o A European knowledge market for patents and licensing
   - Horizon 2020, which provides grants to research and innovation projects through open and competitive calls for proposals, is a financial instrument implementing the Innovation Union

57 http://ec.europa.eu/europe2020/europe-2020-in-a-nutshell/index_en.htm
58 http://ec.europa.eu/research/innovation-union/index_en.cfm?pg=intro
60 http://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards_en
2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with Europe 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>No synergies identified</td>
</tr>
<tr>
<td>SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>No synergies identified</td>
</tr>
<tr>
<td>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>Innovation Union  • Coordinates intra-EU R&amp;D efforts and encourages cross-sector collaborations  • Works to remove obstacles to innovation such as cheaper patenting  • Facilitates easier participation in EU research and innovation programmes[^62]</td>
</tr>
<tr>
<td>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments</td>
<td>European Innovative Partnerships  • A framework that encourages cross-sector partnerships with public and private organizations across the EU to speed up innovations that address a major societal challenge, and gain competitive advantages for growth and job creation in Europe. Opportunity to align programmes here.  • Brings together different stakeholders to increase R&amp;D and coordinate investments[^63]</td>
</tr>
<tr>
<td>SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</td>
<td>• Europe 2020 is the 10-year economic growth strategy that highlights the need for increased, coordinated R&amp;D throughout Europe  • It was proposed by the European Commission and affects the EU’s economic and R&amp;D strategy  • Other initiatives, such as Horizon 2020, support and implement Europe 2020 outlined priorities</td>
</tr>
</tbody>
</table>


b. Overlapping organizations

- Europe 2020 applies to EU Member States, 14 of which participate in EDCTP64
- The EU Commission and EU Council develop Europe 2020 initiatives and evaluation metrics (also match funds from European Member States for EDCTP budget)
- EDCTP2 is partially co-funded by the EU via Horizon 2020 (which is a financial instrument of Europe 2020 initiatives)

3. Comparison Summary

- One of the five headline targets of the Europe 2020 strategy is increasing investment in R&D
- Under this R&D umbrella, there is a focus on increasing innovation through cross-sector, coordinated partnerships across the EU
- Current emphasis is on collaboration between stakeholders in the EU and on areas of health affecting Europeans
- Horizon 2020, which provides grants for EU Members and those outside the EU, is an implementer of policy initiatives including Europe 2020

4. Collaboration Opportunities

1. The Europe 2020 strategy highlights the need for increased R&D and innovation partnerships - there could be a push to the European Commission to expand intra-EU partnerships to organizations outside of the EU.
2. The governing body develops initiatives for the Innovation Union and meets regularly to identify areas of need and progress. This presents an opportunity to offer input on the types of initiatives and areas of health to focus.
3. The European Innovation Scoreboard could incorporate more international metrics other than those already captured: non-EU doctorate students, license and patent reviews from abroad, and international scientific co-publications.

64 http://www.edctp.org/get-know-us/
EU Development Cooperation Policy - European Consensus on Development

1. Programme Summary

The European Consensus on Development is a policy statement written in 2006 that commits the European Union (EU) to eradicating poverty and building a fairer and more stable world. Made jointly by the 3 main EU institutions (Commission, Parliament, and Council), the Consensus on Development identifies shared values, goals, principles, and commitments which the Commission and EU governments will implement in their development policies:

- Reducing poverty: Particularly through the Millennium Development Goals (MDGs). This will also impact sustainability, HIV/AIDS, security, conflict prevention, forced migration, etc.¹
- Democratic values: Respect for human rights, democracy, fundamental freedoms and the rule of law, good governance, gender equality, solidarity, and social justice ¹
- Nationally led development: By the beneficiary countries themselves, based on national strategies (developed in collaboration with non-government bodies) and domestic resources. EU aid will be aligned with national strategies and procedures. ¹

Part I: Sets out common objectives and principles for development cooperation. It reaffirms EU commitment to poverty eradication, ownership, partnership, delivering more and better aid, and promoting policy coherence for development. It will guide Community and Member State development cooperation activities in all developing countries in a spirit of complementarity.

Part II: Clarifies the Community’s role and added value and how the objectives, principles, values, policy coherence for development, and commitments defined in this common vision will be made operational at Community level. It identifies priorities which will be reflected in effective and coherent development cooperation programmes at the level of countries and regions. It also guides the planning and implementation of the development assistance component of all Community instruments and cooperation strategies with third countries.

2. Relevant Programmes/Policies & Synergies with EDCTP2

a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with European Consensus on Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>The European Consensus on Development reaffirms commitment to reaching the MDG/SDG agenda, specifically combatting HIV/AIDS, malaria, and other diseases. The policy states that a roadmap for joint EU actions on the European Programme for Action will be deployed to confront the devastating impact of HIV/AIDS, TB, and malaria in developing countries. The Commission will continue to contribute to global initiatives that are clearly linked to the MDGs/SDGs.</td>
</tr>
</tbody>
</table>

**SO2:** Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation

The European Consensus on Development reaffirms commitment for EU Member States to achieve 0.7% of GNI by 2015, estimating these commitments to be 66 billion EUR by 2010. At least half of this increase in aid will be allocated to African countries. The policy states that particular attention to resource allocation must be paid to least developed countries (LDC’s) and the Community should find ways to increase the focus on the poorest countries with a specific focus on Africa. Community assistance should support recipient countries’ poverty reduction strategies to promote alignment on national policies and sustainability. The EU will enhance its support for building capacity of non-state actors in order to strengthen their voice in the development process and to advance political, social, and economic dialogue.

**SO3:** Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments

The European Consensus on Development supports the broad participation of all stakeholders in countries’ development and encourages all parts of society to take part. This includes civil society, economic and social partners such as trade unions, employers’ organizations, the private sector, NGOs, and other non-state actors of partner countries.

**SO4:** Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments

The European Consensus on Development guides the planning and implementation of the development assistance component of all Community instruments and cooperation strategies with third countries to ensure coherence for development. No mention of leveraging resources and investments between development partners.

**SO5:** Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance

Cooperation and alignment of EU aid is a priority.

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**b. Overlapping organizations**

- The **EU Consensus on Development** provides a common vision that guides the action of the EU, both at its Member States and Community levels, in development co-operation. Fourteen EU Member States participate in EDCTP.

**3. Comparison Summary**

- The European Consensus on Development policy outlines the EU’s commitment to eradicating poverty and building a fairer and more stable world, with particular emphasis on allocating aid to sub-Saharan African countries to progress development.

- The policy prioritizes poverty reduction, particularly through attaining the MDGs/SDGs. This will also impact sustainability, combat HIV/AIDS, malaria, and other diseases.

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66 [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AC%3A2006%3A046%3A0001%3A0019%3AEN%3APDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AC%3A2006%3A046%3A0001%3A0019%3AEN%3APDF)
• The policy affirms the EU's commitment to promoting policy coherence for development, based upon ensuring that the EU shall take account of the objectives of development cooperation in all policies that it implements which are likely to affect developing countries, and that these policies support development objectives.

4. Collaboration Opportunities

1. As the European Consensus on Development emphasizes attaining the MDGs/SDGs specifically in African countries, the EDCTP2 could provide input as to how contributions received from developed European countries could be best utilized to strengthen cooperation with sub-Saharan African countries, and build capacity for conducting clinical trials.

2. The EDCTP2 could advise the European Commission as to which sub-Saharan African countries face the greatest challenges in attaining the MDGs/SDGs, as well as the greatest capacity for building activities in support for conducting clinical trials.
The Agenda for Change

1. Programme Summary

- Adopted in 2011, the Agenda for Change is the basis for the European Union (EU)'s development policy
- Its primary objective is to significantly increase the impact and effectiveness of EU development policy
- Agenda priorities will be maintained for 6 years (Multi-Annual Financial Framework) 2014-2020
- Principles:
  - Differentiation: target resources where they are needed most and where they can have the greatest impact. (e.g., poorest or fragile states. Those already on sustained growth paths or able to generate its own resources will have alternative development partnerships.)
  - Concentration: not engage in more than three sectors per partner country
  - Coordination: the EU and its Member States shall strengthen Joint Programming and work to develop a common results-based approach to provide a basis for improving mutual accountability and transparency on development results
  - Coherence: evaluate the impact of its policies on development objectives
- Policy priorities
  - Human rights, democracy and other key elements of good governance:
    - EU action should center on the support and promotion of democracy, human rights and the rule of law, gender equality, civil society and local authorities, public sector management, corruption, tax policy and administration
    - In its action the EU shall employ a mix of approaches and instruments such as political dialogue, aid and conditionality based on countries’ context, commitments and performance
  - Inclusive and sustainable growth for human development:
    - The EU shall strengthen its action on social protection, health and education
    - Enhance support to those sectors that can have a high impact on development outcomes, like sustainable agriculture and energy, including natural resources management
    - Support sectors that create enabling conditions for inclusive and sustainable growth such as private sector development and fostering regional integration, by using new financial tools in order to leverage further resources to increase the EU's impact on poverty reduction

2. Relevant Programmes/Policies & Synergies with EDCTP2

a. Synergies with EDCTP2

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<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with Agenda for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>No synergies identified – complementary</td>
</tr>
</tbody>
</table>
| SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation | • The Agenda for Change aims to build sustainable infrastructure, which is needed for conducting research  
• The majority of international EU aid is going to sub-Saharan African countries |
| SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments | In addition to EU aid, the Agenda pushes for developing countries to explore additional private domestic and foreign investment to improve infrastructure. This includes public-private partnerships – industry. |
| SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments | No direct synergies identified – does not address research impact, but still could link with international cooperation and private industry involvement. |
| SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance | • New criteria for aid includes the idea of differentiated development partnerships, which examines poverty level, capacity, and potential EU impact.  
• The Agenda outlines Joint Programming of EU and Member States’ aid, which would reduce fragmentation and increase aid impact proportionally to commitment levels |

b. Overlapping organizations
- The EU Commission encourages EU Member States to adopt Agenda for Change principles. Fourteen EU Member States participate in EDCTP.

3. Comparison Summary
- The EU Agenda for change outlines the EU's development policy, which mainly includes aid for countries in sub-Saharan Africa
- The Agenda prioritizes human development, which includes health, education, and social protection and services

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The Agenda discusses the need for developing countries to attract and retain private domestic and foreign investment and improve infrastructure. It encourages up-front grant funding and risk-sharing mechanisms to catalyze public-private partnerships and private investment.70

4. Collaboration Opportunities

1. To best allocate development aid, it is beneficial to understand the context of the country receiving the aid, and to be on favorable terms with the country. EDCTP works with African countries and EU Member States to facilitate sustainable relationships. EDCTP could provide input into larger aid strategy as well as coordinate their strategy with current and future aid efforts.

2. The Agenda highlights the importance of sustainable investment in infrastructure and finding new ways to engage private-public partnerships to increase domestic capacity. It also encourages joint programming of EU Member States. EDCTP and the EU could better align financing for capacity building initiatives in sub-Saharan Africa.
EU Role in Global Health

1. Programme Summary
The European Union (EU) is a political and economic union between 28 European countries. The EU is committed to improving health in developing countries. In 2010, the EU Commission Communication on Global Health identified areas in which European and international action could be more effective:

- Improving Global Governance
- Developing Universal Health Coverage
- Increasing Health Policy Coherence
- Research and Innovation
- Optimizing Skills

Those which are listed above and are not reviewed in the following table (Developing Universal Health Coverage and Increasing Health Policy Coherence) have no obvious alignment with EDCTP2, as they are based on improving health coverage and related policies.

2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>EU Union Role in Global Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>Research and Innovation</td>
</tr>
<tr>
<td>Access to health services, medical technologies, and medicines should benefit all. Research and innovation strategies should be directed towards:</td>
<td></td>
</tr>
<tr>
<td>• Preparation for implementation of Horizon 2020</td>
<td></td>
</tr>
<tr>
<td>• Strengthened Research Process: innovation, implementation, access, monitoring, and evaluation</td>
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</tr>
<tr>
<td>o Addresses a lack of incentive for developing new medicines and technologies in poverty-stricken nations</td>
<td></td>
</tr>
<tr>
<td>o Research should be funded accordingly, with shared global prioritization of the health needs of developing countries</td>
<td></td>
</tr>
<tr>
<td>• Collecting Data and Statistics: globally, by collaborating with national and international organizations working on world health (such as the World Health Organization [WHO])</td>
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</tbody>
</table>

| SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in | Research and Innovation |
| Including the EU strategies listed above, this aim is also meant to build research capacity in public health |
| Several EU Framework Programmes provide funding for HIV/AIDS, TB, and Malaria research, including |


<table>
<thead>
<tr>
<th>Compliance with fundamental ethical principles and relevant national, EU and international legislation</th>
<th>EDCTP273</th>
</tr>
</thead>
<tbody>
<tr>
<td>• An EU initiative established the EDCTP and continues to support EDCTP2 clinical trials in sub-Saharan Africa</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</th>
<th>Improving Global Governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through improved coordination of action undertaken by States or groups of States:</td>
<td></td>
</tr>
<tr>
<td>• Global: to defend a single position within the WHO and the United Nations (UN)</td>
<td></td>
</tr>
<tr>
<td>• Regional: to develop exchange and networks between neighboring States</td>
<td></td>
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<tr>
<td>• National: support policies and control of public funding</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments</th>
<th>Optimizing Skills</th>
</tr>
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<tbody>
<tr>
<td>The EU shall establish mechanisms to optimize:</td>
<td></td>
</tr>
<tr>
<td>• Action in EU and other countries, in a platform to exchange information, and through development of common positions between EU countries and the Commission</td>
<td></td>
</tr>
<tr>
<td>• Monitoring of European Aid and implementation of the EU Code of Conduct on Division of Labor in health</td>
<td></td>
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<tr>
<th>SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</th>
<th>Optimizing Skills</th>
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<td></td>
</tr>
<tr>
<td>• Monitoring of European Aid and implementation of the EU Code of Conduct on Division of Labor in health</td>
<td></td>
</tr>
<tr>
<td>• Facilitating dialogue with global players, uniting with UN agencies and international financial institutions invested in health</td>
<td></td>
</tr>
<tr>
<td>o These include the EU-Africa summit, where leaders discuss joint action on health SDGs</td>
<td></td>
</tr>
</tbody>
</table>

b. Overlapping organizations

- EU countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the UK have members in the EDCTP General Assembly.
- UN: The EDCTP-WHO/Special Programme for Research and Training in Tropical Diseases (TDR) Clinical Research and Development Fellowships are supported by the UN Development Programme (UNDP). The EU holds enhanced observer status at the UN.
- WHO: The EU supports the WHO as the leading global health authority in the UN. The WHO sends representative observers to the EDCTP General Assembly.

3. **Comparison Summary**

The EU and EDCTP2 are focused on maximizing their global health impact, through joint action and policy (EU) and funding and capacity building (EDCTP2). The EDCTP2 Specific Objectives complement the EU’s goals for optimization, global governance, and research and innovation.

4. **Collaboration Opportunities**

1. In their goals for Research and Innovation, the EU aims to improve information systems and data collection practices of partner countries.
   - From available information, these collection practices are in conjunction with WHO and Eurostat, who are collecting health statistics (primarily to track healthcare workers).
   - If the EU has interests in data other than healthcare worker statistics, EDCTP2 may collaborate through their trials network.
   - EDCTP2 may have access to epidemiologically relevant information in their clinical trials network in sub-Saharan Africa. Such data may be of interest to the EU.
   - If the EU is interested in assessing the soundness of their data collection practices, EDCTP2-funded research could adopt data collection practices as established by the EU, and provide vital feedback on the practicality of these practices.

2. Through Optimizing Skills, the EU is working to ensure their efforts, policies, and funds are impactful for global health.
   - One avenue is through the Global Health Policy Forum (established by the European Commission). This Forum works to ensure coherence between internal and external global health policy goals.74
   - The EU supports country-level global health initiatives such as Gavi and the Global Fund to Fight AIDS, Tuberculosis and Malaria.
   - Similarly, EDCTP2 is improving methods to ensure their research is conducted in an impactful manner for global health causes.
   - The EDCTP2 could partner with the EU to assess whether EDCTP-relevant EU policies and/or programmes are effective.

European Research Area

1. Programme Summary

The European Research Area (ERA) is a research and innovation strategy established by the European Commission (EC). The goals for forming the ERA were to establish a European research policy to make national research systems more open, inter-operable and inter-connected with the aim that financial resources can be used with full efficiency, effectiveness and impact across Europe.\(^{75}\)

The five key ERA priorities in which international cooperation is a cross-cutting theme are:

1. More effective national research systems
2. Optimal transnational co-operation and competition
3. An open labor market for researchers
4. Gender equality and gender mainstreaming in research
5. Optimal circulation and transfer of knowledge including via digital ERA

The ERA principles are fully integrated in the Europe 2020 Innovation Union flagship initiative to foster Growth and Jobs.

The ERA has three participating entities:

- EC
- All European Union (EU) member states
- Research Stakeholder Organisations (SHOs)\(^{75}\)
  - European Association of Research and Technological Organisations (EARTO)
  - European University Association (EUA)
  - League of European Research Universities (LERU)
  - NordForsk
  - Science Europe
  - Conference of European Schools for Advanced Engineering Education and Research (CESAER)

ERA’s achievements include formation of an alliance, EU-Life, consisting of 13 top scientific research centers across EU to support and strengthen European research excellence.\(^{76}\) ERA has also put in place a Joint Programming process. The overall aim of the Joint Programming process is to pool national research efforts to make better use of Europe’s precious public R&D resources and to tackle common European challenges more effectively in a few key areas. Member States commit to Joint Programming Initiatives (JPIs) where they implement together joint Strategic Research Agendas, including jointly implementing and/or financing calls and projects.\(^{77}\)

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\(^{75}\) [http://ec.europa.eu/research/era/partnership_en.htm](http://ec.europa.eu/research/era/partnership_en.htm)

\(^{76}\) [http://eu-life.eu/content/about-us](http://eu-life.eu/content/about-us)

\(^{77}\) [http://ec.europa.eu/research/era/what-joint-programming_en.htm](http://ec.europa.eu/research/era/what-joint-programming_en.htm)
2. Relevant Programmes/Policies & Synergies with EDCTP2  
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with ERA</th>
</tr>
</thead>
<tbody>
<tr>
<td>S01: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>No synergies identified</td>
</tr>
<tr>
<td>S02: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>Aligns with ERA's priority #2, which aims to implement joint research agendas in cooperation with non-EU countries where relevant and appropriate</td>
</tr>
<tr>
<td>S03: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>Aligns with ERA's priority #2, which aims to enable transnational research and innovation by exploiting synergies between national and international programmes, strategically aligning different sources of national and other funds at EU level</td>
</tr>
</tbody>
</table>
| S04: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and to achieve leveraging of resources and investments | Aligns with ERA's priority #2, which aims to:  
   - jointly implement and/or finance calls and projects  
   - build provisions for Public-Public Partnerships  
   - implement joint research agendas in cooperation with non-EU countries where relevant and appropriate  
Aligns with ERA's priority #5, which aims to establish open access to scientific publications as a general principle for all EU funded projects |
| S05: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance | Aligns with ERA's priority #2, which aims to jointly implement and/or finance calls and projects within in all EU member states |

b. Overlapping organizations
   - EU member states: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, UK


79 http://ec.europa.eu/research/era/optimal-circulation_en.htm
3. Comparison Summary

EDCTP2 and ERA both make an effort to align and integrate resources and investment with other relevant EU initiatives to maximize the impact of the research being conducted.

4. Collaboration Opportunities

1. The Research Infrastructures (RIs) system\textsuperscript{80} is one of EC’s research and innovation strategies. ERA’s priority #2 encourages effective use of RIs.\textsuperscript{77} EDCTP2 could learn from ERA’s experiences with RIs and apply them towards developing research and clinical trial facilities and Networks of Excellence in endemic countries.

2. ERA’s priority #5 encourages, through assessment of existing initiatives, development of a comprehensive policy approach to open innovation and knowledge transfer.\textsuperscript{78} EDCTP2 could work with ERA to extend that approach towards sharing of knowledge and data generated from EDCTP2 research and clinical trials.

\textsuperscript{80} http://ec.europa.eu/info/research-and-innovation_en
Horizon 2020

1. Programme Summary

Horizon 2020 is one of the Framework Programmes (FPs) for Research and Innovation created by the European Union (EU) as a part of Europe 2020, to financially support and foster research and complement development of the European Research Area (ERA). The goal is to ensure Europe produces world-class science, removes barriers to innovation, and makes it easier for the public and private sectors to work together in delivering innovation.\(^{81}\)

The Horizon 2020 Programme provides grants to research and innovation projects through open and competitive calls for proposals. The Programme strongly supports the three strategic priorities:\(^{82}\)

1. Open Innovation: combine diverse sources of knowledge involving multi-collaborative innovation systems, researchers, entrepreneurs, investors, users, governments and civil society
2. Open Science: open access to research results and the underlying data as well as the need for new initiatives to strengthen research integrity for policy makers, research funders, research institutions and researchers
3. Open to the World: engage more in science diplomacy and in global scientific and technological collaboration to remain relevant and competitive, and to lead the way in developing global research and innovation partnerships to address global challenges

The Horizon 2020 programme is divided into the following sections: \(^{83}\)

1. Excellent Science
2. Industrial Leadership
3. Societal Challenges
4. Spreading Excellence and Widening Participation
5. Science with and for Society
6. Cross-cutting Activities
7. Fast Track to Innovation Pilot
8. European Institute of Innovation and Technology (EIT)
9. Euratom
10. Smart Cyber-Physical Systems

Horizon 2020 aims at achieving a greater impact on research and innovation by contributing to the strengthening of public-public partnerships, including through EU participation in programmes undertaken by several Member States in accordance with Article 185 of the Treaty on the Functioning of the European Union. \(^{84}\) EDCTP2 is one of the public-public partnerships proposed under article 185 \(^{85}\) that falls under the section of Societal Challenge of Health, Demographic Change and Wellbeing mentioned above. \(^{86}\) EDCTP2 is financially supported by the EU and is implemented as part of Horizon 2020. \(^{64}\)


2. Relevant Programmes/Policies & Synergies with EDCTP
   
a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with Horizon 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>S01: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>Horizon 2020 aims to support research to improve the treatment of HIV/AIDS and other diseases. For example, the European HIV Alliance (EHVA) is a project funded by Horizon 2020 to foster the development of an effective vaccine. 87</td>
</tr>
</tbody>
</table>
| S02: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation | • Aligns with Horizon 2020's strategic priority of 'Open to the World,' in which Horizon 2020 aims for global scientific collaborations  
• Horizon 2020 co-funds the Africa-EU Strategic Partnership, which aims to support development of centers of excellence in Africa |
| S03: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments | The Scientific Panel for Health set up by Horizon 2020 helps to build capabilities and to foster knowledge-sharing and stronger collaboration across EU 84 |
| S04: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and to achieve leveraging of resources and investments | • Aligns with Horizon 2020's strategic priority of 'Open to the World,' in which Horizon 2020 aims for global scientific collaborations  
• The Scientific Panel for Health set up by Horizon 2020 helps to build capabilities and to foster knowledge-sharing and stronger collaboration across EU, including public-private partnerships 84 |
| S05: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance | • EHVA is a project funded by Horizon 2020 to foster the development of an effective HIV vaccine 87  
• The Scientific Panel for Health set up by Horizon 2020 helps to build capabilities and to foster knowledge-sharing and stronger collaboration across EU 84 |

b. Overlapping organizations
In line with the objectives of Horizon 2020, any Member State and any country associated with Horizon 2020 should be entitled to participate in EDCTP2 85

87 http://www.ehv-a.eu/about-us
3. **Comparison Summary**

Horizon 2020 is the biggest EU Research and Innovation programme ever and is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe’s global competitiveness. EDCTP2 is one of the many activities of Horizon 2020’s Societal Challenges section. EDCTP2 is an integral part of Horizon 2020 and its activities are in line with the objectives, research, innovation priorities, and general principles of Horizon 2020. Evaluation of EDCTP2 Programme shall be taken into account in the evaluation of Horizon 2020. 

4. **Collaboration Opportunities**

1. EDCTP2 could work with EHVA 87 for conducting research on HIV vaccines and building capacity to conduct the clinical trials at CoE.
2. The Research Infrastructures (RIs) system 88 is one of Horizon 2020’s research and innovation strategies. EDCTP2 could learn from Horizon 2020’s experiences in establishing RIs and apply them towards developing research and clinical trial facilities and Networks of Excellence in endemic countries.
3. EDCTP2 could work with ERA for sharing of knowledge and data generated from ERA’s research activities
4. EDCTP2 could collaborate and exchange information with the Scientific Panel for Health, where appropriate 84

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Second Innovative Medicines Initiative

1. Programme Summary

- The goal of the Innovative Medicines Initiative (IMI) 2 is to develop next-generation vaccines, medicines and treatments, such as new antibiotics.
- Jointly funded as a public-private partnership between the European Union (EU) Horizon 2020 and the European Federation for Pharmaceutical Industries and Associations (EFPIA), IMI 2 will build on the successes and lessons learned under IMI's first phase.
- The initiative works to improve health by accelerating the development of innovative medicines, particularly in areas where there is an unmet medical/public health need in the EU, as well as where global public health need is greatest, for example with funding to respond to the Ebola epidemic.
- IMI 2 does this by facilitating collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small- and medium-sized enterprises (SMEs), patient organizations, and medicines regulators.
- IMI 2 aims to improve coordination across sectors and pave the way for breakthrough vaccines, medicines and treatments to tackle Europe’s growing health challenges, and secure the future international competitiveness of Europe’s pharmaceutical industry. In addition to funding clinical trials and infrastructure-related capacity building projects, IMI supports education and training projects.

Specific aims of IMI 2 with relevance to EDCTP2 include:

- increase the success rate in clinical trials of priority medicines identified by the World Health Organization;
- develop new therapies for diseases for which there is a high unmet need (e.g. Alzheimer’s), limited market incentives (e.g. antimicrobial resistance), or large public health need (e.g. Ebola);
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks.

The focus of IMI 2’s Strategic Research Agenda for the period 2014-2024 maintains a strong focus on the development of new medicines, and also places a heavy emphasis on tools and methods to accelerate patient access to new medicines. The Strategic Research Agenda identified four major axes of research, including adoption of innovative clinical trial paradigms and development of innovative medicines. IMI 2 health priorities align with the World Health Organization’s Priority Medicines for Europe and the World Update Report. These priorities include addressing antimicrobial resistance and vaccine development.

2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with IMI 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SO1</strong>: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>IMI 2 funding for infectious diseases has been specific to Ebola and antimicrobial resistance – both areas align with EDCTP2 diseases – TB. A key objective of IMI 2 is to increase the success rate in clinical trials of priority medicines identified by the World Health Organization. This could potentially align with EDCTP2 diseases.</td>
</tr>
<tr>
<td><strong>SO2</strong>: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>The IMI 2 programme has strategically focused its funding on Ebola vaccine clinical trials and building Ebola research and vaccine production capacity, including large-scale clinical trials in West Africa to produce a safe and effective Ebola vaccine. Alignment with EDCTP2 across clinical trials, product development/phase II/III/IV and capacity building.</td>
</tr>
<tr>
<td><strong>SO3</strong>: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>IMI 2 programme will provide Europeans with more efficient and effective medicines and treatments focusing on NCDs, with some alignment with EDCTP2 disease priorities. Both initiatives will benefit from greater coordination across industry sectors for vaccine development, with more reliable and faster clinical trials.</td>
</tr>
<tr>
<td><strong>SO4</strong>: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments</td>
<td>The IMI 2 programme obtained €1.425 billion from EFPIA companies and up to €213 million can be committed by other life science industries or organizations that decide to contribute to IMI 2 as members or Associated Partners. These contributions are mostly through in-kind support to leverage resources and investments.</td>
</tr>
<tr>
<td><strong>SO5</strong>: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</td>
<td>Where disease interests align, the initiatives should explore opportunities to leverage the others’ geography’s and synergies.</td>
</tr>
</tbody>
</table>

b. Overlapping organizations
   - EDCTP2 and IMI 2 are both co-funded by Horizon 2020
   - IMI 2 overlap with some industry EDCTP2 partner organizations. During the Ebola outbreak in 2014, The European Commission called for EDCTP to expand funding to Ebola, while
working in parallel with industry to further development of vaccines, drugs and diagnostics for Ebola within the IMI 2.90

3. Comparison Summary
   - Both IMI 2 and EDCTP2 aim to support collaborative research that accelerates the clinical development of new or improved interventions for poverty-related and neglected diseases, but with very different scopes to their mission.
   - While EDCTP2 has a broad focus on prevention and treatment of the ‘big three’ infectious diseases, neglected diseases and emerging infectious diseases in sub-Saharan Africa, IMI 2 has focused its funding on Ebola vaccine clinical trials and building Ebola vaccine production capacity.
   - The overlap between EDCTP2 and IMI 2 centers on building Ebola research capacity, including large-scale clinical trials in West Africa and producing a safe and effective Ebola vaccine and vaccines.

4. Collaboration Opportunities
   - A focus of IMI 2’s research is adoption of innovative clinical trial paradigms and developing innovative medicines – potential opportunities for knowledge sharing and collaboration with EDCTP2, particularly around clinical trial design and building Ebola research capacity in Africa. This capacity development could align with some other EDCTP2 disease areas.
   - IMI 2’s aim of accelerating the development of safe and effective vaccines could be coupled with EDCTP2’s expertise in implementing vaccine trials for infectious diseases in sub-Saharan Africa.

The Joint Programming Initiative on Antimicrobial Resistance

1. Programme Summary

By 2050, 10 million people are projected to die yearly from drug-resistant organisms. The Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), largely made up of national research institutes, set out with the goals of curtailing the emergence and spread of antibiotic-resistant genes and bacteria, and reducing the burden of antimicrobial resistance (AMR) by 2040. In their Strategic Research Agenda (SRA), JPIAMR outlines six priority topics: Therapeutics, Diagnostics, Surveillance, Transmission, Environment, and Interventions.

2. Relevant Programmes/Policies & Synergies with EDCTP2

a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with the JPIAMR</th>
</tr>
</thead>
</table>
| SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones | JPIAMR focuses on bacterial resistance, so EDCTP2 Strategic Objective 1 applies to bacterial diseases, antibiotic drug development, and diagnostics development. **Therapeutics**  
  - Develop novel diagnostics and antibiotic alternatives, from basic research to market  
  - Executed through identifying new targets for antibiotics, drug development, improved pharmacokinetics, new treatment protocols and vaccines, and studying effective policy measures  
  **Diagnostics**  
  - JPIAMR estimates 70% of antibiotics are prescribed incorrectly, and existing diagnostic technologies are not practical enough to be used in clinical practice  
  - Their aim is to improve existing, and develop new diagnostic tools  
  **Interventions**  
  - JPIAMR emphasizes a need for controlled studies, and will research strategies for AMR reduction interventions Above in strong alignment with EDCTP2 goals and programmes. |
| SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international | Clinical trials and new interventions for TB and diarrheal diseases, including better diagnostics – opportunity for alignment and collaboration |

91 http://www.jpiamr.eu/about/

### Legislation

| SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments | Can achieve cost effectiveness by aligning programmes around common or co-infection diseases. Explore areas for alignment with EDCTP2. |
| SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments | TB is one of the main diseases for both EDCTP2 and JPIAMR – international cooperation will be important in order to maximize synergies and investments. |
| SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance | Strong opportunity to align and increase impact in common diseases or co-infections. |

### b. Overlapping organizations

- **BMBF (Federal Ministry of Education and Research):** Represents Germany as a development and implementation partner of JPIAMR. Dr. Joachim Klein (Life Sciences Strategy and Policy, BMBF) is a member of the EDCTP General Assembly.
- **Inserm:** JPIAMR member, and Dr. Bernadette Murgue (Assistant Director, Inserm I3M) is a member of the EDCTP General Assembly.
- **Instituto de Salud Carlos III:** JPIAMR member, and Rafael de Andrés Medina and Tomas López-Peña Ordoñez are part of the EDCTP General Assembly.

### 3. Comparison Summary

- The performance indicators for EDCTP2 SO1 cover several areas of synergy with JPIAMR’s SRA. These include progression of candidate medical interventions, guidelines for improved or extended use of medical interventions, and further clinical trials to develop new products. These interventions, products, or clinical trials pertain to antibiotic drug development or AMR, there is overlap with the JPIAMR and EDCTP2 topics of therapeutics, diagnostics, and interventions.
- Below are highlighted areas of alignment between EDCTP2 and JPIAMR AMR R&D initiatives across the antibiotic value chain: (available at:...
4. Collaboration Opportunities

The JPIAMR SRA priority topics are anchored on the following:

- Establishing a biobank of clinical specimens and strains
- Establishing a database containing information on ongoing AMR research
- Collaborating with stakeholders
- Raising awareness of AMR
- Focusing on AMR in bacteria that cause life-threatening infections during hospitalization

Based on EDCTP2’s investment and expertise in clinical trials, they may be posed to assist JPIAMR in establishing a biobank of clinical specimens and strains. This would strengthen cooperation with sub-Saharan Africa (EDCTP2 SO2), and accelerate the control and eradication of poverty-related diseases (EDCTP2 SO1). According to JPIAMR, those participating in cooperative activities for increased impact may be eligible for new funding.

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93 http://www.jpiamr.eu/activities/strategicresearchagenda/

The Global Research Collaboration for Infectious Disease Preparedness

1. Programme Summary

The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) is an international network of research funders who intend to facilitate an effective research response within 48 hours of a disease outbreak with pandemic potential. GloPID-R is not a new funding organization, does not fund projects directly, and does not coordinate public health responses. Instead, GloPID-R coordinates and shares information among the funding organizations, and advances response readiness through research and policy development during interepidemic periods.

GloPID-R’s objectives are as follows:

- Facilitate exchange of information between funders
- Address scientific, ethical, and financial challenges
- Implement a “One Health” approach with cooperation of human and animal health researchers
- Establish a strategic agenda for research response
- Connect infectious disease research networks
- Actively involve developing countries

2. Relevant Programmes/Policies & Synergies with EDCTP2

a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with GloPID-R</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SO1:</strong> Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>Establish a Strategic Agenda for Research Response</td>
</tr>
<tr>
<td>GloPID-R members fund research to combat outbreaks of infectious diseases, including Ebola</td>
<td></td>
</tr>
<tr>
<td>EDCTP2 can align with GloPID-R on response and product development for infectious disease outbreaks</td>
<td></td>
</tr>
<tr>
<td><strong>SO2:</strong> Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>Actively Involve Developing Countries</td>
</tr>
<tr>
<td>GloPID-R members encourage researcher participation in international collaborations through stipulations in funding and research initiatives</td>
<td></td>
</tr>
<tr>
<td>GloPID-R is particularly interested in partnerships between countries in Europe and sub-Saharan Africa</td>
<td></td>
</tr>
<tr>
<td>Clear alignment with EDCTP2 programmes and approaches</td>
<td></td>
</tr>
<tr>
<td><strong>SO3:</strong> Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>GloPID-R facilitates alignment across funders – this is an important information source for EDCTP2 to identify opportunities for coordination and alignment.</td>
</tr>
</tbody>
</table>

95 http://ec.europa.eu/health/ev_world/docs/ev_20140612_c05_en.pdf
SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments

<table>
<thead>
<tr>
<th>Connect Infectious Disease Research Networks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GloPID-R maps relevant research networks worldwide</td>
</tr>
<tr>
<td>2. GloPID-R facilitates coordination of relevant international clinical trials</td>
</tr>
<tr>
<td>3. Examples include the EU-Africa summit, where leaders discuss joint action on health SDGs</td>
</tr>
<tr>
<td>4. GloPID-R can influence cooperation between EDCTP and other partners/funders.</td>
</tr>
</tbody>
</table>

SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance

| GloPID-R can support EDCTP in increasing impact through greater cooperation and coordination. |

b. Overlapping organizations

- European Union: Line Matthiessen (Directorate-General for Research and Innovation at the European Commission) serves as GloPID-R Chair, and the European Union sends representative observers to the EDCTP General Assembly.
- Instituto de Salud Carlos III: Rafael de Andres Medina (Head of the EU and Internalization Dept.) is a member of GloPID-R, and serves on EDCTP European Economic Interest Grouping (EEIG)/Association General Assembly.
- Medical Research Council, UK: Mark Palmer (Head of International Strategy) is a representative member of the GloPID-R, as well as the EDCTP.
- World Health Organization (WHO): Observer for both GloPID-R and the EDCTP.

3. Comparison Summary

The EDCTP2 and GloPID-R share a common interest in clinical trial development and capacity building: EDCTP2 in Africa to combat neglected tropical diseases and emerging infectious diseases, and GloPID-R in various low- and middle-income countries to conduct research on epidemic-potential diseases. Great commonality between organization objectives.

4. Collaboration Opportunities

1. EDCTP2 could become a member of GloPID-R in order to share information and coordinate across other funders in the network.
   - GloPID-R organizes information exchanges between funders, and works with members to establish strategic agendas to address scientific, legal, ethical, and financial challenges.
   - GloPID-R lists opportunities for funding (through their member organizations) on their website – could help to promote EDCTP2 awards and announcements.

2. GloPID-R emphasized in 2016 report that current measures need to address how to rapidly implement a clinical research trial during an outbreak.
   - GloPID-R wants to identify where there is capacity to conduct studies during the next pandemic – EDCTP2 CoE are potential sites or could be developed to meet GloPID needs.
   - EDCTP2 is posed to provide resources.

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- GloPID-R members might offer funding for EDCTP2 to support clinical trials on diseases with epidemic potential, or the two might coordinate in a GloPID-R member/EDCTP2 co-funded clinical trial.
Global Alliance for Chronic Diseases

1. Programme Summary

The Global Alliance for Chronic Diseases (GACD) addresses the burden of chronic non-communicable diseases (NCDs) in low- and middle-income countries (LMICs). Current GACD members are public funding agencies from the European Union and other regions who collectively manage more than 80% of public health research funding. With joint calls issued by GACD, members fund coordinated research programmes on NCDs, and unite research teams to build capacity. GACD’s strategic programme is based on:

- Coordination: Build increasing levels of research collaboration across the member agencies
- Awareness: Raise awareness and conduct outreach beyond the original founding members
- Capacity building: Form global knowledge-sharing platforms for chronic NCD research in LMICs

2. Relevant Programmes/Policies & Synergies with EDCTP2

a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with GACD</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>Explore areas where NCDs link with infectious disease programmes and product development. Clinical trials where there is coinfection.</td>
</tr>
<tr>
<td>SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>Build increasing levels of research collaboration across member agencies – including funders in sub-Saharan Africa and funders from other regions who support research in sub-Saharan Africa. Form knowledge-sharing platforms for researchers in LMICs across both NCD and infectious disease capacity building programmes.</td>
</tr>
<tr>
<td>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>NCD programmes and funding may be linked and coordinated with EDCTP2 national programmes to increase cost-effectiveness</td>
</tr>
<tr>
<td>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and</td>
<td>GACD works to strengthen international cooperation and alignment of public research investments – this can include EDCTP funding. GACD help maximize resource leveraging and cost-effectiveness, while minimizing duplication – coordinate with EDCTP on funding.</td>
</tr>
</tbody>
</table>

97 http://www.gacd.org/gacd/about/strategy
b. Overlapping organizations
- European Union: Ruxandra Draghia-Akli (Director of the Health Directorate at the European Commission, Research and Innovation DG) is a GACD Board Member, and the European Union sends representative observers to the EDCTP General Assembly
- Medical Research Council, UK: Mark Palmer (Head of International Strategy) is a GACD Board Member and Chair of the EDCTP European Economic Interest Grouping (EEIG)/Association General Assembly

3. Comparison Summary
Although GACD and EDCTP2 align in their interests in improving research collaboration and building capacity in LMICs, because GACD is specifically focused on NCDs, there is no tangible overlap between the programmes.

4. Collaboration Opportunities
1. As EDCTP2 focuses on clinical trial development and capacity building in sub-Saharan Africa, and the incidence of NCDs is increasing there, GACD may be interested in EDCTP2 exploring joint programmes where NCDs and infectious diseases are jointly managed.
2. GACD established a Hypertension Research Programme (HT01) combining HIV/AIDS treatment infrastructures in Africa with care for chronic hypertension. EDCTP2 could offer similar clinical trial partnerships to jointly address NCDs (through GACD) and infectious diseases. In such a partnership, EDCTP2 and GACD member organizations could jointly fund.
3. Modeled after GACD’s joint funding proposals, EDCTP2 could issue joint calls with public funding institutions through (or independent of) GACD.

98 http://www.gacd.org/research/current-research-programmes/hypertension_programme/HT01/
EU’s Chemical, Biological, Radiological and Nuclear Risk Mitigation Centers of Excellence initiative

1. Programme Summary
   - The European Union (EU) Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence (CBRN CoE) Initiative is an EU programme launched in 2010.
   - The initiative was developed in response to the need to strengthen the institutional capacity of countries outside the EU to mitigate risks related to CBRN material and agents, including pandemics such as swine flu and epidemics such as Ebola.
   - The CBRN CoE Initiative seeks to boost cooperation at the national, regional and international levels, and develop a common and coherent CBRN risk mitigation policy. The initiative currently covers 54 partner countries across eight CoE regions.
   - The main objective of the EU CBRN CoE Initiative is to facilitate regional cooperation in order to enhance CBRN capabilities. To address the lack of coordination and preparedness related to CBRN risks, the EU has set up a framework for cooperation and coordination among all levels of government and international partners to promote a coherent interagency approach.

   Principles of the EU CBRN Risk Mitigation CoE Initiative with relevance to EDCTP2 include:
   - Networking, regional and international partnerships, consolidating, coordinating and optimizing existing capabilities in terms of expertise, training, technical assistance or equipment.
   - Addressing regional CBRN needs through specific tailored projects in fields of concern such as: bio-safety/bio-security, first response and public health impact mitigation.
   - Strengthening a regional culture of safety and security by increasing local ownership, local expertise and long-term sustainability.
   - Institutional capacity building at regional and national levels; reinforcing national CBRN policy, improving of institutional capacities in legal, regulatory and scientific/technical support.
   - Enhancing cooperation with international organizations and EU member states to ensure synergy and avoid duplication of efforts.

Governance of the EU CBRN CoE:
   - The EU CBRN CoE Initiative is implemented jointly by the United Nations Interregional Crime and Justice Research Institute (UNICRI) and the European Commission's Joint Research Centre (JRC).
   - Overall coordination of the EU CBRN CoE is carried out by UNICRI and JRC in close cooperation with the European Commission's Directorate General for Development and Cooperation - EuropeAid (DG DEVCO) acting as the Initiative’s Decision Making Body, and the European External Action Service (EEAS).

2. Relevant Programmes/Policies & Synergies with EDCTP2
a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with EU CBRN CoE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>No synergies identified</td>
</tr>
<tr>
<td>SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>The EU CBRN CoE broadly contributes to strengthening cooperation with partner countries in sub-Saharan Africa by forming regional and international partnerships, increasing local ownership and improving scientific/technical support</td>
</tr>
<tr>
<td>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>No direct alignment. However there are synergies with the EDCTP2 objective since a principle of EU CBRN CoE is better coordination and cooperation with international organizations and EU member states.</td>
</tr>
<tr>
<td>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments</td>
<td>EU CBRN CoE sharing knowledge on managing bio-risks and providing education and laboratory training to healthcare workers in response to an infectious disease emergency. Diagnostics for disease surveillance and monitoring appears to be an area of common interest. Synergies with EDCTP2 include the EU CBRN CoE aim of networking, forming regional and international partnerships and coordinating and optimizing existing capabilities in terms of expertise, training, technical assistance and equipment.</td>
</tr>
<tr>
<td>SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</td>
<td>The EU CBRN CoE complements EDCTP2 by promoting a coherent interagency approach to enhance coordination and effective response, including development aid. Development aid is integrated into the EU CBRN CoE’s governance, with the European development aid DG DEVCO and EEAS acting as the EU CBRN CoE’s decision making body.</td>
</tr>
</tbody>
</table>
b. Overlapping organizations

- EDCTP2 and the EU CBRN CoE both fund the Laboratory of Clinical Microbiology, Virology and Bioemergencies (CLIMVIB) which conducts biosafety training in laboratory and healthcare settings globally (more details re programme description below – does this programme achieve EDCTP2 objectives re clinical trial capacity building?)
- CLIMVIB builds institutional capacity to mitigate infectious disease emergencies and is currently implementing an EDCTP2 programme in Uganda to train healthcare professionals to respond to infectious disease outbreaks and an international bio-safety risk management programme funded by EU CBRN CoE.
- Both EDCTP2 and the EU CBRN CoE work with the World Health Organization in cooperation with international and regional partners.

3. Comparison Summary

- EDCTP2 and EU CBRN CoE have complementary activities and synergies that could lead to potential partnerships and greater coordination in response to infectious disease outbreaks.
- While EDCTP2 supports broad research efforts to develop new and improved diagnostics and medicines for poverty-related diseases affecting Sub-Saharan Africa, the EU CBRN CoE is strategically focused on bio-security and containing the spread of infectious agents.
- Greater coordination between these two initiatives could lead to a more comprehensive and integrated response to global public health emergencies and building a larger network of regional and international partners.

4. Collaboration Opportunities

1. Opportunities for EDCTP2 and the EU CBRN CoE to collaborate on a training programme for healthcare and laboratory workers in response to an infectious disease emergency. Response should incorporate use of EDCTP2 diagnostics or products in development – phase IV testing or other testing.
2. EDCTP2 and the EU CBRN CoE could both contribute capabilities and resources to a larger partnership across countries aimed at developing a coordinated response to infectious disease threats and strengthening institutional capacity and disease surveillance in Sub-Saharan Africa.

5. CLIMVIB – programme description – 2 year programme in Uganda

OBJECTIVES
The purpose of this project is to build and strengthen individual and institutional preparedness to respond to infectious disease outbreaks resulting in health emergency at the regional and district level in Northern Uganda Region.

ACTIVITIES
To attain the specific objective, the project will assess existing capacities and training needs in order to develop a need-based and tailored training model to train healthcare professionals.

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99 http://www.climvib.eu/category/european-commission/

100 http://www.climvib.eu/endorse-edctp-csa-ebola-337/

(laboratory and other health care personnel such as physicians and nurses) from district level hospitals in the target region. In particular, the project will design and develop a Train-the-Trainer (TtT) training programme to train at least two professionals (one from the laboratories and one from the infectious diseases unit) per identified hospital. These two professionals will be trained not only to enhance their capacities and skills in responding to infectious diseases outbreaks, but also to build or enhance their capacities and skills to further transfer their knowledge in their workplace. In summary, they will be trained to become trainers during the following phase of the project. Training will be evaluated to assess the results and qualify the participants to become trainers. At a later stage, qualified trainers will be supported by the project to deliver training courses in their organization to at least 10 trainees per identified hospital. Training results will be evaluated to assess the overall impact of the educational activities implemented within the framework of the project. Finally, dissemination of the results produced within the framework of the project to a wide audience in order to ensure sustainability, will be ensured at both the local level in the districts of the region and at national level thanks to the final national conference.
The Global Fund to Fight AIDS, Tuberculosis and Malaria

1. Programme Summary

The Global Fund, based in Geneva, Switzerland, is a 21st-century partnership organization between governments, civil society, the private sector, and people affected by the diseases, designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. The Global Fund provides funding and does not implement programmes on the ground but relies on organizations known as Principal Recipients to implement the grants. Principal Recipients can be any type of organization, from government ministry to community-based organization to private sector entity.

From 2002 to 2016, a total of 56 donor governments pledged USD 42 billion to the Global Fund. Top twenty donors included 11 European Union member states, plus Norway and Switzerland, which amounted to more than 47% of the total contributions.

Investments by the Global Fund partnership have saved over 20 million lives and supported expansion of antiretroviral therapy (to 9.2 million people), treatment of TB patients (to 15.1 million people), and distribution of insecticide-treated nets (659 million nets) resulting in aver­sion of 146 million infections between 2012 and 2015.

The Global Fund works with governments to stimulate domestic investments in health by implementing a counterpart financing requirement. Counterpart financing is defined as all domestic public resources allocated to directly supporting the programmes funded by the Global Fund. These resources can include government revenues, government loans from external sources or private creditors, social health insurance, and/or debt relief from the implementing countries.

In April 2016, the Board of the Global Fund unanimously approved the organization’s strategy for the period of 2017 to 2022, titled Investing to End Epidemics. The core objectives of the Global Fund 2017-2022 Strategy are to:

1. Maximize Impact against HIV, TB and Malaria: Innovative approaches to meet diverse country needs are essential to accelerate the end of the epidemics
2. Build Resilient and Sustainable Systems for Health: Strengthening systems for health is critical to attain universal health coverage and to accelerate the end of the epidemics
3. Promote and Protect Human Rights and Gender Equality: Promoting and protecting human rights and gender equality is required to accelerate the end of the three epidemics
4. Mobilize Increased Resources: Increased programmatic and financial resources from diverse sources are needed to accelerate the end of the epidemics

102 http://www.theglobalfund.org/en/overview
103 http://www.theglobalfund.org/en/implementers
104 http://www.theglobalfund.org/en/government
105 http://www.theglobalfund.org/en/impact
107 http://www.theglobalfund.org/en/strategy
2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective or Program</th>
<th>Alignment with The Global Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO1: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>Aligns with the Global Fund’s objective to <em>Maximize Impact against HIV, TB and Malaria</em> by, among other approaches, scaling up evidence-based interventions. Phase IV clinical trials could link with EDCTP and scale up.</td>
</tr>
<tr>
<td>SO2: Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</td>
<td>Aligns with the Global Fund’s objective to <em>Build Resilient and Sustainable Systems for Health</em> since both organizations aim to build health-related capacity in sub-Saharan Africa</td>
</tr>
<tr>
<td>SO3: Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments</td>
<td>EDCTP2 can leverage GF to scale use of products developed and consider phase IV or other monitoring of uptake and impact. GF can prepare to support new EDCTP products.</td>
</tr>
<tr>
<td>SO4: Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and to achieve leveraging of resources and investments</td>
<td>Aligns with the Global Fund’s objective to <em>Mobilize Increased Resources</em> since both organizations rely on international partners to financially support their activities.</td>
</tr>
<tr>
<td>SO5: Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance</td>
<td>Aligns with the Global Fund’s objective to <em>Mobilize Increased Resources</em> since both organizations have common partners among European Union member states and focus on establishing international public-private partnerships</td>
</tr>
<tr>
<td>EDCTP funded the PREGACT trial to study the safety and efficacy of four artemisinin-based combination treatments in African pregnant women with malaria[^108]</td>
<td>Aligns with the Global Fund’s objective to <em>Promote and Protect Human Rights and Gender Equality</em> as, among other focus areas, both organizations aim to improve wellbeing in women with, or at risk for contracting, HIV/AIDS, tuberculosis and malaria</td>
</tr>
</tbody>
</table>

b. Overlapping organizations
   • European countries: Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, UK
   • Private industry partners

3. Comparison Summary
EDCTP2 and the Global Fund have coherence with respect to disease and geographic focus, emphasis on international partnerships, and objective to build capacity in countries burdened with HIV/AIDS, tuberculosis and malaria.

4. Collaboration Opportunities
1. EDCTP2 could partner with the Global Fund to leverage its network of implementing partners to ensure the impact of research is maximized and that synergies can be taken into consideration and to achieve leveraging of resources and investments 109
2. EDCTP2 could partner with the Global Fund to establish Networks of Excellence
3. EDCTP2 and the Global Fund could co-fund grants for phase IV clinical trials of new EDCTP interventions

Gavi
1. Programme Summary
Founded in 2000, Gavi is a public-private partnership committed to increasing access to new and underused vaccines for children living in the world’s poorest communities. Gavi brings together developing country and donor governments, the World Health Organization (WHO), UNICEF, the World Bank, the vaccine industry in both industrialized and developing countries, research and technical agencies, civil society, the Bill & Melinda Gates Foundation, and other private philanthropists.110

Gavi currently helps countries introduce 11 life-saving vaccines.111 Two vaccines – oral cholera and rotavirus – are relevant to EDCTP2’s focus area of poverty-related disease.

Funding streams:112
   • 75% Direct contributions (Grants, government and private donations)
   • 25% Innovative Financing (International Finance Facility for Immunization, and the Advance Market Commitment)

Fifty-four countries will be eligible to apply for Gavi support in 2016, based on a Gross National Income per capita below or equal to US $1,580 on average over the past three years. There are 11 EDCTP2-relevant sub-Saharan African countries eligible for Gavi support: Burkina Faso, Cameroon, Congo (DRC), Ghana, Mali, Mozambique, Niger, Senegal, Tanzania, Uganda, and Zambia.113

110 http://www.gavi.org/
111 http://www.gavi.org/support/nvs/
112 http://www.gavi.org/funding/how-gavi-is-funded/
113 http://www.gavi.org/support/apply/countries-eligible-for-support/
Types of Gavi support:  
- New and underused vaccine support (NVS)
- Immunization services support (ISS)
- Health systems strengthening support (Areas include: health service delivery, health workers, logistics and supply systems, health financing, health information and monitoring, leadership and governance)

Unique to the Gavi business model:  
- During the application process, governments define their funding needs and determine their own priorities/activities before requesting support
- Co-financing model requires recipient countries to contribute towards the cost of the vaccines, ensuring commitment and long-term sustainability. Co-payments eventually increase to cover the full cost of vaccines.
- Applications must be signed by both Ministries of Health and Finance, and applicants must develop a comprehensive multi-year plan which integrates vaccine financing into the wider national budget and national health plan
- Gavi funds are channeled through existing government systems
- Governments report back on performance through annual progress report

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114 http://www.gavi.org/support/apply/
116 http://www.gavi.org/about/gavis-business-model/country-commitment-to-co-financing/
Gavi 2016-2020 Strategy

1. The Vaccine Goal: Accelerate equitable uptake and coverage of vaccines.

2. The Systems Goal: Increase effectiveness and efficiency of immunization delivery as an integrated part of strengthened health systems
   - Support improvements in supply chains, health information systems, demand generation and gender-sensitive approaches
   - Strengthen engagement of civil society, private sector, and other partners in immunization

3. The Sustainability Goal: Improve sustainability of national immunization programmes
   - Enhance national and sub-national political commitment to immunization
   - Ensure appropriate allocation and management of national human and financial resources to immunization through legislative and budgetary means

4. The Market Shaping Goal: Shape markets for vaccines and other immunization products
   - Ensure adequate and secure supply of quality vaccines
   - Reduce prices of vaccines and other immunization products to an appropriate and sustainable level
   - Incentivize development of suitable and quality vaccines and other immunization products

2. Relevant Programmes/Policies & Synergies with EDCTP2
   a. Synergies with EDCTP2

<table>
<thead>
<tr>
<th>EDCTP2 Strategic Objective</th>
<th>Alignment with Gavi</th>
</tr>
</thead>
<tbody>
<tr>
<td>S01: Increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria, and other poverty-related diseases (PRDs), including neglected ones</td>
<td>EDCTP2’s interest in improving diarrhea-related mortality: While Gavi does not fund clinical trials, they fund the introduction and wide-scale use of rotavirus and cholera vaccines in sub-Saharan Africa and elsewhere. EDCTP’s clinical trial focus could support phase III and IV clinical trials in line with Gavi vaccine programmes or disease focus. EDCTP epidemiology and clinical trial capacity building could link with Gavi activities in common countries in sub-Saharan Africa. EDCTP2’s interest in improving prevention of emerging infectious diseases such as Ebola: Gavi has advance purchased Merck’s rVSVΔG-ZEBOV-GP live attenuated Ebola Zaire vaccine, on the understanding that it will be submitted for licensure by the end of 2021.</td>
</tr>
</tbody>
</table>

117 http://www.gavi.org/about/strategy/phase-iv-2016-20/
<table>
<thead>
<tr>
<th><strong>SO2</strong></th>
<th>Strengthen cooperation with sub-Saharan African countries, in particular in building their capacity for conducting innovative research for clinical interventions in compliance with fundamental ethical principles and relevant national, EU and international legislation</th>
</tr>
</thead>
</table>
| 2017. | Gavi strengthens cooperation with sub-Saharan African countries in the following ways:  
- Countries are required to choose which support to apply for and when  
- Countries must demonstrate how their proposals are integrated into their long-term health plans  
- The Interagency Coordination Committee (ICC) brings together WHO to work with health ministries to ensure that applications are based on evidence-based decisions and results are monitored, and UNICEF to help applicants ensure the right vaccines reach the right people.  
Gavi’s health systems strengthening support provides:  
- Service delivery, focusing on infrastructure investments and vehicles  
- Procurement and supply chain management  
- Human resources, emphasizing training and supervision for community health workers and health professionals |
| **SO3** | Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments |
|  | Current Gavi investments from European countries are not integrated, aligned, or coordinated. There is an opportunity for EDCTP2 and Gavi to explore coordination around national programmes and synergies. |
| **SO4** | Extend international cooperation with other public and private partners to ensure that the impact of all research is maximized and that synergies can be taken into consideration and achieve leveraging of resources and investments |
|  | Gavi maximizes its public and private partners’ expertise and existing networks and facilitates collaborations to find new solutions. Gavi relies heavily on country-based systems and partners to deliver its programmes and keep burdensome transaction costs down for governments. Opportunity for Gavi and EDCTP to align cooperation. |
| **SO5** | Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance |
|  | Aligns with Gavi’s objective to mobilize increased resources since both organizations have common partners in the EU and focus on establishing international public-private partnerships |

b. Overlapping organizations  
- European countries: Denmark, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Spain, Sweden, UK  
- Industry and commercial: GlaxoSmithKline, Sanofi Pasteur
3. Comparison Summary
   - EDCTP2 and Gavi partner with many of the same organizations and have common interests in sub-Saharan Africa and certain poverty-related diseases.
   - EDCTP2 aims to strengthen clinical trials capacity, while Gavi's capacity building support currently emphasizes health service delivery, health systems infrastructure, procurement and supply chain management, and health worker training – there are opportunities to align these efforts and leverage each organization's activities.

4. Collaboration Opportunities
   1. Gavi's investments in infrastructure and health worker training are not focused on improving clinical trial capacity, yet this work has the potential to indirectly enable clinical trials by developing the facilities and intellectual capacity to conduct such trials. Skills can be applied to both EDCTP and Gavi programmes.
   2. Gavi's involvement with developing country governments allows governments to see the value of vaccinations and co-finance the support they receive. Gavi has strong connections with the ministries of health and governments of the developing countries they work in. There is potential for the EDCTP2 to collaborate with Gavi to leverage these partnerships to better strengthen cooperation with sub-Saharan African governments.
The Decision 556/2014 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 stipulates that the European Commission has to carry out, with the assistance of independent experts, an interim evaluation of the EDCTP2 programme by 30 June 2017.

Its main objective is to assess the performance of the EDCTP2 and its progress towards the objectives set out in the Decision No 556/2014. The current interim evaluation of the operation of the EDCTP2 covers the period from June 2014 to 31 December 2016.

This evaluation was carried out by a Commission Expert Group registered in the EC Register of Expert Groups under number E03440, from October 2016 to June 2017.