# **FINAL REPORT**

AN INDEPENDENT EVALUATION OF SIDA'S SUPPORT TO PROJECTS IN THE SCOPE OF THE EDCTP2 PROGRAMME

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This report outlines the findings of the 'independent evaluation of Sida's support to projects in the scope of the EDCTP2 programme' (Sida Support Evaluation, SSE). The main purpose of the SSE was to perform an independent assessment of Sida-supported projects within the scope of the EDCTP2 programme. Specifically, the SSE team were requested to:

- Assess the status of project implementation to date of Sida-funded projects, including project management, and the likelihood of successful completion
- Assess the results of Sida-funded projects so far (including at outcome and impact levels, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy, particularly in relation to the research and research capacity building needs of low-income countries in Africa
- Assess the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP

As of 31 December 2018, Sida contributed EUR 10,946,433 to support projects within the scope of the EDCTP2 Programme. This, as of September 2019, comprises EUR 7,946,433 in both commitments and disbursements to the ongoing/completed projects as well as EUR 3,000,000 for the prospective projects; selected proposals and ongoing calls for proposals with Sida's funding commitments.

Based on an initial review of documents received from EDCTP and consultation with EDCTP, the SSE team developed an in-depth evaluation matrix (Annex 3) which can be summarised by three objectives and a series of sub-evaluation questions as follows:

<b>Objective 1:</b> Assess the status of project implementation to date of Sida funded projects, <sup>1</sup> including project management, and the likelihood of successful completion	<ul><li>1.1 Has actual investment matched planned investment?</li><li>1.2 Is implementation of projects and EDCTP's activities with Sida funding on track?</li><li>1.3 Are projects and activities by EDCTP funded by Sida being adequately project managed?</li></ul>
<b>Objective 2:</b> Assess the results of Sida funded projects so far (including at outcome and impact level, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy and Sida's objectives in providing funding to EDCTP, particularly in relation to the research and research capacity building needs of low-income countries in Africa.	<ul> <li>2.1 What are the identified outputs, outcomes and impacts of investments?</li> <li>2.2 How well do Sida supported projects align against EDCTP strategy objectives?</li> <li>2.3 How well does EDCTP and its funded projects utilize Sida funding to meet the needs of Sida's research cooperation priority areas?</li> </ul>
<b>Objective 3:</b> Assess the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP.	3.1 How has Sida support contributed to women's active engagement with research?

The SSE team sought to answer these questions looking at the EDCTP 2 period from January 2016 (start date of first EDCTP 2 award that received Sida funding) and September 2019. It did so through a review of various EDCTP funded research project and EDCTP programme documents (including grant agreements, progress reports, Scientific Advisory Committee (SAC) meetings, budgets, risk matrices etc.) as well as a series of interviews (30 in total) of

<sup>&</sup>lt;sup>1</sup> We use the term 'Sida funded projects' in this report but note that EDCTP is the actual funder or grantor of funds to projects. We also note that many of the projects – especially RIA projects – receive only very small amounts of money that come from the Sida funds allocated to EDCTP2 i.e. that many projects receive funding from EDCTP which comes from multiple donors/ principal funding sources.

EDCTP staff, grant holders (predominately the principal investigators) and various related stakeholders. This data collection and analysis took place over a four month period between July and October 2019.

#### MAIN FINDINGS

Overall we find that EDCTP2 programme has utilised Sida funds to support well-functioning research projects and other activities that fit within the EDCTP and Sida objectives. Specifically:

- 1. 48% of research related projects receiving Sida funds are headed by a female Principal Investigator (PI) (28 out of 58)
- 2. 71% of research related projects receiving Sida funds are coordinated from a low or low-middle income country (41 out of 58)
- 3. 33% of research related projects receiving Sida funding are coordinated by a female PI based in a low or low-middle income country
- 4. Project management systems at EDCTP are functioning well and the flexibility of Sida funding allows EDCTP to utilise the funding provided to ensure project activities continue where other funding short-falls occur.
- 5. EDCTP is learning as it goes along and is making improvements to its project management, contracting and grants management activities as it learns for example, enhancing the wording on impact criteria in grant calls and ensuring finance training is available for a wider range of stakeholders and not just principal investigators and/or their finance managers.
- 6. All projects that are receiving project funding through EDCTP2 are on course to complete and to achieve their milestones and deliverables.

A brief overview of the findings by SSE objective will now be given followed by an overview of the recommendations resulting from these. The recommendations are listed in order of urgency for implementation.

OBJECTIVE 1: ASSESS THE STATUS OF PROJECT IMPLEMENTATION TO DATE OF SIDA FUNDED PROJECTS, INCLUDING PROJECT MANAGEMENT, AND THE LIKELIHOOD OF SUCCESSFUL COMPLETION

## **1.1** Has actual investment matched planned investment?

For the most part, there is a good fit between the projects that have received Sida funding and EDCTP objectives and Sida's Research Cooperation Strategic Results areas.

The majority of projects that have received funding from Sida are focused on research in the three original 'neglected diseases' of HIV, tuberculosis and malaria. The majority of the studies focus on adults although around a third focus on children and young people.

The majority of Sida support has gone to research and innovation projects (RIA projects), the largest area of EDCTP investment. But this is also where there are least numbers of female and low income country (LIC) Principal Investigators (PIs). This is linked to a larger issue of capacity of institutions and numbers of female researchers in Africa more generally.

It was also widely acknowledged that Sida funding has a level of flexibility attached to it (in the way EDCTP can utilise it) that enables EDCTP to be able, in the short term, to meet gaps in funding shortfalls utilising this funding. This was very welcomed by people who we spoke to and is viewed as an important contribution by EDCTP to the Global Health landscape. This level of flexibility outweighs the fact that according to interviewees most of the money from Sida to grant projects goes to DAC-OECD designated upper middle income country (UMIC) and high income country (HIC) researchers. Many interviewees stressed the consortium nature of the projects involved and the importance of seeing the funding given not just in terms of where (geographical location) it was given but how the project as a whole functioned and the outcomes that the project activities as a whole had.

There is less obvious fit perhaps with Sida's Research Cooperation Strategic Results area relating to research that contributes directly to poverty reduction and sustainable development. This is because of a lack of focus explicitly in many projects on a theory of change that moves to broad impact at societal level. It should be noted that there

is a great deal of debate within EDCTP and its stakeholders as to how best it should refocus on broader goals of poverty reduction and sustainability. Questions include: what should be the level of emphasis on research as opposed to translation or health systems strengthening activities. The evaluation team also raise the question of the degree to which achieving broader goals is an issue for EDCTP or it is an issue that researchers themselves should be grappling with?

Firm answers to these questions lie beyond the scope of this evaluation. However, the evaluation team suggests that EDCTP engages proactively with the differing perspectives put forward by stakeholders and works to develop clearer articulation of strategic intent. In particular there is a need to bridge a gap between EDCTP objectives and the overarching vision to "reduce the individual, social and economic burden of poverty-related infectious disease affecting sub-Saharan Africa". Addressing this gap may involve extra resources and collection of data related to project outcomes and impact.

The major barriers to successful planned investment that have been identified by the SSE team relate to EDCTP delays in approvals and the knock-on effect this has to final execution of projects due to the currency fluctuations and devaluation of currencies that have occurred in the intervening period. Another issue relates to what might be termed 'over-optimistic' project proposals. A number of interviewees and progress reports reviewed noted that projects often suffered delays and/or were unable to complete activities due to over ambitious plans in terms of outputs and outcomes at project proposal stage. Due to the nature of the reporting process (that heavily focuses on milestones and deliverables), sometimes this over optimism negatively impacts the view of progress of a project. This has implications on the way projects are planned, proposals are written and the length of time projects are funded for (as many of the outcomes and impacts take significant time to achieve).

That said, the flexibility given to PIs in terms of the overheads available and how they can spend their budgets has proven to be a significant enabler. Another significant enabler has been experience of previous engagement/ existing relationships with project team members and/or other stakeholders, including Sida and Sarec funding.

# 1.2 Is implementation of projects and EDCTP's activities with Sida funding on track?

We can see little cause for concern with respect to projects that have received Sida funding. Two that were supposed to have completed are still on-going with a no-cost extension or on-hold (due to country instability) but for the most part (where issues are within the control of project actors) projects are running on track and any delays that have been incurred appear to be being managed effectively and are not adversely effecting project timelines. In addition, the other activities funded using Sida money – the Ninth EDCTP Forum and the Open Platform – proceeded/ are proceeding well from the documentation that we reviewed.

On the basis of the above the milestones and deliverables within project control have, for the most part across all projects, been achieved as scheduled. Any delays mentioned in progress reports and during interviews have reasonable mitigation measures allied to them. However, the SSE team have picked up the existence of disconnect between the focus on milestones and deliverables in the project proposal and reporting templates and the introduction (in 2019) by EDCTP of a broader focus on outcomes and impact. This move fits well with Sida's approach to monitoring and evaluation (M&E) of its research cooperation support as outlined in their M&E guidelines.

The SSE made a very high level overview of project proposals and progress reports to understand the degree to which outcomes and impacts – as defined by this evaluation (and in line with EDCTP's and Sida's definitions that are based on DAC-OECD definitions) – are being considered by projects funded with Sida funding. We found very few included logical frameworks or similar approaches to considering broader understandings of societal impact. We found that there was a lack of clarity as to the degree to which this was necessary, especially in research and innovation activity (RIA) based projects. The advantages might be more clarity in reporting and assessment but the downside maybe additional burdens on grantees. The pros and cons and alternative ways forward will need to be considered by EDCTP as it clarifies and aligns the relationships between its current projects and the overall strategy and mandate.

# 1.3 Are projects and activities by EDCTP funded by Sida being adequately project managed?

Project management systems at EDCTP and within projects are in place and appear to be functioning well. All project proposals reviewed and interviews conducted with Pls, whose projects have received Sida funding, indicated project level management systems were in place including various combinations of senior management team meetings (or equivalent) and team reporting mechanisms; often tailor designed to the project itself.

However, project PIs noted that often they suffered from lack of capacity or systems within their institutions which led to delays in disbursement or sign off of reports. This was often compounded by a lack of institutional 'buy-in' from senior management in their organisations. As already noted currency fluctuations was an issue and some projects – as recommended by EDCTP – were opening/ had opened Euro bank accounts to try and reduce the risks associated with money transfers.

On the side of EDCTP, the only potential area of concern relates to the limits on reporting by projects to once a year. This means that for some of the projects we investigated we were relying on data that was 10-12 months old. This risk has already been noted by the financial audit committee at EDCTP. On the flip side however, EDCTP appears to have listened to PIs and project team members and are now widening financial management training options that are available; as many African partners found financial (and technical) reporting cumbersome and unfamiliar.

OBJECTIVE 2: ASSESS THE RESULTS OF SIDA FUNDED PROJECTS SO FAR (INCLUDING AT OUTCOME AND IMPACT LEVEL, IF APPLICABLE) AND THE EXTENT TO WHICH THESE CONTRIBUTE TO PROGRESS AGAINST EDCTP'S OVERALL STRATEGY AND SIDA'S OBJECTIVES IN PROVIDING FUNDING TO EDCTP, PARTICULARLY IN RELATION TO THE RESEARCH AND RESEARCH CAPACITY BUILDING NEEDS OF LOW-INCOME COUNTRIES IN AFRICA.

## 2.1 What are the identified outputs, outcomes and impacts of investments?

All research and innovation activity (RIA), capacity support activity (CSA) and training and mentoring activity (TMA) projects that have received Sida funding are on course to complete their deliverables and milestones and/or have mitigation strategies in place for instances where there are delays. Only one project has completed and many are only in year 2 (sometimes of a 4-5 year project) and therefore there is a limited outputs (even in terms of publications) at this point.

The other two activities that have received Sida funding have completed in the case of the Ninth Forum and produced a BMJ special issue while the Open Platform is currently partly up and running (advice on how to write a clinical trial and various resources are available on the site).

As noted above, the degree to which projects are focused on outcomes and impacts differ as there is little consensus as to the definitions. Broadly RIA projects are more focused often on a range of clinical outcomes while TMA and CSA projects are often more focused on a set of policy and societal outcomes. However, the link to poverty reduction and sustainable development often is not clear. EDCTP are aware of the need to be more specific about what they mean by outcomes and impacts and have developed a theory of change/ results framework (first developed in 2017 and a working/ living document i.e. regularly revised). There is also more specific guidance in project calls since 2019 on the need to address impact.

That being said, when the EDCTP results framework is considered against the EDCTP objectives and those of Sida's Research Cooperation Strategic Results areas, the focus of EDCTP's activities are more squarely in the tangible outcomes part of the diagram and less in the impacts side (where many of Sida's Research Cooperation Strategic Results areas focus). This appears partly to be about the way wording of objectives and results areas have been developed.

# 2.2 How well do Sida supported projects align against EDCTP strategy objectives?

Given the above, it is not surprising that the 11 RIA projects that received Sida funding fit well with EDCTP's Objective 1 (increase the number of new or improved medical interventions for poverty-related diseases, PRDs). At least 8 of these are progressing clinical trial studies of one kind or another.

Sida's funding has increased cooperation across all projects that involve multiple partners – by the very nature of the consortium type projects that are funded by EDCTP. This includes networks around ethics but also more southsouth networks. There is a strong emphasis within the CSA on building up research guidelines and in some of the RIAs and TMAs there is also evidence of influencing guidelines; especially at institutional level. CSAs are also heavily focused on building expertise in ethics especially around African based networks (either at national or sub-regional levels). Thus, there is also alignment with EDCTP's Objective 2 (strengthen cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, EU and international legislation). The degree to which Sida funding has impacted on increased coordination and integration of national programmes to increase cost-effectiveness of European investments (EDCTP Objective 3) appears anecdotally to have taken place but no significant finding was found here. There is a strong focus on capacity building through PhD and Masters training across all of the projects Sida has funded. The EDCTP report to Sida for 2018 notes 108 students have benefited to date through TMA projects; although PhDs and Masters feature also in RIA and CSA projects. An analysis of where students are enrolled show that the majority of those through RIA projects are enrolled at European or US universities while in TMA and CSA projects there is more emphasis on African universities for training. The reason given for the need to use Northern universities was the lack of training available in African universities. One or two of the TMA and CSA projects appear to be attempting to change this with the development of new Masters Programmes in African universities. In addition, other (often short term, ad hoc) courses are also being developed through these projects. The sustainability over the long term of some of these courses isn't clear i.e. post EDCTP funding.

PIs interviewed, and a review of materials received, mention different 'mechanisms' of research capacity building. These include research degrees for individuals (MSc, PhD) as already discussed but also and importantly:

- Strengthening institutions to run clinical studies
- Promoting intellectual/scientific leadership
- Other activities around building stronger policy environments

There is some evidence of increased cooperation between European partners (EDCTP Objective 5), some focus on private sector partnerships through a couple of the projects (EDCTP Objective 4). However this is essentially out of the scope of this evaluation because Sida funding has not been used to cover these activities (beyond the ninth EDCTP Forum).

# 2.3 How well does EDCTP and its funded projects utilize Sida funding to meet the needs of Sida's research cooperation priority areas?

There is a good fit with Sida's first Research Cooperation Strategic Results area (capacity building for research, primarily in LICs and regions). 16 LICs have received Sida funding through EDCTP projects while almost 50% of Sida's funding of RIA, TMA and CSA projects goes to LICs (37% - see EQ 3.1.1) and low-middle income countries (LMIC).

With regards to Sida's Research Cooperation Strategic Results area 2 (global, regional and national research of relevance to low-income countries and regions), Sida funded projects are addressing EDCTP's relevant strategic research priority areas which are reviewed annually based on scientific advice.

A very basic review of a couple of LICs (Burkina Faso and Ethiopia) that have received Sida funding through EDCTP programmes shows that the areas the research projects funded focus on do not always match with the results of the burden of disease statistics for those countries. It is unclear how strategic decisions on what priority areas will be chosen each year by EDCTP are made; the methodology of the Research Priority Areas isn't given in the report each year. However, there are obviously strategic decisions as to what to fund that relate to building up systems (e.g. in terms of ethics and research guidelines) as opposed to focusing on disease areas, and, finding the right mix with regards to meeting global and national needs. This will mean that in some cases the funding does not always match data relating to where the largest burden of disease at national level is found.

A number of Swedish partners, including a biotechnology firm, are involved in projects that have received Sida funding which means projects funded are working towards Sida's Research Cooperation Strategic Results area 4 (Swedish research of relevance to poverty reduction and sustainable development in low income countries).

There is a less obvious fit with Sida's Research Cooperation Results area 3 (promotion of research that, through innovation, can contribute to poverty reduction and sustainable development). This is related to disconnect at present between EDCTP's mission, objectives and focus of funded projects on more upstream stages of the medical intervention 'development-testing-commercialisation-delivery' pipeline. Clarification is needed and greater clarity requires further consultation between EDCTP and its stakeholders.

OBJECTIVE 3: ASSESS THE EXTENT TO WHICH SIDA'S CONTRIBUTION HAS SO FAR CONTRIBUTED TO AN IMPROVED GENDER BALANCE IN THE AREAS OF RESEARCH SUPPORTED BY EDCTP

## 3.1 How has Sida support contributed to women's active engagement with research?

The gender balance across projects that have received Sida funding overall is very good. Across different capacity building programmes, the balance has an average of 43% of project staff being female.

We have no data as to whether Sida support has enhanced the careers of female researchers and/or research support staff. Unfortunately, the interviews and data reviewed have been unable to sufficiently provide information on this.

EDCTP are making efforts to address gender issues. This has become more visible in 2018 and 2019 with reviews being commissioned on the make-up of evaluation panels/ the gender dimensions of proposal review processes together with an evaluation of the barriers to female researchers in Africa being commissioned. The Scientific Advisory Committee (SAC) also now has a gender working group.

We have not been able to investigate the degree of training given to researchers on gender equality and/or how to design research taking into account gender equality issues. However, at least one project is highly gender aware (PANDORA) and includes gender issues in its research design and evaluation.

### MAIN RECOMMENDATIONS

Recommendations are listed in order of priority by Objective; starting with those of immediate urgency, those that are of short term priority and those that should be considered.

OBJECTIVE 1: ASSESS THE STATUS OF PROJECT IMPLEMENTATION TO DATE OF SIDA FUNDED PROJECTS, INCLUDING PROJECT MANAGEMENT, AND THE LIKELIHOOD OF SUCCESSFUL COMPLETION

## **IMMEDIATE PRIORITY**

**Recommendation:** In order to address delays to project start up times, EDCTP could build in time for collaboration building and knowledge and skills transfer for new partners. This measure should be designed to enhance project management capabilities within research partnerships. Specifically, start up funding, one year prior to the official start of projects, should be considered. This will allow time to build up relationships and establish systems crucial to successful project management.

**Recommendation:** To reduce administrative burdens associated with projects, funds should be disbursed where possible direct into specific Project Accounts rather than into general accounts of government departments or host institutions. In addition, to mitigate against financial risk associated with project funding, EDCTP should strongly encourage where possible project specific bank accounts in Euro. Although EDCTP has existing guidelines, our interviewees indicated that more encouragement and advice might be needed. It seems likely that this would reduce the bureaucracy associated with draw down of funds and would increase project related efficiencies.

**Recommendation:** To improve the planning and evaluation processes, the proposal template and progress reports should be redesigned to encourage increased and broad reflection on external risks and how to mitigate them. These templates should be adjusted to the type of project as RIA versus CSA projects (for example) require different issues to be considered.

**Recommendation:** To increase the quality of evaluation, monitoring and communication between EDCTP and researchers we recommend adding a formal but light touch six month review meeting/ report so that EDCTP are aware of any issues and support needs.

## SHORT TERM PRIORITY

**Recommendation:** In order to improve the quality of financial management, EDCTP should require compulsory webinar and/or face-to-face training of all project partners financial officers who will be responsible for financial reporting (and not just PIs own institution) at the start of the grant or during a funded start-up period preceding the start of the actual project. An EDCTP helpline for financial queries could also be made available for grantees

with specific financial queries. Feedback sessions with all finance and PI and Co-Is by skype could take place after each reporting period to discuss discrepancies and issues raised by technical and financial reports.

## THINGS TO CONSIDER

**Recommendation:** To increase the profile, recognition and sustainability of EDCTP activities EDCTP should consider putting more resources into engagement activities including with key stakeholders in SSA, such as policymakers, vice chancellors and health systems managers. This would assist principal investigators and allied researchers in ensuring projects function with minimal delays and with maximum buy-in from relevant stakeholders. In addition, such engagement would also help promote the (flexible) Sida approach to funding. Finally, to make sure that its funding partners are recognised and made visible, EDCTP could consider expanding it's recent developments (funding acknowledgements requirements, and generic acknowledgments) that are contractually required for new grant holders as a request to holders of grants that started earlier.

OBJECTIVE 2: ASSESS THE RESULTS OF SIDA FUNDED PROJECTS SO FAR (INCLUDING AT OUTCOME AND IMPACT LEVEL, IF APPLICABLE) AND THE EXTENT TO WHICH THESE CONTRIBUTE TO PROGRESS AGAINST EDCTP'S OVERALL STRATEGY AND SIDA'S OBJECTIVES IN PROVIDING FUNDING TO EDCTP, PARTICULARLY IN RELATION TO THE RESEARCH AND RESEARCH CAPACITY BUILDING NEEDS OF LOW-INCOME COUNTRIES IN AFRICA.

### **IMMEDIATE PRIORITY**

**Recommendation:** In order to enhance clarity around evaluation criteria, EDCTP should work to align its internal strategy, mission statements and evaluation approaches. This requires further discussion with stakeholders including Sida and other donors. EDCTP could consider how best to conduct a dialogue with partners and participating states on the extent to which its mandate and results based framework includes an emphasis on broader societal impact. There is an important issue about the extent to which responsibility for the broader mandate should lay with EDCTP and partners or directly with researchers and associated resource implications.

#### SHORT TERM PRIORITY

**Recommendation:** In relation to the implementing decisions associated with the above recommendation, EDCTP should consider revising the grant call process to ensure clear requirement for the results based framework and theories of change to be included in all proposals. The evaluation team recognises that this is potentially a recommendation with far-reaching consequences and may involve operational and cultural shifts. If a decision to deepen outcomes and impacts work is adopted significant training and support might be needed, especially for African universities and research institutes. The training and support would depend on the type of approach taken in implementing this change. For example, one option for clinical research projects is that grant proposals and reports should contain enough information that allows EDCTP to meaningfully place the clinical research within a results based framework and theory of change. For capacity building activities it would be useful if grant proposals could provide a framework or plan of how the proposed capacity building activities in a proposal contribute to a larger institutional capacity development goal/plan/policy, and outline related risks, assumptions etc.

OBJECTIVE 3: ASSESS THE EXTENT TO WHICH SIDA'S CONTRIBUTION HAS SO FAR CONTRIBUTED TO AN IMPROVED GENDER BALANCE IN THE AREAS OF RESEARCH SUPPORTED BY EDCTP

### **IMMEDIATE PRIORITY**

**Recommendation:** EDCTP should continue to support the activities of the SAC working group on gender and provide a clear indication in annual reports of the way in which working group recommendations have been considered and acted upon.

**Recommendation:** In order to enhance monitoring of gender equity impact of EDCTP funding, EDCTP should consider implementing enhanced gender-aware measures to track career progression of EDCTP funded researchers and alumni. More generally, career tracking of recipients/ trainees of EDCTP grants may assist in determining impact over a longer period of time.

#### SHORT TERM PRIORITY

**Recommendation:** EDCTP should consider measures to correct the gender imbalance between the EDCTP senior management team and EDCTP secretariat.

#### THINGS TO CONSIDER

**Recommendation:** In order to facilitate gender equity goals, EDCTP should consider providing back to work grants to help those who have taken child care related career breaks.

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## ACRONYMS

CSA	Capacity Support Activity	PI	Principal Investigator
DAC – OECD	Development Assistance Committee of the Organisation for Economic Cooperation and Development	RIA	Research and Innovation Activity
EUR	Euro (currency)	RBM	Results Based Management
EQ	Evaluation Question	SAC	Scientific Advisory Committee
HIC	High Income Country	Sida	Swedish International Development Agency
LDC	Least Developed Country	SSE	Sida Support Evaluation
LIC	Low Income Country	ТМА	Training and Mentorship Activity
LMIC	Lower-Middle Income Country	UMIC	Upper-Middle Income Country

## 1.0 INTRODUCTION

This report outlines the findings of the 'independent evaluation of Sida's support to projects in the scope of the EDCTP2 programme' (Sida Support Evaluation, SSE). As detailed in the TOR, the main purpose of the SSE was to perform an independent assessment of Sida-supported projects within the scope of the EDCTP2 programme. Specifically, the TOR requested the evaluating team to:

- Assess the status of project implementation to date of Sida-funded projects, including project management, and the likelihood of successful completion
- Assess the results of Sida-funded projects so far (including at outcome and impact levels, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy, particularly in relation to the research and research capacity building needs of low-income countries in Africa
- Assess the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP

This evaluation therefore accessed and evaluated evidence from a number of different sources towards fulfilling this purpose as outlined in the methodology section.

This report details the background to, and the objectives of, this evaluation (Section 2). It also outlines the evaluation questions that were agreed on; based on these objectives (Section 3). The methodology and research methods are outlined (Section 4), followed by the main results of the evaluation; discussed by overarching research question (Section 5).

# 2.0 BACKGROUND AND CONTEXT

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between 16 African and 14 European countries. Its mission is to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis, malaria and neglected infectious diseases including emerging and re-emerging infections affecting sub-Saharan Africa.

EDCTP came into existence in 2003 with its first phase of activities running from 2004 to 2015 (herein known as EDCTP1). The second phase of EDCTP activities (known as EDCTP2) overlapped with this first phase by a year, running from November 2014 to 2024. Its activities have been outlined in a Strategic Business Plan for the period while yearly work plans determine the scope of work year on year and annual reviews of the disease priority areas also occur.

EDCTP2 has five overarching objectives relating to increasing new medical interventions, strengthening cooperation with sub-Saharan African countries in the area of clinical trials; increasing and coordinating national programmes for cost effectiveness of European investments in health research on poverty-related infectious diseases; expanding international cooperation in the area of clinical research and its funding and; increasing impact of cooperation efforts in this area. EDCTP2 is also focused on a wider range of disease areas, as opposed to a more limited range of focus areas which was the case with EDCTP1. (See Annex 1)

EDCTP funds all phases of clinical trials (I–IV), with a focus on phase II and phase III studies. EDCTP post-licensing (phase IV) studies encompass pharmacovigilance and effectiveness studies (pragmatic trials) as well as medicinal product-focused implementation research. In parallel, EDCTP funds strengthening of the research enabling environment in sub-Saharan Africa through grants for training (fellowships), strengthening ethics and regulatory frameworks, and south-south collaborative research networks, that may also include partners in the north. The second EDCTP programme (EDCTP2) is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020.

EDCTP2 activities are implemented through two mechanisms. The first is the EDCTP Association which is supported by the EU contribution to EDCTP2. The second is the efforts of EDCTP2 participating and partner states. The latter mechanism utilises national funds covering non-EU funded activities and are known as 'Participating and Partner States' Initiated Activities. That said, all 30 countries involved in the EDCTP2 are also full members of the EDCTP Association. Sweden, represented by the Swedish International Development Cooperation Agency (Sida), is one of the Participating States of the EDCTP Association.

The EDCTP Association is the legal structure established to deliver the EDCTP programme of work and is overseen by the EDCTP General Assembly which includes representatives of all PSs. There is an EDCTP Executive Secretariat with offices in The Hague, The Netherlands and Cape Town, South Africa. This is responsible for day-to-day management of the programme. The Secretariat and General Assembly are advised by a Scientific Advisory Council made up of a range of experienced stakeholders from across the public, private and third sectors.

	Participating Stat Activities	EDCTP Foundation				
Funding Body	European participating states	participating participating states		Others (private sector, participating states, development organisations etc.)		
Amount committed	≥€683 million	≥€ 30 million	≥€ 683 million	≥€ 500 million		
Details of administration	Administered by PSs and their funding rules apply		Administered by EDCTP and Horizon 2 rules apply			

 Table 1: EDCTP funding arrangements

(Adapted from EDCTP2 Strategic Business Plan 2014 – 2024, page 32)

The funding arrangements for EDCTP2 are laid out in Table 1. The European Union has committed € 683 million for EDCTP2 provided that this is matched by contributions from the European Participating States. Sweden, through Sida, has been making significant cash contributions to EDCTP2 through the EDCTP Secretariat to support projects since January 2016. Sida funds support product development and capacity building with the latter viewed as a priority.

The ongoing/completed Sida supported projects result from the implementation of the EDCTP work plans (EDCTP calls for proposals and other activities in the EDCTP work plans 2015-2018), managed by the EDCTP Secretariat, and from the implementation of a "Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme for implementation research on infectious diseases of poverty "—a Participating States Initiated Activity, managed by WHO-AFRO).

As of 31 December 2018, Sida contributed EUR 10,946,433 to support projects within the scope of the EDCTP2 Programme. This comprises EUR 6,946,433 in both commitments and disbursements to the ongoing/completed projects as well as EUR 4,000,000 for the prospective projects; selected proposals and ongoing calls for proposals with Sida's funding commitments.

Of the EUR 6,946,433 committed/ disbursed this was made up of EUR 4,436,000 (5.09% of the total EDCTP budget of EUR 86,998,424 to research and innovation activities) to support clinical trial research (HIV and malaria treatment and vaccines, diarrhoeal disease vaccines as well as TB diagnostics) and EUR 2,261,389 (30.63%<sup>2</sup> of the total EDCTP budget of EUR 5,224,769 to training and mentoring activities) to support capacity development for clinical trials and related research in sub-Saharan Africa; Career Development Fellowships, Ethics and regulatory capacity and grants to sub-Saharan African researchers through the Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme. In addition, since the SSE started, Sida has contributed a further EUR 1,000,000 to research projects as of end September 2019 (from the EUR 4,000,000 that was allocated for prospective/ ongoing calls).

<sup>&</sup>lt;sup>2</sup> Excluding direct to project cash funding of EUR 660,722 on top of EDCTP budget provided to CSA2016S-1618 grant.

Furthermore, the TOR state that Sida contributed EUR 249,044 (31.13 % of the total EDCTP budget of EUR 800,044) towards cross-cutting issues through support to Open Source Platform and the Ninth EDCTP Forum 2018.

Our analysis of the data, presented in Annex 2, supports this. Annex 2 also includes details of grants given in 2019 (not listed in the TOR) that include a contribution from Sida.

Sida and EDCTP's relationship has been long-standing, since almost the beginning of the programme (from 2004). During this time Sida, has provided in-kind and monetary support. This has included support to build capacity of staff within EDCTP as well as supporting clinical development and research capacity building in African countries. A key element of Sida's support is its flexibility; because it is provided into EDCTP's central funding allocation the money allows the organisation (EDCTP) to continue activities at times when funding from Europe and/or other funders has yet to be received. Finally, Sida has been important in supporting cooperation activities conducted by EDCTP.

Sida's relationship with EDCTP Secretariat is managed out of the Sida's Research Cooperation department. This department is tasked with achieving Sida's research strategy which focuses on strengthening research of high quality and of relevance to poverty reduction and sustainable development (see Annex 1).

## 2.1 EVALUATION PURPOSE

The terms of Sida funding to EDCTP are spelt out in a Grant Agreement document. The Agreement provides conditions for EDCTP to implement funding on the basis of a Sida sanctioned evaluation and monitoring process which includes provision for the independent evaluation which is the basis of this report. Specifically, Article 6.5 of the Grant Agreement for the use of Sida's cash contribution to the EDCTP Secretariat for supporting projects in the scope of the EDCTP2 programme signed between EDCTP and Sida in December 2015 requires EDCTP to commission "an independent evaluation regarding the outcome and effect of the Sida cash contribution<sup>3</sup>". It is therefore for this reason that EDCTP launched this evaluation to provide EDCTP and Sida with lessons learned on the successful projects supported by Sida but also to highlight challenges, constraints and bottlenecks, if any, related to their implementation.

The scope of this evaluation begins with the first SIDA supported project (TRIA2015-1076) which began implementation on 01/12/2016. The evaluation period under consideration continues up until September 2019.

This evaluation had three main objectives as laid out in the SSE TOR. These have been slightly amended below on the basis of further information from EDCTP.

The purpose of the evaluation was to perform an independent assessment of Sida-supported projects within the scope of the EDCTP2 programme. Specifically, the evaluation sought to:

- Assess the status of project implementation to date of Sida funded projects, including project management, and the likelihood of successful completion
- Assess the results of SIDA funded projects so far (including at outcome and impact level, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy and Sida objectives in funding EDCTP, particularly in relation to the research and research capacity building needs of low-income countries in Africa
- Assess the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP

Much of the support that Sida provides is in partnership with other funders. The SSE team's understanding was that while Sida was keen to review the effectiveness of its contributions, it was less concerned with establishing attribution of success in relation to its own particular financial inputs. The evaluation therefore considered how well investments aligned with Sida's ambitions in supporting EDCTP both in terms of meeting EDCTP's objectives as well as Sida's own research strategy result areas. It was not concerned with determining attribution issues against Sida funds specifically.

<sup>&</sup>lt;sup>3</sup> See Grant agreement for the use of Sida's cash contributions to the EDCTP Secretariat for supporting projects in the scope of the EDCTP2 Programme.

## **3.0** Aligning the objectives to evaluation questions

The table in Annex 3 provides an overview of our evaluation objectives and their mapping onto the evaluation questions. It also identifies the indicators and relevant data sources used in this SSE. We 'road tested' this evaluation matrix during the inception period by conducting initial data analysis by desk review of materials provided and found through internet searches against a number of the evaluation questions. We also sought feedback on the matrix from EDCTP senior staff during an inception meeting.

It should be noted that we kept the evaluation questions to a minimum. We focused on a series of overarching main questions followed by a number of sub-questions attached to them. This was to aid the ability to ensure that our data collection and analysis matched the objectives and allowed us to make very specific, relevant and directly related recommendations. It ensured that the recommendations could easily be mapped from the data analysis, back to the evaluation questions and against the objectives of the evaluation.

An overview of the main evaluation questions by Objective are outlined in Table 2 below. We purposively decided to consider the objectives of EDCTP and of Sida's research strategy using separate evaluation questions although we recognized that there was overlap in the data that would be utilized to answer each of these questions. However, this was important in order for us to ensure we could effectively provide recommendations against both areas in this report.

## Table 2: Overview of final overarching evaluation questions

<b>Objective 1:</b> Assess the status of project implementation to date of Sida funded projects, including project management, and the likelihood of successful completion	<ul><li>1.1 Has actual investment matched planned investment?</li><li>1.2 Is implementation of projects and EDCTP's activities with Sida funding on track?</li><li>1.3 Are projects and activities by EDCTP funded by Sida being adequately project managed?</li></ul>
<b>Objective 2:</b> Assess the results of Sida funded projects so far (including at outcome and impact level, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy and Sida's objectives in providing funding to EDCTP, particularly in relation to the research and research capacity building needs of low-income countries in Africa.	<ul> <li>2.1 What are the identified outputs, outcomes and impacts of investments?</li> <li>2.2 How well do Sida supported projects align against EDCTP strategy objectives?</li> <li>2.3 How well does EDCTP and its funded projects utilize Sida funding to meet the needs of Sida's research cooperation priority areas?</li> </ul>
<b>Objective 3:</b> Assess the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP.	3.1 How has Sida support contributed to women's active engagement with research?

#### $3.1\,\text{A}$ discussion of definitions of outcomes and impact

We added a series of questions on the degree to which projects that have received Sida funding have achieved outputs, outcomes and impacts. In discussing these terms at inception stage, we noted that there was a potential disconnect between the definition of these from those with a scientific/ medical/ public health background and those from a more international development background. As such, it was important for us to define what we – the SSE team – meant by these terms of output, outcomes and impact and how they were therefore used in this evaluation.

#### 3.1.1 RESULTS BASED METHODOLOGY

Increasingly, international development partners have promoted various monitoring, evaluation and learning methodologies to be used by their grant holders in order to ensure donor funding is effectively utilized and the maximum impact is achieved. These include DFID's Logical Framework Matrix approach, IDRC's Outcomes Mapping Methodology and more recent Research Quality Plus approach and Sida's Results Based Management approach. All of these are underpinned by the idea that projects and programmes should have a 'Theory of Change' that guide their design, implementation and evaluation. A theory of change assumes that any intervention will have direct and indirect results at a variety of timeframes. The aim of any intervention is to ensure progress towards wider societal goals (these could be the Sustainable Development Goals, national development strategy targets or community agreed long term changes that they wish to see achieved). Therefore, the starting point of any activity should be the question 'what problem do we want to solve?' and then 'how do we get there?'

Thus, Sida's Results Based Management (RBM) Handbook (2014) highlights that their approach moves the focus from what the project did (measurement of activities conducted e.g. number of trainings held, policies reviewed etc. and outputs produced e.g. numbers of publications or clinical trial guidelines completed) to what happened from the development of these outputs (outcomes and impacts).

Underlying this approach is the idea that all action is normative and that activities should be focused on having a tangible impact on society (while recognizing that sometimes the impact is not the desired impact and can sometimes be negative in consequence).

Thus, the Sida RBM Handbook recommends starting from problem definition and objective writing. Specifically, that once you have identified your problem definition then you come up with one or more objectives as to how you intend to solve that problem. It is based on these objectives that you then determine your impacts, outcomes and outputs.

Usually objectives and the impacts that underlie them are long term objectives; often that are not directly within the project or programme staff's direct capacity to influence. However, it is expected that the outcomes of the project or programme will enable positive change towards achieving the desired objective. Thus, outcomes are usually within the purview of a project or programme's influence and are the results that the project or programme aims to make in the medium term i.e. by the end of the project period. Activities and outputs are the deliverables that lead to the outcomes and it will usually be possible to see a direct correlation between the activity or output and the outcomes that are achieved. As noted earlier, that being said, not all outcomes and impacts are positive or intended. Projects and programmes can lead to unintended and negative outcomes and impacts. It is for this reason that alongside defining – preferably at project inception – it is recommended that a series of assumptions (of potential risks) are also considered.

#### 3.1.2 OUTPUTS, OUTCOMES AND IMPACT

Based on the above, this SSE defines these terms as outlined in Table 3 below.

#### Table 3: Outputs, outcomes and impact:

Output	The tangible and identifiable products or actions that result from an intervention. These include publications, trained individuals, modified policy documents, clinical trial guidelines etc.
Outcome	The likely or achieved short-term and medium-term effects of an intervention's outputs
Impact	Positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended

These definitions take into account the DAC/OECD recommendations and definitions relating to evaluation. The definition of output is a modified version of the Sida and DAC definitions. The definition of outcomes and impact is the DAC definition.<sup>4</sup> It should be noted that Sida utilize the term objectives instead of impact.

## 3.1.3 Use of these terms in this SSE

The SSE team define the terms in the above ways. In so doing, Evaluation Question 1.2.2. (Have outputs and outcomes within project control been achieved as scheduled/ per work plan?) and Evaluation Question 2.1 (What are the identified outputs, outcomes and impacts of investments?), will be considered using these definitions. That being said, we have also taken into account the identified outputs, outcomes and impacts or objectives identified by the projects that have received Sida funding. This is in addition to EDCTP's own Theory of Change (see Figure 1). We have noted in the main results section where differences in definition occur.



## Figure 1: EDCTP Theory of Change (as per M&E document 2019)

<sup>&</sup>lt;sup>4</sup> Taken from DAC Glossary of Terms for Evaluations (2010) available here: <u>https://www.oecd.org/dac/evaluation/2754804.pdf</u> (accessed 29/10/19)

## 4.0 METHODOLOGY OF THE EVALUATION

We concentrated our data collection around two main data collection mechanisms: in-depth literature review and a series of key informant interviews.

## 4.1 IN-DEPTH LITERATURE REVIEW

Following our piloting of the evaluation matrix and conduct of an initial literature review during the inception phase, we conducted further analysis of a series of documents; complemented by an internet search for further documentation/information as needed. Analysis took the form of thematic review of each document with pertinent data being entered into a master data sheet developed against each evaluation sub-question data line as appropriate.

Table 4 outlines the types of documents that were reviewed. This is a purposive list developed to obtain materials that contain the requisite data needed to conduct the evaluation thoroughly. This list is based on discussions with EDCTP staff and our extensive experience of conducting similar evaluations. A full list of all the documents reviewed is provided in Annex 4.

Document details	Documents Reviewed				
Documents pertaining to	Grant agreement				
EDCTP and Sida's research agreement	Annual Reports to Sida				
EDCTP programme	EDCTP2 Business Plan				
documents	EDCTP Research Agenda v.3 Feb 2019				
	EDCTP Annual Reports 2014, 2015, 2016, 2017, 2018				
	Clinical trials 2013 – 2018 document ('Tackling infectious diseases')				
	Various excel documents providing details of research projects funded including grant tracker documentation				
	SAC minutes and related slides				
	Internal project management reports (e.g. risk matrices; senior management team minutes)				
Research grants related documents	RIA, TMA and CSA project proposals (for projects that have received Sida funding) including technical and financial documents				
	Project progress reports for RIA, TMA and CSA where available				
	Project management documents from project PIs where available.				
Open Source Platform	Proposal and contract documents and progress reports (where available)				
	Review of website				
Ninth EDCTP Forum	Forum statistics				
	Review of website				
	BMJ piece relating to the event				
	Participants feedback				

## **Table 4: Document review details**

#### **4.2 KEY INFORMANT INTERVIEWS**

We conducted three different groups of interviews.

#### 1. Senior staff within EDCTP

We formally interviewed the Executive Director of EDCTP and one project officer from EDCTP. We also received feedback from other EDCTP staff on the inception report.

### 2. Principal investigators from a sample of projects that have received Sida funding

Due to the time constraints, it was not possible to interview all 28 PIs from the RIA, TMA and CSA projects and all the Joint WHO-AFRO/TDR/EDCTP Small Grants PIs. Therefore, we interviewed a sample of each type of grant holder. We started with a target sample of 70% of PIs who were contacted for interview across the RIA, CSA and TMA projects and 30% of Joint WHO-AFRO/TDR/EDCTP small grant PIs. In some cases we interviewed other representatives of projects and not the PI (based on availability of project staff). We did not get a large response from WHO small grants PIs and also did not receive emails for all Joint WHO-AFRO/TDR/EDCTP small grants PIs. Our aggregated response rate however was a respectable 46%.

The breakdown of PIs interviewed was as follows in Table 5.

Project type	Total # PIs/ project representatives interviewed	% interviewed against total PIs with projects that received Sida funding	Total female	Total male	Total LIC/ LMIC based	Total UMIC/ HIC based
RIA	7	64%	2	5	3	4
TMA	5	50%	1	4	5	0
CSA	5	71%	4	1	3	2
Joint WHO- AFRO/TDR/ EDCTP small grants	6	20%	4	2	6	0
Total	23	46%	11	12	17	6

Table 5: Interviewee breakdown

A list of interviewees is available in Annex 5.

## 3. Other stakeholders who are familiar with EDCTP's and Sida's activities

We also undertook 5 interviews with other stakeholders. These included key informants who could provide a further source of information on the history and process of the Sida-EDCTP relationship. It also included those who could provide a wider lens on research capacity building efforts in developing countries to gain a third party perspective on the current state of the field.

#### 4.3 LIMITATIONS AND MITIGATIONS

Some limitations were identified and mitigation measures undertaken:

1. The evaluation team relied largely on documented and narrative accounts from diverse stakeholders. *Extensive primary research was out of scope.* 

Mitigation measures: We made sure that we included a diversity of stakeholders and perspectives.

2. The short timeframe associated with Sida funding means that the evaluation was unlikely to result in definitive findings about the success or otherwise of Sida contributions. This was particularly the case with regard to impact and outcome measures.

<u>Mitigating measures:</u> We incorporated questions into interviews about the likely direction of project investments and asked interviewees about the key current and future enablers of success and barriers.

3. We found it difficult to access interviewees during the inception period and this continued into the main data collection period.

<u>Mitigating measures</u>: We utilised introduction letters from EDCTP to assist us with gaining access to interviewees and also conducted multiple follow up emails and where possible calls to try and improve completion rates.

## 5.0 RESULTS

OBJECTIVE 1: ASSESS THE STATUS OF PROJECT IMPLEMENTATION TO DATE OF SIDA FUNDED PROJECTS, INCLUDING PROJECT MANAGEMENT, AND THE LIKELIHOOD OF SUCCESSFUL COMPLETION

#### 1.1 HAS ACTUAL INVESTMENT MATCHED PLANNED INVESTMENT?

#### 1.1.1 What is the profile of Sida support?

From the project documents we have reviewed, we have identified the following breakdown by types of projects funded by EDCTP utilising Sida funds – see Table 6.

#### Table 6: Disaggregation by project type and PI details

	RIA	ТМА	CSA	Joint WHO- AFRO/TDR/EDCTP small grants
# of projects	11	10	7	30
Total funding from Sida allocated to these projects (EUR) including 2019 figures	5,436,000	1,000,000	1,174,722	86,667
# projects with female PI	1	3	5	15
# projects where PI is LDC/LIC / LMIC based	2	6	5	28
# project where PI is female and based in LDC/ LIC or LMIC	1	1	2	15

LDC = least developed country, LIC = low income country and LMIC = low-middle income country. These categorisations are taken from the DAC list of ODA recipients effective for reporting on flows in 2018, 2019 and 2020. RIA = Research and Innovation; TMA = Training and mentoring; CSA = capacity support activities

#### Table 7: Further disaggregation of project by PI details

CSA	LDC/ LIC/ LMIC	Other	ТМА	LDC/ LIC/ LMIC	Other	RIA	LDC/ LIC/ LMIC	Other	WHO small grants	LDC/ LIC/ LMIC	Other
F	2	1	F	1	2	F	1	0	F	14	1
м	3	1	м	5	2	М	3	7	м	14	1

NB: 2 Joint WHO-AFRO/TDR/EDCTP Small Grants went to researchers in Gabon which is DAC classified as UMIC.

It is worth noting that EDCTP in their report to Sida in 2018 highlighted the difficulty of measuring leadership of clinical trials by researchers from sub-Saharan Africa (one of EDCTP's progress markers). A proxy measure is used for this as a result; namely proportion of grant allocation to sub-Saharan Africa. This comment and the figures in Tables 6 and 7 raise questions with regards the pipeline for African research leaders. While the pipeline is outside of the scope of this SSE, the SSE does investigate – through interview data – the barriers and opportunities faced by PIs based in LICs in Africa, especially female PIs in a number of evaluation questions below.

## 1.1.2 Have investments occurred in areas that were originally planned?

Sida and EDCTP strategic areas are outlined in Annex 1. RIA projects that received Sida funds fit squarely in EDCTP Objective 1 (increase number of new or improved medical interventions) and EDCTP Objective 2 (on capacity to conduct clinical trials). The TMA and CSA projects that received Sida funds also fit with EDCTP Objective 2. Some of the projects (RIA2016V-164 (MMVC) which works with two private pharmaceutical/ biotech companies) relate to EDCTP Objective 4 (extending international cooperation with other public and private partners). In addition, it is expected that third parties will contribute €309.59 million through RIA and CSA projects (SAC minutes 21 May 2019). EDCTP Objectives 4 and 5 (increase impact due to effective cooperation with relevant EU initiatives) have also been fostered by the use of Sida funding for the Ninth EDCTP Forum meeting. More generally, it was noted by a number of interviewees that Sida funding has been strategically important for EDCTP in meeting its Objectives 3 (Increase cost-effectiveness of European public investments), 4 and 5 due to the flexibility that is given in how it is utilised. Specifically, that the funding has increased efficiency due to its ability to ensure no funding shortfalls during project disbursements periods.

The focus of Sida funded projects against the EDCTP disease priority areas, population groups and geographical regions is provided in Tables 8, 9 and 10. We find that just shy of 50% of projects focus on the original 'big 3' diseases (HIV, Tuberculosis and Malaria) that were the focus of EDCTP's first phase of activity. A significant portion of projects focus on diseases affecting children while the majority of projects funded are focused in East African countries, followed by West African countries. The focus on priority disease areas fits with Sida's Research Cooperation Strategic Results area 2 (focus on research of relevance to LICs).

	RIA	ТМА	CSA	Joint WHO- AFRO/TDR/EDCTP small grants	Total
Children	4	4		4	12
Young people	1			2	3
Migrants/ displaced peoples				1	1
Pregnant women	2			1	3
Women and children		1		2	3
Women		1		2	3
Adults	3	4		24	31
N/A or not known	2	2	7		11

#### Table 8: Projects disaggregated by population group

*NB:* Sometimes more than total number of projects because have multiple population groups as focus of study.

## Table 9: Projects disaggregated by African region

	RIA	ТМА	CSA	Joint WHO- AFRO/TDR/EDCTP small grants	Total
West Africa	6	1	5	13	25
Central Africa	5	0	0	3	8
East Africa	15	4	12	12	43
Southern Africa	8	4	0	2	14

NB: Sometimes the numbers are more than total number of projects because have multiple countries across more than 1 African Union Region as focus of study. North Africa is not included because it is not an EDCTP target area.

Table 10: Funding broken down by African LIC and other country classifications (including 2019)

	EDCTP funds total received (RIA, TMA, CSA)	%age of funds received	Sida funds received (RIA, TMA, CSA and small grants) <sup>5</sup>	%age of funds received
DAC listed LIC	€ 122,850,000.00	32.5%	€ 2,863,857.69	37.2%
DAC listed LMIC	€ 32,210,000.00	8.5%	€ 746,203.99	9.7%
DAC listed other (UMIC/ HIC)	€ 222,520,000.00	58.9%	€ 4,087,327.33	53.1%
Total	€ 377,580,000.00		€ 7,697,389.01 <sup>6</sup>	

\* Figures taken from SAC slides, 21 May 2019 (slides 67 & 68). \*\* Figures taken from 'List of EDCTP Signed Grants by donor funding including Sida' excel workbook.

All of the projects funded with Sida money have one or more elements of capacity building outlined in their proposals; even if not explicitly required to speak about capacity building in their proposal. As such they fit with Sida's Research Cooperation Strategic area 1 (capacity building for research). However, the degree to which projects focus on capacity building in low income countries is mixed.

Table 10 outlines details of how much support low income countries have received from EDCTP2 funds and specifically from the Sida available funds during EDCTP2. This is compared to those who have received funding from other parts of the world. It should be noted this is based on specific allocation by named organisation in a project as opposed to only looking at where the Principal Investigator is based (this is outlined in Table 7).

Sida's Research Cooperation Strategic Results area 3 (research that can contribute to poverty reduction and sustainable development) is met by all the projects that have received funding from Sida due to their focus on capacity building within the health research system, improved ability to conduct clinical trials which ultimately should have an impact on health system performance and thereafter mortality and morbidity figures in LICs. However, the degree to which poverty reduction and sustainable development objectives are an explicit part of the funded projects' proposals and action plans varies. As will be discussed later, the definitions of impact vary and there is a lack of an appropriate RBM or equivalent MEL strategy in many of the projects – or the EDCTP required documentation on application – to ensure Sida's Research Cooperation Strategic Results Area 3 is effectively addressed.

<sup>&</sup>lt;sup>5</sup> Small grants funding is not 100% in terms of breakdown by country and proportion received from Sida. Therefore, we have taken the € 86,667 that is recognised in all the documents we have reviewed as the amount Sida has contributed to the Joint WHO-AFRO/TDR/EDCTP Small Grants scheme and divided it proportionally against LIC, LMIC and other country classifications as per the proportion of the 30 funded projects based in countries in these categorisations.

<sup>&</sup>lt;sup>6</sup> Previous amount of Sida contribution – minus that given for support to the Ninth Annual Forum and the Open Source Platform – was € 6,697, 389 (as noted in most of the documents that were reviewed for this project, including the original Terms of Reference for this SSE. The extra € 1 million was given in 2019 to two RIA projects (Simplici-TB and PREGART).

Sida's Research Cooperation Strategic Results Area 4 (Swedish research of relevance to poverty reduction and sustainable development in LICs) is met by five (5) projects that include Swedish partners (notably PROFORMA, MMVC, ETEC, RaPaed TB, PreEPVacc – 4 RIA and 1 CSA).

With regards the degree to which Sida's funding has been spent on activities as per individual project and EDCTP work plans; all progress reports from projects are reviewed by EDCTP staff and regular reviews of progress against work plans are conducted by projects and by EDCTP. The SSE Team could find no reports in SAC minutes or Annual Reports of any major deviations from work plans. That said, some projects have noted (either in their progress reports or during interviews for this SSE) that they have incurred delays due to country instability (a CSA project based in Sudan), external assessor report delays (a CSA project focused on Ethiopia and Ghana), have lost Pls (another CSA project in West Africa), difficulty in recruiting participants (a TMA project in Tanzania) or gaining stakeholder buy-in (several CSA projects). It was also noted in one of the interviews conducted that there was a delay in the 2019 disbursement from Sida to EDCTP.

# 1.1.3 What have been the barriers and enablers to successful planned investment?

A series of enabling factors were also identified by interviewees. Most notably, Sida's flexible approach to EDCTP was identified as an enabler by many interviewees who were asked questions related to funding approaches. In addition, other enablers that have been identified were:

- 1. Flexibility of funding/ budget reporting (i.e. ability to move money across budget lines at project level)
- 2. 25% overhead provides PIs with leverage within their institutions and also increased profile and ability to fund finance officer time
- 3. 50%, or other high levels of, initial disbursement provides cushion against future funding delays.<sup>7</sup>
- 4. High levels of existing expertise within project teams and/or previous collaborative agreements with partners (i.e. better to work with those who have experience and have worked with before for efficiency).<sup>8</sup>
- 5. Buy-in and support from national and international stakeholders
- 6. Support of some EDCTP project officers who willing to give advice as and when needed e.g. on how to fill progress report forms. Several interviewees also mentioned EDCTP training on Project Management as being useful. In addition, this training is increasingly being broadened out to include a wider range of project team members (i.e. beyond the principal investigator's own organisation).
- 7. Ability to mobilise/ leverage additional funds to provide a cushion while waiting for EDCTP funds to arrive (so as not to delay project start/ reduce timeline available for research activities)

As noted above there have been some barriers incurred by Sida funded projects. These can be divided into those related to project administration with EDCTP, issues at project level and those external (and often outside of the control) of projects. These are outlined in Table 11.

**Recommendation:** In order to address delays to project start up times, EDCTP could build in time for collaboration building and knowledge and skills transfer for new partners. This measure should be designed to enhance project

<sup>&</sup>lt;sup>7</sup> Several interviewees noted that they received 50% of their funding up front however, the policy currently at EDCTP is to pre-finance the first 18 months of a project.

<sup>&</sup>lt;sup>8</sup> That being said, one interviewee noted that while they would perhaps have chosen different partners if they were to do this again (to only use those partners they had worked with before) in reality the project aimed to build capacity and this means recognising the need to bring on inexperienced partners and work with them to build their skill sets.

management capabilities within research partnerships. Specifically, start up funding, one year prior to the official start of projects, should be considered. This will allow time to build up relationships and establish systems crucial to successful project management.

**Recommendation:** To improve the planning and evaluation processes, the proposal template and progress reports should be redesigned to encourage increased and broad reflection on external risks and how to mitigate them. These templates should be adjusted to the type of project as RIA versus CSA projects (for example) require different issues to be considered.

EDCTP related	Project related	External factors
• Delay in reviewing project reports	<ul> <li>PI losses and staff retention</li> </ul>	<ul> <li>Country instability – political crises; hospital strikes etc.</li> </ul>
<ul> <li>Delay in project starts vs. project proposal submission (knock on effects including budget costs needing to be revised)</li> <li>Delay in receiving funds into EDCTP from financial contributors</li> <li>Cumbersome procurement and contractual processes between EDCTP and grantees</li> <li>Reporting templates are cumbersome and sometimes feel repetitive and/or designed for one type of project</li> </ul>	<ul> <li>Slow recruitment of trial participants and/or ability to find suitable candidates</li> <li>Time taken to receive ethics approvals for trials/ research activities</li> <li>Slow disbursement of funds within project organisations (e.g. through Ministries of Health and/or universities)</li> </ul>	<ul> <li>External assessor delays and resulting legal case</li> <li>Difficulty of getting stakeholder buy-in</li> <li>Insecurity of funding for sustainability of long term initiatives (e.g. ethics review online systems)</li> <li>Inflation and/or devaluation of the currency requiring adjustments to project budgets/ reduction in activities/ changes to type of equipment purchased - this is compounded by delay in receipt of funds and subsequent knock on effect of delayed implementation.</li> <li>Procurement challenges for equipment and reagents</li> <li>The need for a trial to adapt to policy changes e.g. a change in guidelines (country and/or WHO) or new emerging evidence warranting a redesign of either standard of care, or the new intervention, and thus protocol revision (and approvals) before study start.</li> <li>Delays in obtaining approvals due to approval body members not being available</li> </ul>

1.2 IS IMPLEMENTATION OF PROJECTS AND EDCTP'S ACTIVITIES WITH SIDA FUNDING ON TRACK?

## 1.2.1 Have milestones been met?

Annex 2 provides details of which projects have received Sida funding and the status of their activities. All RIA and TMA projects with Sida funding are ongoing. Only 1 CSA projects had been completed during the SSE evaluation period (CREDU). One other CSA project (CTC-TEP) was supposed to have completed but due to delays with an external assessor report has received a no-cost extension and another CSA project (Enhancing Ethics) was supposed to have completed but has been put on hold due to country instability.

# Table 12: Number of projects (receiving Sida funds) implemented by year documented in EDCTP2 work plans

Work plan year	Implementation start date				
	2016	2017	2018	2019	
2015	2	5			
2016		2	15		
2017			2	2	
2018					

Annex 2 does not include details on the length of time between grant proposals being submitted, contract signing and implementation. It is clear from a review of document 'List of EDCTP signed grants by donor funding including Sida' that several projects were listed in one EDCTP work plan but not implemented until the following year; in a couple of cases this was two years later – see Table 12.

As can be seen in Table 13, only one project which has received Sida funding has been deemed – on review of the progress reports and interview data – by the SSE team to be a cause for some concern. This is a project based in Sudan which has been placed on hold due to the country's instability but which is the first project funded with a PI in Sudan and has an all-female project team.

Table 13: Status of projects that have received Sida funding

State of progress	RIA	ТМА	CSA
On track	3	4	2
Some delay	4	4	2*
Cause for concern	0	0	1**
Completed			1
Not known***	4	2	1

\*One project has received no cost extension due to delays in receipt of an external assessor's report

\*\*One project on hold due to country instability

\*\*\* Status not known because one TMA progress report not received (progress report due in September 2019) and others progress report not due until end 2019 or into 2020

A few project reports – and backed up by interview data – suggest delays have been suffered by many of the projects. Some of the delays have been overcome, and the projects are now back on track (and so they are listed as 'back on track' in Table 13). However, one project is delayed due to country instability, while another is deemed delayed because it has been granted a no-cost extension (but is generally deemed to be on track). The others may still be suffering from these delays. These delays are usually the result of delayed receipt of consensus among stakeholders and/or delays in receipt of ethics/ regulatory approval for trials/ research activities. In a few cases it is the result of delays in recruitment of staff or students.

One issue the SSE team had however is that some projects appear to have suffered from minor delays. However, in some cases, the projects' last report was submitted in late 2018 or very early 2019 and therefore – other than one RIA project that received a site visit in mid-2019 to one of its partner sites – it's difficult to gauge if they are still on course until the next annual progress report is received. As noted in EQ 1.3.3, the financial audit committee has commented on the use of a single annual progress report.

We are also unable to assess the status of Joint WHO-AFRO/TDR/EDCTP small grants (many of which should be completed by now) due to the lack of progress/ close out reports as well as the difficulty of interviewing the selected number of grantees. That being said, the latest SAC minutes (21 May 2019) noted that all Joint WHO-AFRO/TDR/EDCTP small grants would complete in 2019.

The Open Source Platform (https://edctpknowledgehub.tghn.org) appears to be on track but it is difficult to assess due to the paucity of documentation with regards to the activity. The platform has been launched (as outlined in the EDCTP Annual Report to Sida 2018) and the platform functions when the website was visited. However, the activity does not appear to have been mentioned in the EDCTP Annual Work Plan or many of the Annual Reports received. The 21<sup>st</sup> May 2019 SAC meeting slides outline three main objectives of this platform, namely the development of an:

- Online protocol builder (template for clinical trial protocols)
- Repository for clinical trial protocols
- Interactive tool for sourcing commentaries to draft protocols

An update from the Global Health Network (contracted to produce the platform) in June 2019 highlighted that online protocol builder was in progress. That an existing resource (SEPTRE) would be used. On visiting the site in November 2019, it appears this is still yet to 'go live'. However, advice on how to draft protocols was live and functioning and a series of free resources and guidelines were available to download from a dedicated resources section. The repository for clinical trial protocols appears to still be in progress and 'on track' as per the June 2019 update email the SSE team reviewed. This project is a 24 month project in total starting February 2018.

The Ninth EDCTP Forum has been completed. Detailed reporting on the Forum was conducted by EDCTP including feedback from participants. Post-Forum activities included a special supplement to an issue of the British Medical Journal (BMJ) was also published in April 2019.<sup>9</sup> Of the 51 respondents to feedback requests after the Forum, the vast majority felt that the objectives of the forum were fully met. Only one respondent didn't think that the objective regarding enhancing engagement between African and other scholars as not met at all. The event was deemed well organised although several of those who left qualitative comments in the review section of the feedback survey stated that the e-poster session could have been improved. There was a strong request during the feedback survey of more emphasis on opportunities for researcher networking. The forum was attended by 550 participants from more than 50 countries. The programme comprised keynote addresses by policy makers, research leaders, and prominent speakers from Europe and Africa in 5 plenary presentations. There were 9 symposia, 45 oral presentations in parallel sessions, and 74 electronic poster presentations. Participants included 24 fellowship holders of which 20 came from LICs (n=16) and LMICs. Alumni participants numbered 38 of which 30 were from LIC (n=19) and LMICs.

# 1.2.2 Have outputs and outcomes within project control been achieved as scheduled/ per work plan?

It is worth noting here that the 2019 call for RIA projects now has advice on writing an impact statement into the proposal and the need for this to reference the expected impacts for each objective/ impact area outlined in the EDCTP M&E Document. In addition, impact criteria (during evaluation stage of the proposals) are made very explicit in the call document. Calls in earlier years made reference to impact criteria and often referenced EDCTP strategic research agenda document and, where applicable, relevant global or EU action plans.

This is a possible explanation on the very varied approaches to considering outputs, outcomes and impact by project teams during proposal writing. In the case of the RIA projects, the proposals range from a list of very in-depth and considered impacts on society (sometimes with estimated time horizons included for this impact) to those which are highly focused on more limited range of clinical outcomes. The CSA projects had a larger percentage of proposals that had a formal log frame or a semblance of the same included in them. Of the TMA projects, the majority were focused on clinical outcomes and capacity building impacts for the individual grant recipient and/or their institutions/ peers.

That said, while every proposal had to include an impact statement plus a list of deliverables and milestones, very few proposals included indicators to measure success towards outputs, outcomes and impacts/ objectives – where these are mentioned. In progress reports, the format of discussions on progress towards outcomes and impacts actually focuses on progress towards milestones and deliverables plus a narrative on progress towards capacity building goals in particular as well as the status of clinical trials. This is in part due to the need for these progress reports to meet EU Horizon 2020 format requirements.

<sup>&</sup>lt;sup>9</sup> <u>https://gh.bmj.com/content/4/Suppl\_3</u> (accessed 04/11/19)

Because of the lack of a dedicated format for reporting against outputs, outcomes and impacts/ objectives it remains – as outlined in the inception report – difficult to measure the extent of progress against these. This is further hampered by the relative status of projects (with many still only just starting/ in initial implementation stages – see Table 12 above). As such, there is little ability to also gauge the barriers and enablers to outputs and outcomes or impacts beyond what is provided under the discussion on deliverables and milestones in progress reports. There is also no dedicated space in progress reports (beyond a generic question entitled 'Other comments') that enables PIs to record unintended or unexpected results (either negative or positive). It should be noted that the final report format for projects is the same as progress reports and therefore these same issues are faced at final reporting too.

### 1.3 ARE PROJECTS AND ACTIVITIES BY EDCTP FUNDED BY SIDA BEING ADEQUATELY PROJECT MANAGED?

## 1.3.1 Are project management systems and procedures in place within funded projects?

Many of the projects that have received Sida funding have strong management systems in place including regular senior team/ executive committee/ steering committee meetings that keep the PI and their fellow coordinators abreast of activities and review project progress. Many of these meetings take place monthly. In some cases, their frequency was more during project start up. In many cases there are multiple layers for management meetings i.e. overarching management teams (often given other names) made up of the project coordinators from each of the collaborating organisations plus site level management teams.

For the projects where we interviewed staff and reviewed project level documentation, we saw evidence of regular meeting minutes (not always comprehensively taken) and, in most cases, a recognition of the need to consider risks and mitigation factors on a regular basis (although not always through an updated risk register type document). Many projects, especially those conducting clinical trials, also had various different forms of contracts and project level policies and procedures in place. Some projects – but not all – required collaborating partner organisations to report to the Pl's organisation on a more regular basis (e.g. quarterly) than was required by EDCTP (which only requires annual reporting).

It was noted that EDCTP has previously provided financial training for PIs at The Hague and in countries on a rotational basis (i.e. not necessarily linked to the start date of new grants) but there was recognition of the importance of providing this more routinely to coordinators/ collaborating partners due to the lack of capacity in many African organisations (see below).

That said, it was noted by one interviewee that grantees in 2019 had received financial training for all partners in their consortium (not just the lead organisation's financial officer). This was also confirmed by EDCTP; from 2019 EDCTP had moved towards a more inclusive approach to such training and were now opening financial management training to all partners in a funded consortium (and not just the PI's own organisation).

**Recommendation:** In order to improve the quality of financial management, EDCTP should require compulsory webinar and/or face-to-face training of all project partners financial officers who will be responsible for financial reporting (and not just PIs own institution) at the start of the grant or during a funded start-up period preceding the start of the actual project. An EDCTP helpline for financial queries could also be made available for grantees with specific financial queries. Feedback sessions with all finance and PI and Co-Is by skype could take place after each reporting period to discuss discrepancies and issues raised by technical and financial reports.

# **1.3.2** Has project management (PIs and their administrative support staff within their institutions) identified obstacles, enablers and mitigation measures?

The quality of financial management systems has been noted by the majority of interviewees as a significant bottleneck during management of projects. That said, several interviewees noted that EDCTP (unlike some other funders) allows for funding administrative/ finance staff as part of the budget team and these were deemed invaluable for ensuring greater levels of project management good practice. However, in some RIA projects the Project Coordinator's financial manager was spending a lot of time supporting their collaborating partners in managing the funding/ completing reporting etc. While EDCTP has introduced a broader and more inclusive approach to financial training, interviews suggested that there remains a need to provide training to collaborating partners.

Linked to this, it was noted by several interviewees that the financial management requirements of EDCTP grants were more burdensome than other grant funders. The emphasis on deliverables means that there is often a set of outputs that investigators wouldn't always conduct but which have to be conducted because they are contractually obligated.

A second area which was identified by interviewees which impacts project management is buy-in, or lack thereof, by senior management staff within host and/or partner organisations. This often leads to delay in receipt of funds by the project staff where this is not available. It was not clear if more knowledge of the source of the funds (i.e. from donors like Sida) would have been helpful in this regard; however, we found several projects where even the PIs did not know that they had received funding from Sida. This has been acknowledged by EDCTP and efforts are underway to ensure more acknowledgement of individual donors including details on how to acknowledge donors being written into grant agreements.

**Recommendation:** To increase the profile, recognition and sustainability of EDCTP activities EDCTP should consider putting more resources into engagement activities including with key stakeholders in SSA, such as policymakers, vice chancellors and health systems managers. This would assist principal investigators and allied researchers in ensuring projects function with minimal delays and with maximum buy-in from relevant stakeholders. In addition, such engagement would also help promote the (flexible) Sida approach to funding. Finally, to make sure that its funding partners are recognised and made visible, EDCTP could consider expanding it's recent developments (funding acknowledgements requirements, and generic acknowledgments) that are contractually required for new grant holders as a request to holders of grants that started earlier.

A final area of contention in some projects has been the difficulty of getting Euro bank accounts and/or specific project bank accounts for funds. The former has led to significant issues in terms of the overall funding that is actually available as a result of devaluation of currencies/ exchange rate fluctuations. The latter has led to significant delays in project start times when receipt of funds to project coordinators from central administrated bank accounts occurs.

**Recommendation:** To reduce administrative burdens associated with projects, funds should be disbursed where possible direct into specific Project Accounts rather than into general accounts of government departments or host institutions. In addition, to mitigate against financial risk associated with project funding, EDCTP should strongly encourage where possible project specific bank accounts in Euro. It seems likely that this would reduce the bureaucracy associated with draw down of funds and would increase project related efficiencies.

A number of the projects use social media and/or online document sharing platforms to ensure all partners in the consortiums have access to documents and receive news and updates about the project.

# **1.3.3** Are project management systems and procedures in place within EDCTP to monitor funded projects/ activities?

EDCTP has a series of policies and procedures that occupy the grants management process. These include:

- 1. SOPs document for the grants management process
- 2. Financial Management Assessment Questionnaire
- 3. Site Visits
- 4. Audits of projects
- 5. Risk register and regular review
- 6. Various committees and review boards with functioning minuting system

The EDCTP Audit Committee at their October 2017 meeting noted that asking for financial reporting only after one year does mean that potentially financial issues arising in projects are not known about immediately on their occurrence. This was also raised in the May 2018 Audit Committee meeting where it was explained that projects often have their own interim reporting deadlines. This was also noted during our interviews and review of reporting materials received from several project coordinators during the course of this SSE.

**Recommendation:** To increase the quality of evaluation, monitoring and communication between EDCTP and researchers we recommend adding a light touch six month review meeting/ report so that EDCTP are aware of any issues and support needs.

A side point that relates to project management of funding by Sida relates to the issue of the ability of EDCTP to utilise the Sida funding more flexibly than other forms of funding as noted earlier (in the background section and EQs 1.1.2 and 1.1.3).

OBJECTIVE 2: ASSESS THE RESULTS OF SIDA FUNDED PROJECTS SO FAR (INCLUDING AT OUTCOME AND IMPACT LEVEL, IF APPLICABLE) AND THE EXTENT TO WHICH THESE CONTRIBUTE TO PROGRESS AGAINST EDCTP'S OVERALL STRATEGY AND SIDA'S OBJECTIVES IN PROVIDING FUNDING TO EDCTP, PARTICULARLY IN RELATION TO THE RESEARCH AND RESEARCH CAPACITY BUILDING NEEDS OF LOW INCOME COUNTRIES IN AFRICA.

### 2.1 WHAT ARE THE IDENTIFIED OUTPUTS, OUTCOMES AND IMPACTS OF INVESTMENTS?

## 2.1.1 How do those identified in initial grant proposals match reality?

As noted above in EQ 1.2.1 the proposals reviewed – and funded in some way by Sida funds – all included a variety of outputs, outcomes and expected impacts from the investments being requested. In addition, the review process is very specific about ensuring that grant proposals meet the criteria outlined in the call; which are increasingly more specific about the types of outcome and impacts EDCTP is looking for.

It is difficult to make an assessment as to the degree to which projects have met their outcomes and impacts because (a) only three Sida funded projects have completed and the majority are only in their second year and (b) there is not always a clear indication of 'outcome' and 'impact' in proposals when defined using the definitions taken from the OECD/ Sida M&E guidelines and EDCTP's own M&E document which focuses on achieving a set of more 'developmental' goals around improving livelihoods. As noted earlier this is because the focus has been predominately on an intermediary stage of impacts linked increasingly to three pathways of change around clinical research, capacity building and (less in the case of Sida funded project activities) coordinating partnerships.

These intermediary impacts would most likely be termed by many theory of change practitioners as 'outcomes' because they are still predominately within the control of the project actors.

The difficulty for EDCTP of focusing purely on these pathways of change; on these outcome areas as opposed to more downstream impact raise questions around, for example, how to get clinical research to the bedside in the form of commercialised drugs or vaccines or how improved ethics guidelines lead to increased community engagement in research. Similarly, questions around how training researchers in PhDs leads long term to increased clinical research capacity and ultimately to reduced disease burden. The difficulties of answering these questions is something that was raised in all the wider stakeholder interviews we have conducted. There was a very clear understanding that the role and function of EDCTP was a difficult one and that it was going to have to find a way of meeting two competing but also complementary agendas relating to immediate clinical outcomes focus and longer term disease burden impact.

Several of the RIA interviewee the SSE team spoke to recognized the ability to conduct sub-studies as a relevant aspect of the project, including studies to better understand diseases processes, as well as studies on feasibility and cost-effectiveness: what is needed to persuade the ministry of health to adopt that intervention. They recognised that these are important to translate findings to policy.

EDCTP appear to be actively trying to address this. For example, the SSE team became aware during the evaluation of a CSA call on health intervention delivery systems in 2018. (<u>http://www.edctp.org/call/capacity-development-to-facilitate-delivery-and-uptake-of-new-or-improved-medical-interventions-in-african-health-systems/</u>). From this call, one project selected (PROFORMA) has received Sida funding. PROFORMA is working towards building pharmacovigilance structures and post-market surveillance systems in East Africa.

Additionally, it should be noted that one PI interviewed sees EDCTP as increasingly playing an absolutely crucial role in moving big picture agenda's forward. Because there are so few funders that fund large scale definitive trials, the confirmatory type of trials. The trials that are funded by EDCTP are game changer type of studies, which drive policy in the field of malaria prophylaxis, treatment, burden reduction. "So, without EDCTP2 and beyond that would be a disaster for malaria."

The extent to which EDCTP should reorient its activities to achieving broader health systems goals, rather than maintain a focus on R&D, research more broadly and innovation was the subject of significant disagreement between external stakeholders interviewed. For most of these stakeholders, the current move towards expanding the research agenda into key areas related to building capacity in clinical trials and research related to medical interventions was considered broadly the right course. One interviewee noted that EDCTP could be more nimble

and responsive to changing contexts and issues (climate change for example) and this would allow for more relevant outcomes and greater impact. Two interviewees felt that this move had to be much more radical than it has been too date with development related activities to support SSA health systems being part of EDCTP's mandate and mission.

# 2.1.2 What is the role of the project review process in ensuring fit with objectives in terms of impact?

As noted above during the project proposal call stage there is a clear outline of the importance of considering impact; and as of 2019 there is a focus in call documents on the three pathways of change that work towards EDCTP vision of reduced burden of poverty related diseases (PRDs) in Sub-Saharan Africa:

- i. Clinical research: producing and disseminating high quality and relevant PRDs research results.
- **ii. Capacity development**: enhancing capacity for both regulating and conducting high quality and relevant PRDs research.
- **iii. Coordination and partnerships**: promoting synergies and efficient use of public resources, as well as enhancing PRDs research impact prospects.

The EDCTP has also developed a Monitoring and Evaluation Guiding Document which – as of late 2018 – includes a specific results framework document for CSA grants relating to ethics and regulatory issues. In fact, the interviews with externals highlighted that Sida's intervention with EDCTP was a facilitating factor for moves towards this broader agenda.

According to EDCTP's SOPs for grants management during the project proposal review process, reviewers are expected to score for the criteria of 'impact'.



Figure 2: Placement of EDCTP and Sida objectives against the EDCTP Theory of Change (source: authors)

The SOPs document also outlines that during periodic technical review of projects (usually on an annual basis), PIs are expected to complete a "questionnaire covering issues related to the action implementation and the economic and societal impact, notably in the context of the key performance indicators and monitoring requirements." (SOPs Document, page 54). In addition, final close out of projects must include a final technical report that demonstrates the "socio-economic impact of the action" (SOPs document, page 55).

This is in line with a pilot initiative being undertaken by EDCTP with CSA ethics grants that requires these grantees to try and comply with wording in the EDCTP M&E Guiding Document (page 39) which states that "Grantees must provide an update on the results framework with each Periodic and the Final Report."

However, as made clear above in EQ 1.2.1 not all progress reports appear to provide details of socio-economic impact or updates on results frameworks; because many do not include a dedicated results framework in their original proposals.

The EDCTP Results Framework (see Figure 2) matches well with the EDCTP objectives and could be seen to map onto Sida's Research Cooperation priority areas – although the interpretation of the level of impact expected from the objectives differs; in part due to the semantics used in developing the wording of the objectives/ strategic results areas.

## 2.2 How well do Sida supported projects align against EDCTP strategic objectives?

# 2.2.1 To what extent does Sida funding contribute to developing new, or progress existing, medical interventions?

This question is most applicable to the RIA projects (of which 11 have received Sida funding by end September 2019). Of these 8 clearly involve clinical trials (1 is a Phase I trial, 1 is a Phase I/II trial, 1 is as Phase II trial, another is a more specific Phase IIb trial and 2 are Phase III trials plus 2 projects that started in 2019 where we are not sure what stage trials are being conducted as we have been unable to view the project proposals as yet). The other projects (n=3) are more complex in their activities being involved in setting up networks to conduct clinical trials and/or setting up a series of intervention trials.

Four of the RIA projects that have received Sida funding are investigating new medical products. One is investigating the use of an existing licenced product for a new use while a further two projects are testing novel candidates.

In addition, six of the 10 TMA projects that have received Sida funding are also progressing clinical trials.

The extent to which research works towards developing or progressing medical interventions relates to the issues of outcomes and impact in the previous section (when a broader definition of medical intervention is used).

## 2.2.2 To what extent does Sida funding contribute to the development of research guidelines?

During review of grant proposals it appears that all but one (CSA2016S-1618 – PROFORMA, mentioned above) of the CSA projects that have received Sida funding contribute to the development of research or clinical guidelines or a technical review. In addition, a number of the RIA projects are expected to contribute to research guideline development or revision. That said, not all the RIA proposals are clear on this, as some are dependent on the findings of the clinical trials and the degree to which research findings from the trials/ studies are taken up by other stakeholders.

Reviewing the progress reports of the CSA projects we find that 2 out of 4 projects have demonstrated improved guidelines nationally while others are still to make an impact. In one instance the time for ethics review has been reduced as a result of the project intervention. However, there has been a significant issue with ensuring buy-in and consensus building with all stakeholders. This resulted in the one CSA project that has completed (CREDU) not being able to achieve one of its objectives relating to the establishment of a coordinated national framework on clinical research. It was noted that a longer timeframe for the project would have been required.

# **2.2.3** Are Sida funded projects on course to increase research capacity in African health research facilities (numbers and expertise, across countries)?

The following quote from one of the PIs interviewed highlights the complexity of capacity building efforts being undertaken by EDCTP:

"Both, because we collaborate with Northern partners. For the Northern partners what is important is to have scientific publications in high impact journals, so that is what they want. But for us, in Africa, what we want is to reduce the burden of diseases, we want to train people, we want of course to have also publications for being able later to apply to new grants, so yea, in these projects we have so many partners, we want both. I would say, European partners want publications for their institutions, and for us we want to train human resources and we want publications. We want both, high quality science and we want to see people trained."

This tension is widely noted in other research contexts and for some implies a need for SSA to develop its own criteria for research excellence (Tijjsen and Kraemer-Mbula, 2017). EDCTP comes at this issue from a slightly different angle but its growing support for capacity building is acknowledging the need to try and tackle questions of excellence vs. equity and criteria used in evaluating success.

A review of grant proposals and progress reports, highlight that many of the projects that have been supported with Sida funding in the TMA but also RIA and CSA categories will build capacity on the ground in African research facilities/ universities or in other stakeholder group organisations (e.g. government ministries of health in the case of ethics training).

The 2018 EDCTP report to Sida (page 21) notes that:

"Longer-term capacity support for 108 SSA researchers in the form of degree training, postgraduate training and career development training has been provided through the EDCTP TMA scheme, as well as integrated in the RIA and CSA grant schemes. 67 SSA researchers have been supported through ongoing/completed TMA fellowship grants with a further of 22 in the process of grant agreement preparation. Excluding the individual fellows themselves, an additional 41 SSA researchers were supported towards an academic degree, postdoctoral training and other forms of long-term training (diploma, certificates and internships).

Equally, EDCTP beneficiaries reported 108 short-term trainings and workshops that have trained almost 2000 individuals in total."

In this evaluation however we have focused specifically on projects that have received Sida funding within the RIA, TMA and CSA project lists. The details that have been identified so far are outlined at a very high level only in Table 14 below.

	RIA	ТМА	CSA
Infrastructure	3	1	
Individual capacity building (Masters, PhD, post-doc opportunities etc.)	6	10	3
Other forms of capacity building (e.g. short courses)	9	10	7

## Table 14: Research capacity building through research projects.<sup>10</sup>

There was overwhelming support across the board from interviewees that EDCTP's capacity building efforts should be commended and continued. Some went as far to say that EDCTP was filling a gap that other funders were enlarging (as they moved away from supporting dedicated capacity building efforts through their funding of research projects).

What can be noted at this time is the following:

 All RIA Masters and PhD training is taking place at European Universities (apart from one PhD which appears to be a joint PhD between University of Cape Town/ Institute Pasteur) whereas the most TMA grants are focusing on PhD and Masters training at the home (African) institution (although often with co-supervision support from Northern based colleagues). One CSA project has a PhD programme in Sweden; the others are more concentrated in local universities in Africa. The reason for the focus of training at universities outside Africa appears to be the result of a lack of capacity or quality of programmes in African universities.

<sup>&</sup>lt;sup>10</sup> We have not been able to review the project proposals or final grant agreements for the two projects funded in 2019 and therefore these two projects are not included in the figures here.

- 2. It is not overtly clear in four of the RIAs, from the documents reviewed, if individual capacity building will take place
- 3. The degree of institutionalisation of most of the short courses that are being offered is unclear. One TMA project (TMA2016SF-1508) clearly states that through the funding received a 1.5 year Masters programme and the development of a five-week course on Genomic Medicine will be introduced to the university (which one assumes will continue after the project has completed). One of the CSA projects is working to build capacity on undergraduate and Masters level in one East African country.
- A number of the projects allude to longer term institutional improvement in clinical trial capacity or setting up of new research groups. It will be difficult to determine how sustainable these activities will be (given the timeframe of this evaluation).
  - 4. Support to research infrastructure is not a major element of the projects funded. Of the RIA proposals three projects have<sup>11</sup> clearly indicated a request for infrastructure support e.g. building mobile labs.

PIs interviewed, and review of materials received, mention different 'mechanisms' of research capacity building: i) Research degrees for individuals (MSc, PhD), ii) Strengthening institutions to run clinical studies, iii) promoting intellectual/scientific leadership, iv) Other activities.

## • Research degrees for individuals (MSc, PhD)

Most RIA and TMA projects include MSc or PhD programs for several African researchers, or research within the project serves as research for PhD fellowships. In some, European researchers who work on the project also pursue a PhD on the site. Several PhDs are linked to sub-studies built around the main research project. The sub-studies themselves aren't deemed by interviewees as different from other funders per se; however it was noted that few funders allow sub-studies to include associated PhD students.

## • Strengthening institutions to run clinical studies

There was a significant level of acknowledgement across interviewees from RIA, TMA and CSA that EDCTP grants provided capacity building at an institutional level in terms of building up capacity of individual organisations and/or groups of organisations to run or oversee (including regulate) clinical trials and clinical research projects. It was noted that it wasn't just PIs or even finance managers whose capacity was built but *"fieldworkers, through to qualitative researchers, data managers."* 

Perhaps most important, one interviewee from a TMA project stated that the funding 'keeps us at home' and helps researchers find a place within their home institution where they can remain research active. This was also noted by at least one other interviewee from the RIA projects in terms of how their tracking of EDCTP grants over time have showed how involvement by a PhD student in one project led to them remaining research active (usually in future EDCTP grants as post-doctoral fellows). Finally it was noted by a number of interviewees that PhD students were often 'bonded' to their institutions post their PhD studies so that they would 'give back' to their institutions for the opportunity of being able to do a funded PhD. This was deemed necessary to ensure institutions benefited from capacity building efforts.

It was noted that it wasn't easy often to try and build individual capacity because of the structures in place in countries. It was noted by several interviewees that the academic training and career progression structures in many African countries remains weak; reducing the options for those engaged in these projects. As a result, while some do feel these projects help them stay; one other interviewee noted that it's still very difficult to retain staff; especially when they go to the UK or US for training.

In addition, there was acknowledgement of the difficulty of measuring the impact of capacity building at an institutional level.

A few interviewees focused on the importance of infrastructural support as a way of building institutional capacity while others talked of institutional infrastructure capacity building in terms of network building connections that were made possible by EDCTP grants, reflecting substantial variety in capacity levels at the different institutions.

<sup>&</sup>lt;sup>11</sup> As with footnote 11.

Institutions that have over time been able to develop advanced clinical research capacity, become attractive partners for collaborative industry sponsored clinical trials in disease areas that are new to the site.

# • Promoting intellectual/scientific leadership

There was acknowledgement, especially in the RIA interviews – and to a lesser extent in the TMA proposals and progress reports – that many of the Sida co-funded projects result in building scientific leadership skills as a result of provision of opportunities to lead projects for African based researchers. Less than two-thirds of the co-funded project PIs are African based PIs, a figure that should increase, especially for female PIs, who lack behind in benefiting from Sida funding (see Table 4). At least one PI interviewed stress the need to do more to bring to the fore more female investigators and their ability to become independent researchers.

It was noted by one interviewee that becoming a leader in scientific research was not just about writing successful proposals or scientific papers but knowing *"how to discuss with ministers, to build trust with local stakeholders, to build trust in the community"* and stressed that this was learnt 'on the job' i.e. often not through formal training.

It was noted by at least two interviewees that it was the responsibility of PIs to build capacity of collaborating groups but that this places an additional burden on projects; which often wasn't sufficiently budgeted for in the original proposal (e.g. cost of transferring knowledge and skills relating to financial management often wasn't budgeted for).

It was noted by a number of interviewees that the longevity of funding available through EDCTP (the opportunity of receiving funds for follow up projects through EDCTP 1 and then 2) has provided the time frame for building scientific leadership capacity.

## • Other capacity development effects

Several interviewees noted that there was capacity building beyond formal training and that learning occurred in a wider setting – often informally and as an unintended consequence of research activities e.g. TB diagnosis techniques become known by a wider range of stakeholders involved in the trial and beyond and not just the funded trial staff.

Furthermore, a few interviewees noted that capacity was built in terms of policy influencing and/ or advisory board capacity to consider national policies and how they impact on the research project.

One interviewee specifically mentioned an initiative within their project to strengthen linkages across African institutions. This is because they had found that African researchers had more established linkages with European or US researchers than with those in their own country or next door countries. This is also mirrored to a certain extent in the make-up of the projects as per the findings under Objective 1 above.

Finally, one interviewee noted that in one of their partner countries the research funding from EDCTP was creating a situation where medical students were becoming interested in careers in research; because a cohort of medical epidemiologists was starting to become established and get known in the country for the work they were doing.

## Other support

Due to the lack of detail available on the Joint WHO-AFRO/TDR/EDCTP Small Grants that have received Sida support it is not clear the extent of research capacity building support that is being provided through these; beyond the very important role of giving early career researchers the opportunity to gain principal investigator experience. It is also unclear from the documents received and interviews conducted whether there is any additional capacity building support provided to the grant holders (e.g. training on project reporting, publishing, influencing policy makers with research etc.). The interviews with small grants holders held also revealed that many were surprised by the fact funding came from EDCTP and one even stated that they had never applied to EDCTP before because they thought they only funded clinical trials. One interviewee noted that the small grant had enabled them to build capacity of communities in malaria prevention. A couple of interviewees noted that this was their first grant and therefore a useful opportunity for them to lead skills in project leadership – many noted that they had actually miss judged their budgets when they wrote their applications and that they would revise how they wrote their budgets in future proposals. In interviews conducted with wider stakeholders it was noted that WHO and EDCTP have not always found it easy to work together due to administrative complexities.

Finally, the Open Source Platform is a resource in and of itself is designed to provide information on open access data sharing, data management and clinical trial protocols relating to research (clinical trial) projects. The platform was launched in late 2018 but we have found no data with regards to initial uptake and use (e.g. web statistics on

visits; reviewers from visitors etc.). As such, we are unable to assess the level of capacity built through this platform at this time.

# 2.2.4 Are Sida funded activities resulting in growth in expertise in ethics (numbers of experts and functioning regulatory bodies)?

While a number of RIA and TMA projects support some level of ethics training, the majority of EDCTP support in this area (and by virtue of this, where Sida funding is committed in the area of ethics) is in the CSA projects. Of these, four countries in West Africa and three countries in East Africa are the target for this work (note: Kenya in East Africa is actually the focus of two projects). Three of the seven CSA projects do this through a focus on pharmacovigilance; four projects focus solely on research ethics training and capacity building – three are also creating regional networks.

It is unclear if any of the Joint WHO-AFRO/TDR/EDCTP Small Grants supported have a focus on research ethics. There are a number of documents stored within the Open Source platform that are classified as ethics related documents. A review of the programme of the Ninth EDCTP Forum found that it contained 1 paper parallel session, 1 poster session, 1 workshop session and a 'meet the experts' session that all focused on research ethics.

# 2.2.5 Are these Sida funded projects and activities leading to increased cooperation and funding from a wider group of partners?

Sida's funding has increased cooperation across all projects that involve multiple partners – by the very nature of the consortium type projects that are funded by EDCTP. However, in addition, the CSA projects funded in part by Sida funds are leading to the creation of new networks of ethics and regulatory experts and/or the connection of national level regulatory and ethics networks with regional and global networks.

The same can be said of the TMA projects that receive Sida funding. For example, the PRACE project has built a network of scholars around a new post graduate training course, notably between local and international faculty who teach on the course. It also engages with other networks such as SPARKS and has become involved in conducting clinical trials for two multinational pharma companies.

Some of the projects are dedicated to building South-South networks e.g. CTC-TEC while the majority are North-South in focus (although may include elements of South-South cooperation and networking within them).

It was noted by one interviewee that EDCTP funded projects in the South could learn from linking with Asian research institutes which are significantly more established (and so expand the number of countries that are allowed to participate).

EDCTP has leveraged private sector funding and funding from elsewhere (as noted in EQ 1.1.2) but it is not clear if this has been the result of Sida funding.

That said it was noted by one interviewee that there was a need for EDCTP to play a bigger role in brokering relations with other networks; e.g. with the African Academy of Sciences. In addition, as noted during the discussion above on the building of ethics capacity there is a need for buy-in to build networks and partnerships and this is not easy and takes time. It needs significant awareness creation and understanding as to why the network is important.

It has also been noted by several interviewees that projects have worked better where there have been existing collaborations i.e. where partners have worked together before.

Finally, as noted above in EQ 1.1.2, these projects have led to co-funding being leveraged in the region of  $\notin$  309.59 million from third parties.

The discussion above has been focused on the project level partnerships and networking that has occurred as a result of the project funding. However, EDCTP has a broader role in bringing together stakeholders and in leveraging funding at a global level. The support Sida provided for the Ninth Annual Forum is part of these efforts to bring together different actors and provide opportunities for dialogue and discussion.

Comments from two external stakeholder interviewees focused on the need for EDCTP to engage much more extensively with Southern partners. Both of these interviewees thought that the limited nature of most SSA countries to contribute significantly is linked to the limited extent to which LIC and LMIC partners set the agenda for EDCTP work. One thought that EDCTP could achieve more by spending more time and effort with policymakers in SSA, explaining the EDCTP programme and do what can be done to adjust research programmes. However, both
interviewees considered that EDCTP's mandate was limiting and for one, structural constraints associated with EDCTP's relationship with the EU prevents the depth of partnerships that EDCTP can form with Global South country partners.

One interviewee noted that the partnership between WHO and EDCTP was limited due to administrative complexities.

For one interviewee, the main challenge in relationship to partners was the nature of strategic planning and integration between European countries. For this interviewee, European countries should be much more prepared to align their entire global health and international development research funding. This would reduce duplication and waste. This interviewee thought the European Commission would become more insistent on greater levels of integration.

### 2.2.6 Are the activities leading to increased activities and/ or more awareness among European stakeholders?

Sida funded activities in EDCTP 2 are focused on contributing towards the funding of RIA, CSA and TMA projects together with funding of the Ninth Annual Forum and the Open Platform. In these activities, the Ninth Annual Forum brought together a wide range of European stakeholders. A review of the participants list shows that there were 262 participants from Europe (47% of the total participants) who participated as speakers, paper presenters, SAC members, students, guests and EDCTP staff. They came from the private sector, research institutions and universities, product development partnerships, international development partners, UN and EU organisations as well as a couple of EU government ministries.

The RIA, CSA and TMA projects involve significant European partners. Predominately European based universities and research institutes but also a couple of biotechnology/ pharmaceutical companies.

We have not investigated EDCTP's broader activities in bringing together European actors because these have not received Sida funding.

2.3 How well does EDCTP and its funded projects utilise Sida funding to meet the needs of Sida's research cooperation areas?

### 2.3.1 To what degree does Sida funding build capacity in LICs?

The details of the capacity that has been build is captured in EQ 1.1. and 2.2. Sida funding has provided support to 16 LICs as outlined in Table 15 below.

#### Table 15: LICs supported

Burkina Faso	Mali
Central African Republic	Mozambique
Democratic Republic of Congo	Sénégal
Ethiopia	Sudan
Gambia	Tanzania
Guinea	Uganda
Madagascar	Zambia
Malawi	Zimbabwe

Many of these countries (notably Uganda and Tanzania) have received funding for multiple projects and organisations. Of particular note, a project in Sudan (despite being suspended due to country instability) is a great example of a female led project in an LIC – the PI of the project and her co-investigators are all female in Sudan.

A key part of this element of Sida's strategy is science communication and there is some evidence from the interviews of at least one project that has focused on communications with communities around clinical trial research. More generally, all the projects funded by EDCTP include a communications plan in their proposals.

# 2.3.2 Does Sida funding support projects/ activities that meet national, regional and global priorities (neglected disease interventions but particularly in terms of human capital in health research and ethics)?

With the time available for this SSE it was impossible for the team to do a thorough analysis to answer this question. However, it is clear that all the projects that have received Sida funding fit completely with EDCTP's priority areas (with the possible exception of a project on snakebites – see EQ 1.1.2). EDCTP's priority disease areas are revised annually and are based on advice from experts within the Scientific Advisory Committee (SAC). That said, a very brief analysis of two selected LICs (first country from West Africa and first from East Africa in alphabetical order) where projects that have received funding from Sida highlights that some funding is more targeted to national level disease burden but not all (see Table 16).

In addition, there is no explanation of how the EDCTP research priorities are chosen/ amended each year i.e. what methodology is utilised. Therefore, it is less than clear as to why certain decisions are made – although it is clear that trade-offs between meeting national disease reduction strategies, regional disparities in disease burden within countries, broader systems levels goals (such as building ethics capacity)and scientific relevance are needed.

	Ethiopia	Burkina Faso
Global Burden of Disease 2017 report – 5 highest listed (healthdata.org; accessed 12/11/19)	<ol> <li>Neonatal disorders</li> <li>Diarrheal disease</li> <li>Lower respiratory infection</li> <li>Tuberculosis</li> <li>Ischemic heart disease</li> </ol>	<ol> <li>Malaria</li> <li>Lower Respiratory Infection</li> <li>Neonatal disorders</li> <li>Diarrheal disease</li> <li>Ischemic Heart disease</li> </ol>
Research focus of projects funded	Visceral leishmaniosis Ethics review process Malaria treatment in pregnant women	Malaria

### Table 16: Global Burden of Disease and where Sida funding is allocated

# 2.3.3 To what extent does EDCTP2 Sida funded activities focus on the promotion of research that, through innovation, can contribute to poverty reduction and sustainable development?

EDCTP projects that have received Sida funding do contribute to poverty reduction and sustainable development if the assumption holds that medical research and research capacity building are a valid poverty reduction strategy. An assessment of the extent to which the assumption holds is beyond the scope of this SSE, and subject to complex pathways between research and health and poverty.

On the one hand a lack of dedicated results frameworks in project proposals or (where they exist) that consider poverty reduction and sustainable development as an end goal means that it is difficult for us to be able to answer this question. That said, EDCTP's results framework does speak of poverty reducing diseases.

A word search conducted of project proposals found that 'poverty-related diseases' or similar terminology was used several times in most RIA proposals but less so in CSA and virtually never in TMA proposals (a total of 10 proposals out of 26 proposals reviewed). Only three proposals reviewed actually made reference to how clinical trial research or improved health can reduce poverty and/or ill health was caused by poverty. There was a similar lack of acknowledgement of sustainable development terminology in proposals. Where the word sustainability was mentioned it was often in relation to building sustainable staffing (approx. four proposals) or infrastructure capacity or in building sustainable health delivery systems (approx. 8 proposals). One proposal mentioned the term 'sustainable development' and another 'the sustainable development goals' but without going into detail. Another proposal talked of how the project would be related to building sustainable agricultural systems and industrialisation strategies.

However, a key issue – raised by stakeholder interviews and through review of project proposals is that much of the work being conducted and funded (including with Sida funding) is not 'innovation' activity; it is not downstream commercialisation activities – as the term innovation refers to. It might be possible to argue that the few projects involving private sector partners (some of which have received Sida funding – see EQ 1.1.2) are potentially working towards building a pathway to commercialisation but there is no clear indication of this in proposal proposals.

One of the issues here may be the difficulties in pinning down EDCTP's mission. There are different wordings of it in different places. And while statements about EDCTP's overall strategy and intent of EDCTP can be found in various strategy documents and in a forward looking document entitled *EDCTP2: A forward-looking EDCTP Portfolio Analysis for period 2019-24,* there is a lack of coherence across the documents.

For example, on the EDCTP website the wording is as follows:

### "Mission

EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in sub-Saharan Africa."

On the other hand, the mission written in the 2018 v2 Strategic Research Agenda document is worded slightly differently:

"EDCTP's overall mission to accelerate the development of new or improved medical interventions against poverty-related neglected diseases and enhance research capacity."

Both of these definitions are much narrower than the objectives of EDCTP outlined in Annex 1 (and taken from the EDCTP current Strategic Plan).

**Recommendation:** In order to enhance clarity around evaluation criteria, EDCTP should work to align its internal strategy, mission statements and evaluation approaches. This requires further discussion with stakeholders including Sida and other donors. EDCTP could consider how best to conduct a dialogue with partners and participating states on the extent to which its mandate and results based framework includes an emphasis on broader societal impact. There is an important issue about the extent to which responsibility for the broader mandate should lay with EDCTP and partners or directly with researchers and associated resource implications.

**Recommendation:** In relation to the implementing decisions associated with the above recommendation, EDCTP should consider revising the grant call process to ensure clear requirement for the results based framework and theories of change to be included in all proposals. The evaluation team recognises that this is potentially a recommendation with far-reaching consequences and may involve operational and cultural shifts. If a decision to deepen outcomes and impacts work is adopted significant training and support might be needed, especially for African universities and research institutes. The training and support would depend on the type of approach taken in implementing this change. For example, one option for clinical research projects is that grant proposals and reports should contain enough information that allows EDCTP to meaningfully place the clinical research within a results based framework and theory of change. For capacity building activities it would be useful if grant proposals could provide a framework or plan of how the proposed capacity building activities in a proposal contribute to a larger institutional capacity development goal/plan/policy, and outline related risks, assumptions etc.

OBJECTIVE 3: ASSESS THE EXTENT TO WHICH SIDA'S CONTRIBUTION HAS SO FAR CONTRIBUTED TO AN IMPROVED GENDER BALANCE IN THE AREAS OF RESEARCH SUPPORTED BY EDCTP

3.1 How has Sida support contributed to women's active engagement with research?

## 3.1.1 How have Sida funded projects incorporated female researchers and support staff?

Under EQ1.1.1 above we have outlined the number of female PIs that are working on Sida funded projects through EDCTP2. In addition, a review of the progress reports and grant proposals for the RIA, TMA and CSA projects highlight the following composition of research staff (and non-research staff where findings are available). Unfortunately, we cannot guarantee that these figures are accurate as a number of projects did not include details allowing us to make this level of breakdown. However, the figures provide an indication of the gender balance across the projects funded by Sida and suggest an aggregate average across the board of 43%.

### Table 17: female researchers by country classification

	RIA	CSA
Proportion of female researchers from HIC	46/111 (41%)	5/12 (42%)
Proportion of female non-researchers HIC	23/35 (65%)	1/6 (16%)
Proportion of female researchers from LDC/LIC/LMICs	92/196 (47%)	7/42 (17%)
Proportion of female non-researchers from LDC/LIC/LMICs	130/277 (47%)	5/11 (45%)

We have not included a column for the TMAs in Table 17 however we note from SAC minutes of 21 May 2019 that of all the TMA fellowships (not just those funded by Sida) 37% (40 out of 109 fellows) are female. We have already recorded in EQ1.1.1 that 3 of the 10 TMAs supported by Sida have female PIs of which one is based in an LDC/ LIC or LMIC.

It should be noted that some projects are predominately female run (Enhancing Ethics in Sudan) and we have not been able to include data for the two projects that started to receive funding in 2019 (PREGART and Simplici-TB).

At this point we have no data on the gender composition of attendees at the Ninth EDCTP Forum meeting.

We have been able to ascertain that data is available on EDCTP's review panel make up. For example, the 2018 Annual Report to Sida by EDCTP provides information that their 2018 expert review panel (who reviewed grant proposals received in the 2018 call for proposals) was made up of seven female experts and one male expert. In addition, a review of the Scientific Advisory Committee meetings highlights a call from the SAC for EDCTP calls to be required to include females as investigators (with clear roles to be outlined in the proposal); focus more on training women in the early stages of their careers and encourage institutions to promote female candidates for fellowships. They have also requested EDCTP to ask institutions about their policies on gender equality. The March 2018 SAC meeting also recommended that EDCTP commission an in-depth study (i.e. qualitative assessment) to understand the barriers encountered by female scientists. It is not clear at this stage in the SSE if this study has been commissioned as yet. That said, another study analysing the gender balance in evaluation procedures managed by EDCTP over the period December 2014 (start of EDCTP2) to August 2019 has been conducted.

# 3.1.2 Has Sida support enhanced the careers of female researchers and research support staff?

We have no data to answer this question. Unfortunately the interviews and data reviewed have been unable to sufficiently provide information on this specifically for Sida co-funded projects within EDCTP2. However the observation of one PI of a RIA grant consortium that builds on a decade of collaborative EDCTP funded projects suggests that enhancement is going on: "at all of the sites we do see young female researchers who are taking on their role and engaging in this study and learning".

### 3.1.3 How far has EDCTP2 Sida funded activities improved gender equality perspective in research?

We have not been able to investigate the degree of training given to researchers on gender equality and/or how to design research taking into account gender equality issues.

Pandora has a significant gender element to its research design. As noted by the PI:

"We do sensitization in schools, we organized also conferences to share where the problems are, why so few female scientists, to try to change the stereotypes. In the cities we put big posters and publicity on our project, PANDORA, but with the gender issue, with a sentence and so on, in the city everywhere, and people are really surprised, and now start to discuss: Oh, there are so few women in science... We also we have TV and radio discussion on that issue with journalists. At the university we organize discussions, so that what we do, and it works.

In our management we recommend to all our partners within the project that when there are two candidates/CVs with the same competence, to give preference to the female. But only with equal competencies. And we really encourage young female scientists to remain in science and to apply for specific grants. We collect informations from L'Óreal, from different journals. And we send within the network and push young women to apply for these grants. So we really have this gender program."

In another programme, it was noted that they also work with young women in schools and "get to see that science is within reach". The interviewee noted that two girls who had been involved in the programme had been accepted into medical school.

### 3.1.4 Is EDCTP gender aware in its operations?

The SAC has a working group that is working on gender and therefore a number of outputs are being commissioned/ have been released. The EDCTP are increasingly keen on reporting results of their work by gender (as noted by fellowship gender figures included in the 2018 Annual Report and M&E framework document which includes indicators disaggregated by gender). That said, it appears only two indicators are collected on a routine basis disaggregated by gender: one on gender breakdown of fellowships granted and; one on lead author of peer reviewed publications resulting from EDCTP grants/ activities.

**Recommendation:** In order to enhance monitoring of gender equity impact of EDCTP funding, EDCTP should consider implementing gender-aware measures to track career progression of EDCTP funded researchers and alumni. More generally, career tracking of recipients/ trainees of EDCTP grants may assist in determining impact over a longer period of time.

In addition, we note that the SMT of EDCTP is all male although there is a significant number of female staff in the rest of the organisation.

**Recommendation**: EDCTP should consider measures to correct the gender imbalance between the EDCTP senior management team and EDCTP secretariat.

# **3.1.5** What are the barriers and opportunities to improving female involvement with research (as researchers, participants or community bystanders)?

The issues outlined in EQ 3.1.4 above are those that the EDCTP SAC are aware of and they are working to address this balance including commissioning reports as outlined above. One external stakeholder interviewee noted that the scientific advisory committee is keen to look at barriers and opportunities for female researchers but to date there is limited evidence on this point. One interviewee noted that EDCTP might provide re-entry grants for researchers who have taken childcare related research grants. Tackling implicit bias is a priority and the working group will consider ways in which to do this.

**Recommendation:** EDCTP should continue to support the activities of the SAC working group on gender and provide a clear indication in annual reports of the way in which working group recommendations have been considered and acted upon.

**Recommendation:** In order to facilitate gender equity goals, EDCTP should consider providing back to work grants to help those who have taken child care related career breaks.

This report has outlined the results of an independent assessment of Sida-supported projects within the scope of the EDCTP2 programme. Specifically, the evaluating team has:

- Assessed the status of project implementation to date of Sida-funded projects, including project management, and the likelihood of successful completion
- Assessed the results of Sida-funded projects so far (including at outcome and impact levels, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy, particularly in relation to the research and research capacity building needs of low-income countries in Africa
- Assessed the extent to which Sida's contribution has so far contributed to an improved gender balance in the areas of research supported by EDCTP

We have found EDCTP2 programme has utilised Sida funding effectively. A large reason for this is the flexibility this funding has in terms of what types of activities it can be spent on and when. The funding has been used to support research projects in Africa that have involved a large number of female PIs and work in low and low middle income countries.

The key issue that has been raised by this evaluation is the need for further discussion of how to match EDCTP's vision, mission, objectives and activities funded; notably how far it attempts to directly impact the reduction in the burden of poverty related diseases (PRDs) in Sub-Saharan Africa (the EDCTP vision).

### ANNEX 1: EDCTP AND SIDA OBJECTIVES

#### **EDCTP Overarching Objectives**

- 1. Increase the number of new or improved medical interventions for poverty-related diseases (PRDs), including neglected ones
- 2. Strengthen cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, EU and international legislation
- 3. Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments
- 4. Extend international cooperation with other public and private partners to ensure that the impact of all research is maximised and that synergies can be taken into consideration and to achieve leveraging of resources and investments
- 5. Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance.<sup>12</sup>

#### **EDCTP2 disease priority areas**

- 1. HIV
- 2. Tuberculosis
- 3. Malaria
- 4. Neglected Infectious Diseases
- 5. Emerging and re-emerging infectious diseases with epidemic potential
- 6. Diarrhoeal diseases
- 7. Lower Respiratory Tract Infections
- 8. Ethics, Regulatory and Pharmacovigilance

The initiative also supports projects that cover multiple disease areas i.e. more than one of the above list.<sup>13</sup>

### Sida's research cooperation strategy results areas

### Strengthened research of high quality and of relevance to poverty reduction and sustainable development

1. Focusing on capacity-building for research, primarily in low-income countries and regions

- More partner countries have capacity to independently undertake research training and conduct highquality research.
- More women undergo research training and conduct research.
- Strengthened conditions and capacity among national and regional research actors to participate in international research and research dialogue.
- More partner countries and regional research actors have capacity to formulate and implement national and regional research strategies.

<sup>&</sup>lt;sup>12</sup> EDCTP2 Workplan 2018 – page 4.

<sup>&</sup>lt;sup>13</sup> EDCTP Strategic Research Agenda, Version 3, February 2019

- More partner countries and regional research actors have improved competence and strengthened infrastructure for scientific communication.
- Strengthened capacity among universities in partner countries to communicate research findings that are potentially beneficial to the development of society.

2. Focusing on global, regional and national research of relevance to low-income countries and regions

- More research findings of relevance to development at global and regional research organisations and at universities in partner countries.
- Greater impact of a gender equality perspective in research.
- Findings from relevant international research have a greater impact on national and regional research.
- Findings from national and regional research have a greater impact on international research.

3. Focusing on the promotion of research that, through innovation, can contribute to poverty reduction and sustainable development

- More interfaces, networks and cooperation established between actors from research institutions on the one hand, and the business sector, public authorities and civil society on the other.
- Improved conditions for researchers to develop innovative ideas with the potential to contribute to the emergence of new products and services that contribute to poverty reduction and a sustainable society.
- Reinforcement of the role of universities and their contribution to innovation processes and systems.

4. Focusing on Swedish research of relevance to poverty reduction and sustainable development in low-income countries

- Strengthened high-quality research in Sweden that is of relevance to poverty reduction and sustainable development in low-income countries.
- Strengthened knowledge exchange and collaboration between researchers in Sweden and researchers in low-income and lower middle-income countries, with a focus on research that is of high quality and of relevance to poverty reduction and sustainable development.

# ANNEX 2: OVERVIEW OF SIDA SUPPORT TO EDCTP2 ACTIVITIES

# (01 JAN 2016 TO 31 JUL 2019)

Νο	Project reference	Area of support	Project topic	Dates	Total EDCTP Contribution (EUR) commitments & disbursement	Sida contribution (EUR) commitments & disbursement	Sida contribution (% of total EDCTP contribution)
Calls for prop	oosals managed by EDC	TP SEC					
Research and	d Innovation activities (	RIA)					
1	RIA2016E- 1609	Clinical trial research	Emerging Infectious Diseases	01/03/18 - 28/02/22	9,997,501.14	250,000.00	3%
2	RIA2016E- 1612	Clinical trial research	Emerging Infectious Diseases	01/12/17 - 30/11/22	9,999,393.75	250,000.00	3%
3	RIA2016MC- 1623	Clinical trial research	(Paediatric) TB Diagnosis	01/02/18 - 31/07/22	2,999,632.37	436,000.00	15%
4	RIA2016V- 1644	Clinical trial research	HIV and HIV- associated infections vaccines	01/01/18 - 31/03/23	14,999,955.00	250,000.00	2%
5	RIA2016V- 1649	Clinical trial research	Malaria vaccines	01/04/18 - 30/09/23	14,999,999.99	250,000.00	2%
6	RIA2017S- 2008	Clinical trial research	HIV and HIV- associated infections vaccines	01/01/19 - 31/12/23	9,254,000.00	500,000.00	5%
7	RIA2017S- 2024	Clinical trial research	Diarrhoeal diseases vaccines	01/01/19 - 31/12/22	7,368,180.50	500,000.00	7%

8	TRIA2015- 1076	Clinical trial research	Malaria in pregnancy treatment	01/12/16 - 30/11/20	7,389,049.37	1,000,000.00	14%
9	TRIA2015- 1092	Clinical trial research	HIV Treatment	01/01/17 - 31/12/20	9,990,712.00	1,000,000.00	10%
10	RIA2017MC- 2009	Clinical trial research	Malaria in pregnancy treatment	01/06/19– 31/05/24	3,902,469	500,000.00	13%
11	RIA2017S- 2012	Clinical trial research	Tuberculosis	01/01/19– 30/12/22	12,000,804	500,000.00	4%
					102,901,697.12	5,436,000.00	5%
Capacity Supp	ort Activities (CSA)		·		· · ·		
1	CSA2015ERC -863	Capacity development	Ethics and regulatory	01/07/19 - 30/06/19	299,406.25	100,000.00	33%
2	CSA2015ERC -876	Capacity development	Ethics and regulatory	01/03/17 - 28/02/20	300,000.00	100,000.00	33%
3	CSA2015ERC -880	Capacity development	Ethics and regulatory	01/04/17 - 31/03/20	299,881.48	100,000.00	33%
4	CSA2015ERC -872	Capacity development	Ethics and regulatory	01/05/17 - 30/04/19	261,377.25	100,000.00	38%
5	CSA2015ERC -873	Capacity development	Ethics and regulatory	01/02/17 - 31/07/19	291,042.50	100,000.00	34%
6	CSA2016ERC -1418	Capacity development	Ethics and regulatory	01/04/18 - 31/03/22	300,000.00	14,000.00	5%
7	CSA2016S- 1618*	Capacity development	Pharmacovigilanc e	01/03/18 - 28/02/23	3,000,000.00	660,722.00	22%
					4,751,707.48	1,174,722.00	25%
to project casl	receives funds slightly n funding on top of ED(	CTP budget	rest (which appear to	have separate	contracts relating to S	Sida funds).  This re	ceived funds direct
	mentorship activities (	INA)		1			1
17	TMA2016CD F-1546	Capacity development	Career Development Fellowship (TB)	01/04/18- 30/03/18	148,627.30	100,000.00	67%

Total support	to clinical trial researc	h and related act	tivities	1	86,998,424.12	4,436,000.00	5%
					3,213,061.98	1,000,000.00	31%
26	TMA2016SF- 1514	Capacity development	Senior Fellowship (Malaria)	01/04/18- 31/03/23	468,551.25	100,000.00	21%
25	TMA2016SF- 1511	Capacity development	Senior Fellowship (Diarrhoeal diseases)	01/04/18- 31/03/22	499,456.25	100,000.00	20%
24	TMA2016SF- 1509	Capacity development	Senior Fellowship (NIDs)	01/04/18- 31/03/23	499,962.50	100,000.00	20%
23	TMA2016SF- 1508	Capacity development	Senior Fellowship (HIV and HIV- associated infections)	01/04/18- 31/03/23	500,000.00	100,000.00	20%
22	TMA2016SF- 1437	Capacity development	Senior Fellowship (NIDs)	01/07/18- 30/06/23	499,718.50	100,000.00	20%
21	TMA2016CD F-1598	Capacity development	Career Development Fellowship (HIV and HIV- associated infections)	01/12/18- 30/11/21	149,000.00	100,000.00	67%
20	TMA2016CD F-1582	Capacity development	Career Development Fellowship (HIV and HIV- associated infections)	01/07/18- 30/06/21	150,000.00	100,000.00	67%
19	TMA2016CD F-1576	Capacity development	Career Development Fellowship (TB)	01/04/18- 31/03/21	149,696.18	100,000.00	67%
18	TMA2016CD F-1555	Capacity development	Career Development Fellowship (Malaria)	01/08/18- 31/01/21	148,050.00	100,000.00	68%

Total support to capacity development related activities (excl. CSA2016S-1618)					7,964,769.46	1,514,000.00	19%
Other activiti	es managed by EDCTP	SEC			II		1
27	Open Source Platform	Cross-cutting	Open Source Platform	Ongoing	200,044.00	200,044.00	100%
28	Ninth EDCTP Forum 2018	Cross-cutting	Ninth EDCTP Forum 2018	Completed	600,000.00	49,000.00	8%
Sub-total oth	er activities managed b	y EDCTP SEC			800,044.00	249,044.00	31%
Participating	States Implementing A	gencies (PSIAs) r	nanaged by WHO-A	FRO			1
29	PSI2017WH O-9991	Capacity development	Implementation and operational research on various PRDs	Ongoing	260,000.00	86,667.00	33%
Sub-total PSIA	As managed by WHO-AF	RO	•	·	260,000.00	86,667.00	33%
Grand total					93,023,238.00	6,946,433.00	7,23%
appears to ha	he contract figures do n ave received 286K from /e assume therefore that	EU and 100K from	n Sida from analysis	of 'List of EDCTP	Signed Grants by dono	or funding includin	-

Objectives	EQ #	Level 1 Evaluation questions	Level 2 Evaluation Questions [Indicators/ Data to be collected/ sub EQs to ask]	Data sources
<b>Objective 1:</b> Assess the status of project implementation to	1.1	Has actual investment matched planned investment?		
date of Sida funded projects, including project	1.1.1	What is the profile of Sida support?	# projects/activities (and €) supported in each EDCTP intervention area (RIA, TMA, CSA)	Review of documents received
management, and the likelihood of			# projects/ activities (and €) with PIs based in LDC/LIC and LMICs	Review of documents received
successful completion			# projects/ activities (and €) supporting EDCTP disease priority areas	Review of documents received
			Which population(s) are being studied? (Adults, children, pregnant women, adolescents), in which countries?	Review of documents received
	1.1.2	Have investments occurred in areas that were originally planned?	Fit of project profiles with EDCTP and Sida agreement and/or strategies	Review of documents received

			Has money been spent on activities as per individual project and EDCTP work plans?	Review of documents received
	1.1.3	What have been the barriers and enablers to successful planned investment?	What have been the barriers and enablers to successful planned investment?	Review of documents received; interviews
	1.2	Is implementation of projects and EDCTP's activities with Sida funding on track?		
	1.2.1	Have milestones been met?	# projects planned for implementation	Review of documents received
			# projects in progress and stage of progress	Review of documents received
			Are implementing projects/activities where expected based on original implementation plans submitted with project proposal	Review of documents received
			If any projects/activities have completed, did they complete on time and in budget?	Review of documents received
	1.2.2	Have outputs and outcomes within project control been achieved as scheduled/ per work plan?	% projects that defined outputs and outcomes in proposals	Review of documents received
			# (by type) of outputs and outcomes given in project proposals	Review of documents received

		% outputs and outcomes achieved by end August 2019 across all funded activity	Review of documents received; interviews
		% projects ahead and behind schedule	Review of documents received; interviews
1.2.3	What are the reasons for deviation?	What have been the barriers and enablers to achieving outputs and outcomes?	Review of documents received; interviews
1.2.4	What unintended/ unexpected outputs, outcomes and impacts have occurred?	What unintended/ unexpected outputs, outcomes and impacts have been reported?	Review of documents received; interviews
1.3.	Are projects and activities by EDCTP funded by Sida being adequately project managed?		
1.3.1	Are project management systems and procedures in place within funded projects?	Evidence of relevant planning and tracking tools in place e.g. updated gantt charts; regular financial reporting; project meeting minutes; updated risk matrices; relevant ethics and regulatory approvals	Review of documents received
1.3.2	Has project management (PIs and their administrative support staff within their	Risk matrices updated	Utilises findings from last question

		institutions) identified obstacles, enablers and mitigation measures?	Evidence of documented and articulated changes to investment and project plans	Utilises findings from last question supported by interviews with PIs.
	1.3.3	Are project management systems and procedures in place within EDCTP to monitor funded projects/ activities?	Planning and tracking tools utilised within EDCTP	Review of documents received; Interviews
<b>Objective 2:</b> Assess the results of SIDA funded projects so	2.1	What are the identified outputs, outcomes and impacts of investments?		
far (including at outcome and impact level, if applicable) and the extent to which these contribute to progress against EDCTP's overall strategy and Sida's objectives in providing funding to EDCTP, particularly in relation to the research and research capacity building needs of	2.1.1	How do those identified in initial grant proposals match reality?	See EQ 1.2	
	2.1.2	What is the role of the project review process in ensuring fit with	What are the main stages of project review process?	Review of documents received
	objectives in terms of impacts?		To what degree is output, outcome and impact key criteria during the review process?	Review of documents received
			To what extent does the review process and criteria fit EDCTP and Sida priority areas and objectives?	Review of documents received; interviews

low-income	2.2	How well do Sida		
countries in Africa		supported projects align against EDCTP strategic objectives?		
	2.2.1	To what extent does Sida funding contribute to developing new, or	# projects conducting Phase I, II, III, IV clinical trials and/or implementation research	Review of documents received
		progress existing medical interventions?	# Projects involving a trial investigating a new medical product? How which, how many at pre-licencing; different use of already licenced product?	Review of documents received
			Does the study contribute to efforts to reduce time to completion of clinical trials? If yes, how	Review of documents received; interviews
			Will the product be made available after the trial?	Review of documents received; interviews
			Have any results been published and/or accessible to the public/ other researchers?	Review of documents received
	2.2.2	To what extent does Sida funding contribute	Have study results contributed to guidelines, or are they expected to do so?	Review of documents received; interviews

	to the development of research guidelines?	What are the barriers and opportunities for research guideline development specifically affecting Sida funded projects	Review of documents received; interviews
2.2.3	Are Sida funded projects on course to increase research capacity in African health research facilities (numbers and expertise,	% projects that funded by Sida that have plans to increase research infrastructure? Details of infrastructure type (e.g. laboratories, clinical facilities)	Review of documents received
	across countries)?	% project include training at Master, PhD level (by discipline); fit with national/ regional figures?	Review of documents received
		Details of other training e.g. clinical research, ethics training that will be provided during Sida funded activities	Review of documents received
		How did the training contribute to increased research capacity?	Review of documents received; interviews
		Barriers and opportunities identified by project staff in building capacity	Review of documents received; interviews
2.2.4	Are Sida funded activities resulting in growth in expertise in ethics (numbers of	# projects that fund ethics support using Sida funding; type of support funded	Review of documents received

		experts and functioning regulatory bodies)?	How does Sida funded ethics support fit within the needs/ current situation within national setting? i.e. perceived gap the support is filling	Review of documents received; interviews
			increased capacity in country	Review of documents received; interviews
			What are the barriers and opportunities for building ethics capacity faced by Sida funded projects/ activities?	Review of documents received; interviews
	2.2.5	Are these Sida funded projects and activities leading to increased	Types of in-country/ regional partner Sida funded projects/ activities are working with Evidence of any new partnerships	Review of documents received; interviews
		cooperation and funding from a wider group of partners?		Review of documents received; interviews
			Evidence of Sida funding during EDCTP 2 having leveraged new partnerships and funding at global level by EDCTP? Including with the private sector	Review of documents received; interviews
			Barriers and opportunities identified during evaluation for Sida funding to increase cooperation and funding	Review of documents received; interviews
	2.2.6	Are the activities leading to increased activities and/or more awareness	Answered through 2.2.5 above	

	among European stakeholders?		
2.3	How well does EDCTP and its funded projects utilise Sida funding to meet the needs of Sida's research cooperation priority areas?		
2.3.1	To what degree does Sida funding build capacity for research in LICs?	To what extent do Sida funded projects enable LIC based researchers to conduct training programmes? What is the sustainability of these programmes (post funding)?	Overlaps with EQ 2.2
		How much research results out of Sida funded activities through EDCTP?	Overlaps with EQ 2.2
		Has Sida funding led to increased opportunity for LIC based researchers to participate in international dialogue on research through conference participation?	Review of documents received

			Has there been an increase in Sida funded researchers developing research strategies directly through Sida funding of research projects/other activities?	Overlaps somewhat with EQ2.2 (guidelines questions) but also requires review of input to other strategies
			To what extent are Sida funded researchers and/or their organisations engaging in science communication activities, through the Sida funded projects?	Overlap somewhat with EQ1.1 but also needs follow up with document review and interviews
2.3.2	2.3.2	support projects/funded projects/ activities in linebut requiactivities that meetwith global research agenda(s) -detailed activities	Overlap with EQ1.1 but requires more detailed analysis of documents	
		interventions but particularly in terms of human capital in health research and ethics)?	Are the research questions for Sida funded projects/ activities in line with local disease control priorities and health research priorities (by burden of disease maps; country research policies)	Overlap with EQ1.1 but requires more detailed analysis of documents
			Are the results from Sida funded research from EDCTP 2 having an impact on the design and/or focus of future research (measured by reference in future project proposals; strategies etc.)	Review of documents provided; interviews

	2.3.3	To what extent does EDCTP 2 Sida funded activities focus on the promotion of research that, through innovation, can contribute to poverty reduction and sustainable development.	Has Sida funding created opportunities for EDCTP 2 funded researchers to engage in new/ broaden existing networks? # of exchange visits or similar opportunities for North-South and South-South cooperation Evidence of joint publications between African and Swedish researchers as a result of Sida funding of EDCTP 2 activities Has Sida funding led to innovation of new products or services within EDCTP 2 activities? Has Sida funding led to an increased role in a PI's university/ research organisation expanding its role in the innovation system of the country?	Answer provided through EQ 2.2.5 Answer provided through EQ 2.1 and 2.2 Review of documents Review of documents; interviews Review of documents; interviews
<b>Objective 3:</b> Assess the extent to which Sida's contribution has so far	3.1	How has Sida support contributed to women's active engagement with research?		
contributed to an improved gender balance in the areas	3.1.1	How have Sida funded projects incorporated female researchers and support staff?	No. of women involved in Sida supported projects (disaggregated by job type, tenure status etc.)	Review of documents received

of research supported by EDCTP			Has Sida funding of EDCTP 2 activities changed the gender balance within recipient institutions?	Review of documents received; external data; interviews
	3.1.2	Has Sida support enhanced the careers of female researchers and research support staff?	# female researchers and support staff who have been promoted as a result of Sida funding	Review of documents received; interviews
	3.1.3	How far has EDCTP 2 Sida funded activities improved gender equality perspective in research?	Evidence of improved gender equality perspective in research methodologies, reports, publications.	
	3.1.4	Is EDCTP gender aware in its operations?	Evidence of gender equality policies; balance in review committees etc.	Review of documents received
	3.1.5	What are the barriers and opportunities to improving female involvement with research (as researchers, participants or community bystanders)?	Evidence of barriers and opportunities	Review of documents received, interviews; possible future scenarios workshop

### ANNEX 4: FULL LIST OF DOCUMENTS REVIEWED

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
1	EDCTP - PERIODIC REPORT of the ACTION	AMBITION-cm	1 January 2017 – 31 December 2017	London School of Hygiene and Tropical Medicine, United Kingdom
2	EDCTP - PERIODIC REPORT of the ACTION	EDCTP Ethics 2015-873	1 February 2017 – 31 January 2018	University of Khartoum, Sudan
3	EDCTP – 1st PERIODIC REPORT of the ACTION	IMPROVE	1 December 2016 - 30 November 2017	Liverpool School of Tropical Medicine (LSTM), United Kingdom
4	EDCTP - PERIODIC REPORT of the ACTION	EAPI	1 March 2017 - 28 February 2018	University of Nairobi, Kenya
5	EDCTP - PERIODIC REPORT of the ACTION	REECAO	1 April 2017 – 31 March 2018	University of Bamako, Mali
6	EDCTP - PERIODIC REPORT of the ACTION	СТС-ТЕР	1 May 2017 – 30 April 2018	MRC Unit The Gambia, The Gambia
7	EDCTP - PERIODIC REPORT of the ACTION	CREDU	1 July 2017 – 30 June 2018	Uganda National Council for Science and Technology (UNCST)
8	EDCTP – 2nd PERIODIC REPORT of the ACTION	IMPROVE & IMPROVE- 2	IMPROVE: 1 December 2017 to 30 November 2018 IMPROVE-2: 1 July 2017 to 30 November 2018	Liverpool School of Tropical Medicine (LSTM), United Kingdom
9	EDCTP - PERIODIC REPORT of the ACTION	AMBITION-cm	1 January 2018 – 31 December 2018	London School of Hygiene and Tropical Medicine (LSHTM), United Kingdom
10	EDCTP - PERIODIC REPORT of the ACTION	PrEPVacc	1st January 2018- 31st December 2018	Imperial College of Science, Technology and Medicine, United Kingdom
11	EDCTP – 1st PERIODIC REPORT of the ACTION	RaPaed-TB	1 February 2018 to 31 January 2019	Ludwig-Maximilians- Universitaet Muenchen (LMU), Germany
12	Periodic Report – Year 1	ALERRT	01 December 2017 to 30 November 2018	University of Oxford (UOXF), United Kingdom
13	EDCTP - PERIODIC REPORT of the ACTION	PROFORMA	01/03/2018 – 28/02/2019	Karolinska Institutet, Sweden
14	EDCTP - PERIODIC REPORT of the ACTION	EAPI	1 March 2018 to 39 February 2019	University of Nairobi, Kenya
15	Spreadsheet - Summarising Grant Annual Progress Reports	Report Due Dates	n/a	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
16	Spreadsheet – SIDA	SIDA Supported Grants	n/a	EDCTP
17	Supported Grants Grant Proposal	and their Collaborators PANDORA-ID-NET	n/a	Fondation Congolaise pour la Recherche Médicale(FCRM), Republic of Congo
18	Grant Proposal	ALERRT	n/a	The Chancellors, Masters and Scholars of the University of Oxford(UOXF), United Kingdom
19	Grant Proposal	RaPaed TB	n/a	Ludwig-Maximilians- Universitaet Muenchen (LMU), Germany
20	Grant Proposal	PrEPVacc	n/a	Imperial College of Science, Technology and Medicine, United Kingdom
21	Grant Proposal	MMVC	n/a	The Chancellors, Masters and Scholars of the University of Oxford(UOXF), United Kingdom
22	Grant Proposal	CAP012 SAMBA Trial	n/a	Centre for the Aids Programme of Research in South Africa (CAPRISA), South Africa
23	Grant Proposal	ETEC Vaccine Efficacy	n/a	Scandinavian Biopharma Holding AB (SBH), Sweden
24	Grant Proposal	IPTp with dihydroartemisinin- piperaquine and azithromycin for malaria, sexually transmitted and reproductive tract infections in pregnancy in high sulphadoxine- pyrimethamine resistance areas in Kenya, Malawi, and Tanzania	n/a	Liverpool School of Tropical Medicine (LSTM), United Kingdom
25	Grant Proposal	High Dose AMBISOME on a Fluconazole Backbone for Cryptococcal Meningitis Induction Therapy in sub- Saharan Africa: A	n/a	London School of Hygiene & Tropical Medicine (LSHTM), United Kingdom

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
		Randomised Controlled		
		Non-inferiority Trial		
26	Grant Proposal	HATUA -KENYA	n/a	Kenya Medical Research Institute (KEMRI), Kenya
27	Grant Proposal	PROFORMA	n/a	Karolinska Institutet, Sweden
28	Grant Proposal	Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda	n/a	Uganda National Council for Science and Technology (UNCST), Uganda
29	Grant Proposal	Coast to Coast: Transcontinental Ethics Partnership	n/a	Medical Research Council (MRC) Unit - The Gambia
30	Grant Proposal	East Africa Pharmacovigilance Initiative	n/a	University of Nairobi, Kenya
31	Grant Proposal	Improving Ethical Review Process in Sudan through Capacity Building of National Regulatory Authorities	n/a	University of Khartoum, Sudan
32	Grant Proposal	Renforcement de l'Ethique des Essais Cliniques en Afrique de l'Ouest (REECAO)	n/a	Ministère de la Santé et de l'Hygiène Publique, Mali
33	Grant Proposal	Host-directed therapy: Myeloid derived suppressor cell ablation by phosphodiesterase inhibitor	n/a	Stellenbosch University, South Africa
34	Grant Proposal	ESSLDPQ P4502D6	n/a	Tropical Pesticides Research Institute, Tanzania
35	Grant Proposal	Evaluate 4mTB	n/a	Stellenbosch University, South Africa
36	Grant Proposal	MIDAS	n/a	Centre for the Aids Programme of Research in South Africa (CAPRISA), South Africa
37	Grant Proposal	Kenya CVHIV	n/a	University of Nairobi, Kenya
38	Grant Proposal	PRACE	n/a	African Institute of Biomedical Science and Technology (AiBST); Zimbabwe
39	Grant Proposal	MEPIE Study	n/a	Mbale Regional Referral Hospital, Uganda

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
40	Grant Proposal	EvaLAMP & db-NALFIA	n/a	Mekelle University, Ethiopia
41	Grant Proposal	BuruliNox	n/a	Kwame Nkrumah University of Science and Technology (KNUST), Ghana
42	Grant Proposal	ROVAS-2	n/a	Centre for Infectious Disease Research in Zambia (CIDRZ), Zambia
43	Annual Progress Report	Annual Progress Report on the use of Sida's cash contributions to the EDCTP Secretariat for supporting projects in the scope of EDCTP2 programme	01 January 2018 – 31 December 2018	EDCTP
44	Contract	Grant Agreement for the use of SIDA's Cash Contribution to EDCTP Secretariat for Supporting Projects in the Scope of the EDCTP2 Programme	15 <sup>th</sup> of December 2015	SIDA
45	Handbook	Sida's Evaluation HandbookGuidelines and Manual for Conducting Evaluations at Sida	April 2018	SIDA
46	Strategy Document	Strategy for research cooperation and research in development cooperation	2015 - 2021	Government Office of Sweden
47	Grant Proposal	An Open Source Platform for Developing Protocols in Poverty Related Disease	February 2018	University of Oxford, Global Health Network, United Kingdom
48	Call for Applications	Joint WHO- AFRO/TDR/EDCTP Small Grants Scheme for Implementation Research on Infectious Diseases of Poverty	November 2017	WHO/ EDCTP
49	Donor Agreement	EDCTP/ WHO Agreement – Small Grants Scheme	13 <sup>th</sup> of December 2015	EDCTP/ WHO
50	Annual Progress Report	DLR Contract I 2017 - Annual Progress Report	Reporting period: 1 January 2018 – 31 December 2018	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
		Funding code: 01KA1711		
51	Annual Progress Report	Annual Progress Report 2018 - Report provides an overview of the work carried out and progress made during the reporting period 01 January 2018 till 31 December 2018 in the implementation of the second European and Developing Countries Clinical Trials Partnership programme (EDCTP2), as entrusted by the European Commission.	Reporting Period: 1 January 2018 to 31 December 2018	EDCTP
52	Annual Progress Report	DLR Contract II 2017 - Annual Progress Report Funding code: 01KA1712	1 January 2018 – 31 December 2018	EDCTP
53	Work Plan	EDCTP2 Work Plan 2014	19 December 2014; version 18	EDCTP
54	Work Plan	EDCTP2 Work Plan 2015	5 October 2015	EDCTP
55	Work Plan	EDCTP2 Work Plan 2016	2 June 201	EDCTP
56	Work Plan	EDCTP2 Work Plan 2017	23 May 2017	EDCTP
57	Work Plan	EDCTP2 Work Plan 2018	9 May 2018	EDCTP
58	Work Plan	EDCTP2 Work Plan 2019	22 May 2019	EDCTP
59	Annual Report	EDCTP Annual Report 2014	n/a	EDCTP
60	Annual Report	EDCTP Annual Report 2015	n/a	EDCTP
61	Annual Report	EDCTP Annual Report 2016	n/a	EDCTP
62	Annual Report	EDCTP Annual Report 2017	n/a	EDCTP
63	Periodic Report	EDCTP-funded clinical studies for medical interventions 2003- 2018	n/a	EDCTP
64	Business Plan	EDCTP STRATEGIC BUSINESS PLAN FOR 2014–2024	n/a	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
65	Strategy Document	EDCTP Strategic	Version 3 –	EDCTP
05	Strategy Document	Research Agenda	February 2019	LDCH
66	Spreadsheet	List of EDCTP Signed Grants by Donor Funding Including from SIDA	n/a	EDCTP
67	Spreadsheet	List of EDCTP2 Grants (Signed and Awarded)	n/a	EDCTP
68	Status Document	Joint Meeting of the EDCTP Scientific Advisory Committee (SAC) & General Assembly (GA) on Wednesday, 22 May 2019	Meeting document 4	EDCTP
69	Inception Report	Assessment of the performance and impact of the first programme of the European and Developing Countries Clinical Trials Partnership (EDCTP)	Final version 7 - March 2014	Technopolis Group
70	Evaluation Report	Evaluation of the Second European and Developing Countries Clinical Trials Partnership Programme(2014- 2016)	2017	Alash'le Abimiku, Elizabeth Bukusi, Jennifer Dent (Rapporteur), Nancy Edwards, Mats Ulfendahl (Chair)
71	Fellowship Profile	Towards improved vaccines for malaria	2017	National Institute for Medical Research, Tanzania
72	Fellowship Profile	Understanding malaria parasite diversity	2017	Kenya Medical Research Institute, Kenya
73	Fellowship Profile	Combating HIV drug resistance in children	2017	Joint Clinical Research Centre, Uganda
74	Fellowship Profile	Assessing next- generation TB diagnostics	2017	Stellenbosch University, South Africa
75	Fellowship Profile	Applying new technologies in TB research	2017	University of Cape Town Lung Institute, South Africa
76	Fellowship Profile	Rapid diagnosis of visceral leishmaniasis	2018	Mekelle University College of Health Sciences, Ethiopia
77	Fellowship Profile	Strengthening clinical research capacity in Tanzania	2018	Kibong'oto Infectious Disease Hospital, Tanzania

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
78	Fellowship Profile	Building capacity in clinical pharmacogenomics	2018	African Institute of Science and Technology, Zimbabwe
79	Fellowship Profile	Shortening treatment of Buruli ulcer	2018	Kwame Nkrumah University of Science and Technology, Ghana
80	Fellowship Profile	Enhancing rotavirus protection in children	2017	Centre for Infectious Disease Research, Zambia
81	Fellowship Profile	Understanding natural immunity to malaria	2018	African Research Collaboration for Health Ltd/ KEMRI- Wellcome Trust Research Programme, Kenya
82	Fellowship Profile	Building malaria research capacity in Uganda	2018	Mbale Regional Referral Hospital, Uganda
83	Fellowship Profile	Understanding HIV's impact on TB immunity	2017	University of Cape Town, South Africa
84	Fellowship Profile	Chronic conditions in older people living with HIV	2018	Infectious Diseases Institute, Uganda
85	Fellowship Profile	Understanding the impact of diabetes on TB	2018	Noguchi Memorial Institute for Medical Research, Ghana
86	Fellowship Profile	Cardiometabolic risk factors and HIV	2018	South African Medical Research Council, South Africa
87	Fellowship Profile	Gut health, HIV and diabetes	2018	National Institute for Medical Research, Tanzania
88	Fellowship Profile	Strengthening vaccine research in Gabon	2018	Centre of Medical Research Lamberéné, Gabon
89	Fellowship Profile	Immunological signatures of TB infection	2018	University of Cape Town, South Africa
90	Fellowship Profile	An innovative approach to HIV cure	2018	Dr George Kyei, Noguchi Memorial Institute for Medical Research, Ghana
91	Fellowship Profile	Optimising malaria treatment for people living with HIV	2018	Infectious Diseases Institute, Uganda
92	Fellowship Profile	Dissecting the origins of lung disease	2018	University of Cape Town, South Africa
93	Fellowship Profile	Understanding the impact of pre-exposure	2018	Centre for the AIDS Programme of

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
		prophylaxis on immunity		Research in South Africa (CAPRISA), South Africa
94	Fellowship Profile	A clearer picture of adverse drug reactions	2018	University of Cape Town Lung Institute, South Africa
95	Project Brief	SOLID study	2016	Institute of Tropical Medicine, Belgium
96	Project Brief	Stop TB/HIV at One study	2016	Liverpool School of Tropical Medicine, United Kingdom
97	Project Brief	ScreenTB study	2016	Stellenbosch University, South Africa
98	Project Brief	DIAMA Study	2016	Center National Hospitalier de Pneumo-Phtisiologie, Benin
99	Project Brief	VirTUAL study	2017	University of Liverpool, United Kingdom
100	Project Brief	MAMAH study	2016	ISGlobal, Spain
101	Project Brief	CHAPS study	2018	King's College London, UK
102	Project Brief	FREEBILY study	2018	Leiden University Medical Centre, The Netherlands
103	Project Brief	TREATS study	2018	London School of Hygiene and Tropical Medicine, UK
104	Project Brief	AfriKADIA study	2018	Drugs for Neglected Diseases Initiative, Switzerland
105	Project Brief	COAST-Nutrition	2018	Imperial College, United Kingdom
106	Project Brief	BREATHER Plus study	2018	Baylor College of Medicine Children's Foundation, Ugand
107	Project Brief	PREGART study	2018	Hawassa University, Ethiopia
108	Project Brief	EMPIRICAL study	2018	Servicio Madrileña de Salud, Spain
109	Project Brief	Neo bnAb study	2019	Ludwig Maximilian University of Munich, Germany
110	Project Brief	ASAAP study	2018	Kwame Nkrumah University of Science and Technology, Ghana
111	Project Brief	PediCAP study	2018	Fondazione PENTA Onlus, Italy
112	Project Brief	PYRAPREG study	2018	Université des Sciences, des Techniques et des

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
				Technologies de Bamako, Mali
113	Project Brief	BabyGel study	2018	University of Liverpool, UK
114	Project Brief	MoxiMultiDoseMod study	2019	Luxembourg Institute of Health, Luxembourg
115	Project Brief	STOP study	2018	Fundación Privada Instituto de Salud Global (ISGlobal), Spain
116	Project Brief	HAT-R-ACC study	2018	Drugs for Neglected Diseases Initiative, Switzerland
117	Project Brief	PEP4LEP study	2018	Nederlandse Stichting voor Leprabestrijding, The Netherlands
118	Project Brief	FibroScHot study	2018	University of Cambridge, UK
119	Project Brief	PEOPLE study	2018	Prins Leopold Instituut voor Tropische Geneeskunde, Belgium
120	Project Brief	CAP-TB study	2018	Foundation for Innovative New Diagnostics, Switzerland
121	Project Brief	CAP012 SAMBA project	2019	Centre for the AIDS Programme of Research in South Africa, South Africa
122	Project Brief	Simplici-TB study	2018	University of St Andrews, United Kingdom
123	Project Brief	PREVAC-UP study	2018	Institut National de la Santé et de la Recherche Médicale, France
124	Project Brief	ETEC Vaccine Efficacy study	2019	Scandinavian Biopharma Holding AB, Sweden
125	Project Brief	THECA study	2019	University of Cambridge, United Kingdom
126	Project Brief	PravaTB study	2019	University of Cape Town, South Africa
127	Project Brief	SINDOFO study	2018	Eberhard Karls Universität Tübingen, Germany
128	Project Brief	WANECAM II study	2018	Université des Sciences, des Techniques et des Technologies de Bamako, Mali

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
129	Project Brief	INTENSE-TBM study	2018	University of Bordeaux, France
130	Project Brief	CLICK-TB study	2018	GSK I&D, Spain
131	Project Brief	AdjustEBOVGP-Dx study	2018	Makerere University, Uganda
132	Project Brief	EPIRISK-Ebov study	2018	Fondation Congolaise pour la Recherche Médicale, Republic of Congo
133	Project Brief	CAPA-CT 2 study	2018	Infectious Diseases Institute, Uganda
134	Project Brief	PEAU-EBOV-RDC study	2018	Institut National de Recherche Biomédicale, Democratic Republic of the Congo
135	Project Brief	MobEBO-DRC study	2018	University of Stirling, UK
136	Project Brief	PAMAFRICA	2019	Medicines for Malaria Venture, Switzerland
137	Project Brief	PfTBV study	2019	Université des Sciences, des Techniques et des Technologies de Bamako, Mali
138	Project Brief	The PREPARE study	2019	St George's University of London, UK
139	Project Brief	The ShigOraVax study	2019	European Vaccine Initiative EWIV, Germany
140	Project Brief	CAPRISA 018 study	2017	Centre for the AIDS Programme of Research in South Africa, South Africa
141	Project Brief	PredictTB study	2017	Stellenbosch University, South Africa
142	Project Brief	CHAPAS 4 study	2017	University of Zimbabwe College of Health Sciences
143	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	31 March – 1 April 2016	EDCTP
144	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	1-2 September 2016	EDCTP
145	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	30-31 March 2017	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
146	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	14-15 September 2017	EDCTP
147	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	7 May 2018	EDCTP
148	Minutes	Minutes of the Scientific Advisory Committee (SAC) Meeting	16 Sep 2018	EDCTP
149	Journal	DECISION No 556/2014/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States	15 May 2014	European Union
150	Strategy Document	Strategic Business Plan for the second phase of the European and Developing Countries Clinical Trials Partnership programme (EDCTP2, 2014-2024)	Revised Version 1 May 2016	EDCTP
151	Strategy Document	EDCTP STRATEGIC BUSINESS PLAN FOR 2014–2024	n/a	Ian Jones – EDCTP Communications
152	PERIODIC REPORT of the ACTION	ROVAS-2	1stApril 2018 – 31stMarch 2019	Centre for Infectious Disease Research in Zambia (CIDRZ) Zambia
153		CTC-TEP	1st May 2018 –30th April 2019	Medical Research Council Unit The Gambia at the London School of Hygiene & Tropical Medicine
154	Minutes	Minutes of the EDCTP Audit Committee meeting held by teleconference	14 March 2017	EDCTP
155	Minutes	Minutes of the EDCTP Audit Committee	18 May 2017	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
		meeting held by		
156	Minutes	teleconference Minutes of the EDCTP Audit Committee meeting held by teleconference	27 October 2017	EDCTP
157	Audit Report	Kenya Medical Research Institute: IMPROVE – TRIA-2015- 1076 SMART: MA2015SF- 1001	December 2018	PriceWaterhouseCoop ers
158	Audit Report	University of Nairobi: GREAT: SRIA20151066(KAVI) EAPI- EDCTPCSA Ethics- 876	December 2018	PriceWaterhouseCoop ers
159	Audit Report	University of Stellenbosch Optimal Diagnosis TMA 2015SF-1041 Predict TB: SRIA2015- 1065 Screen TB	10 May 2019	PriceWaterhouseCoop ers
160	Audit Report	University of Cape Town Lung Institute DTBD: TMA2015SF- 1043 Predict TB: SRIA2015- 1065 PanACEA: TRIA2015- 1102	10 May 2019	PriceWaterhouseCoop ers
161	Audit Report	University of Cape Town AMBITION: TRIA2015- 1092 (AMBITION cm) Predict TB: SRIA2015- 1065	10 May 2019	PriceWaterhouseCoop ers
162	Audit Report	TASK Foundation NPC Predict TB: SRIA2015- 1065 PanACEA: TRIA2015- 1102	10 May 2019	PriceWaterhouseCoop ers
163	Site Visit Report	Malawi Site Visit Report	16-19 May 2017	EDCTP
164	Site Visit Report	Tanzania Site Visit Report	13-17 November 2017	EDCTP
165	Site Visit Report	Senegal Site Visit Report,	26-30 November 2018	EDCTP
166	Site Visit Report	Central Africa Network on Tuberculosis, HIV/AIDS and Malaria	29 – 31 October 2018	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
		(CANTAM) Republic of	(	
		Congo, Brazzaville		
167	Site Visit Report	Côte divoire Site Visit	10-13 June 2019	EDCTP
		Report		
168	Spreadsheet	EDCTP Risk Register	March 2019	EDCTP
169	Working Document	Measuring results of EDCTP: A guiding	July 2019	EDCTP
		document for Monitoring and		
		Evaluation of EDCTP2 Programme		
170	Policy Document	Standard Operating Procedures	13 <sup>th</sup> of July 2018	EDCTP
171	Spreadsheet	EDCTP2 Clinical Studies and SSA Trainees	n/a	EDCTP
172	Policy Document	EDCTP2 Evaluation Procedures and	August 2019	EDCTP
170	Cantract	Gender Balance	15 <sup>th</sup> of December	
173	Contract	Grant Agreement for the use of SIDA's Cash	15 <sup>th</sup> of December	Sida/EDCTP
		Contribution to EDCTP	2015	
		Secretariat for		
		Supporting Projects in		
		the Scope of the		
		EDCTP2 Programme		
174	Contract	Annex II General	Version of February	Sida/EDCTP
		Conditions	2015	
175	Contract	Annex III – Transfer of	Version of February	Sida/EDCTP
		Ownership of Assets	2015	
176	Contract	Annex IVa – Audit	n/a	Sida/EDCTP
		Terms of Reference (ToR)		
177	Contract	Annex IVb – Terms of Reference (ToR) for	n/a	Sida/EDCTP
		auditors for an Independent Audit		
		Report under a delegation agreement		
		financed under Horizon 2020, the EU		
		Framework		
		Programme for		
		Research and		
		Innovation		
178	Progress Report	Sida Annual Progress Report	01 January 2015 – 31 December 2015	EDCTP
179	Progress Report	Sida Annual Progress	01 January 2016 –	EDCTP
119	FIORIESS REPORT	Report	31 December 2016	
	Progress Report	Sida Annual Progress	01 January 2017 –	EDCTP
180				

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
181	Email	SIDA Annual Report for the year Ended 31	5 <sup>th</sup> of October 2018	Sida
182	Email	December 2017 EDCTP Strategic Objectives	28 <sup>th</sup> of September 2018	EDCTP
183	Email	2018 Narrative and Financial Reports to SIDA	7 <sup>th</sup> of May 2019	Sida
184	Email	2018 Narrative and Financial Reports to SIDA (2)	7 <sup>th</sup> of May 2019	Sida
185	Email	Amendment to Agreement with EDCTP for Payment Q1 2017 in Q4 2016	3 <sup>rd</sup> of December 2016	EDCTP
186	Email	2 <sup>nd</sup> Amendment to the Grant Agreement for the use of SIDA's Cash Contribution to the EDCTP Secretariat for supporting projects in the scope of the EDCTP2 Programme	29 <sup>th</sup> of November 2017	EDCTP
187	Report	Annual Report 2018 – 15th Anniversary of the EDCTP Programme	September 2019	EDCTP
188	Meeting Slides	Scientific Advisory Committee Meeting	31 March to 1 April 2016	EDCTP
189	Meeting Slides	Scientific Advisory Committee Meeting	1 to 2 September 2016	EDCTP
190	Meeting Slides	Scientific Advisory Committee Meeting	30 to 31 March 2017	EDCTP
191	Meeting Slides	Scientific Advisory Committee Meeting	14 to 15 September 2017	EDCTP
192	Meeting Slides	Scientific Advisory Committee Meeting	7 May 2018	EDCTP
193	Meeting Slides	Scientific Advisory Committee Meeting	16 September 2018	EDCTP
194	Meeting Slides	Scientific Advisory Committee Meeting	21 May 2019	EDCTP
195	Spreadsheet	Ninth EDCTP Forum – On Site Registrations – List of Participants	n/a	EDCTP
196	Blog	Ninth EDCTP blog with reports on selected sessions and interview videos with participants: http://blog.edctpforu m.org	n/a	EDCTP

No.	Туре	Title/ Project	Period	Author/ Coordinator
			(if applicable)	
197	Journal Publication	BMJ:	n/a	BMJ
		https://gh.bmj.com/co		
		ntent/4/Suppl_3		
198	Evaluation	Ninth EDCTP Forum	n/a	EDCTP
199	ToR	Terms of Reference for	n/a	EDCTP
		the development of an		
		online Open Source		
		Platform for		
		developing, discussing		
		and depositing clinical		
		trial protocols for		
		poverty-related		
		diseases (PRD		
200	Proposal	An Open Source	July 24th 2017	The Global Health
		Platform for	(revised 12 October	Network, University of
		Developing Protocols	2017)	Oxford, United
		in Poverty Related		Kingdom
		Disease		
201	Email	EDCTP Progress	6 <sup>th</sup> of September	EDCTP
		Update	2019	
202	Contract	Contract for	8 <sup>th</sup> of February	EDCTP
		Consultancy Services –	2018	
		Open Source Platform		
203	Budget	ALERRT Budget and	n/a	EDCTP
		Annex 2		
204	Financial Report	ALERRT First Financial	n/a	EDCTP
-		Report		
205	Budget	AMBITION-cm Budget	n/a	EDCTP
		and Annex 2		
206	Financial Report	AMBITION-cm First	n/a	EDCTP
		Financial Report		
207	Financial Report	AMBITION-cm Second	n/a	EDCTP
207		Financial Report	1170	Loon
208	Budget	BuruliNox Budget and	n/a	EDCTP
200	Dudget	Annex 2	in a	Eben
209	Financial Report	BuruliNox First	n/a	EDCTP
209	Finalicial Report	Financial Report	ii/a	LDCIP
210	Dudgot	C2C-TEP Budget and	n/a	ГРСТР
210	Budget	Annex 2	n/a	EDCTP
211	Financial Denant			FDCTD
211	Financial Report	C2C-TEP First Financial	n/a	EDCTP
		Report		
212	Financial Report	C2C-TEP Second	n/a	EDCTP
		Financial Report		
213	Budget	CAP012 Samba Trial	n/a	EDCTP
		Budget and Annex 2		
214	Budget	CREDU Budget and	n/a	EDCTP
		Annex 2		
215	Financial Report	CREDU First Financial	n/a	EDCTP
		Report		
216	Financial Report	CREDU Final Financial	n/a	EDCTP
		Report		

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
217	Budget	EAPI Budget and Annex 2	n/a	EDCTP
218	Financial Report	EAPI First Financial Report	n/a	EDCTP
219	Financial Report	EAPI Second Financial Report	n/a	EDCTP
220	Budget	Enhancing Ethics in Sudan Budget and Annex 2	n/a	EDCTP
221	Financial Report	Enhancing Ethics in Sudan First Financial Report	n/a	EDCTP
222	Budget	ESSLDPQ P4502D6 Budget and Annex 2	n/a	EDCTP
223	Financial Report	ESSLDPQ P4502D6 First Financial Report	n/a	EDCTP
224	Budget	ETEC Vaccine Efficacy Budget and Annex 2	n/a	EDCTP
225	Budget	EvaLAMP & db-NALFIA Budget and Annex 2	n/a	EDCTP
226	Financial Report	EvaLAMP & db-NALFIA First Financial Report	n/a	EDCTP
227	Budget	Evaluate 4mTB Budget and Annex 2	n/a	EDCTP
228	Financial Report	Evaluate 4mTB First Financial Report	n/a	EDCTP
229	Budget	HATUA KENYA Budget and Annex 2	n/a	EDCTP
230	Financial Report	HATUA KENYA First Financial Report	n/a	EDCTP
231	Budget	IMPROVE Budget and Annex 2	n/a	EDCTP
232	Financial Report	IMPROVE First Financial Report	n/a	EDCTP
233	Financial Report	IMPROVE Second Financial Report	n/a	EDCTP
234	Budget	KENYA CVHIV Budget and Annex 2	n/a	EDCTP
235	Budget	MEPIE Study Budget and Annex 2	n/a	EDCTP
236	Financial Report	MEPIE Study First Financial Report	n/a	EDCTP
237	Budget	MIDAS Budget and Annex 2	n/a	EDCTP
238	Financial Report	MIDAS First Financial Report	n/a	EDCTP
239	Budget	MMVC Budget and Annex 2	n/a	EDCTP
240	Financial Report	MMVC First Financial Report	n/a	EDCTP
241	Budget	MyTB Budget and Annex 2	n/a	EDCTP

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
242	Financial Report	MyTB First Financial Report	n/a	EDCTP
243	Budget	PANDORA-ID-NET Budget and Annex 2	n/a	EDCTP
244	Financial Report	PANDORA-ID-NET First Financial Report	n/a	EDCTP
245	Budget	PRACE Budget and Annex 2	n/a	EDCTP
246	Financial Report	PRACE First Financial Report	n/a	EDCTP
247	Budget	PREGART Budget and Annex 2	n/a	EDCTP
248	Budget	PrEPVacc Budget and Annex 2	n/a	EDCTP
249	Financial Report	PrEPVacc First Financial Report	n/a	EDCTP
250	Budget	PROFORMA Budget and Annex 2	n/a	EDCTP
251	Financial Report	PROFORMA First Financial Report	n/a	EDCTP
252	Budget	RaPaed TB Budget	n/a	EDCTP
253	Financial Report	RaPaed TB First Financial Report	n/a	EDCTP
254	Budget	REECAO Budget and Annex 2	n/a	EDCTP
255	Financial Report	REECAO First Financial Report	n/a	EDCTP
256	Financial Report	REECAO Second Financial Report	n/a	EDCTP
257	Budget	ROVAS-2 Budget and Annex 2	n/a	EDCTP
258	Financial Report	ROVAS-2 First Financial Report	n/a	EDCTP
259	Budget	Simplici-TB Budget and Annex 2	n/a	EDCTP
260	PERIODIC REPORT of the ACTION	Burulinox	APRIL 2018 – MARCH 2019	Kwame Nkrumah University of Science and Technology (KNUST), Ghana
261	PERIODIC REPORT of the ACTION	CREDU	1 <sup>st</sup> July 2018 –30 <sup>th</sup> June 2019	Uganda National Council for Science and Technology (UNCST), Uganda
262	PERIODIC REPORT of the ACTION	EvaLAMP & db-NALFIA	01 July 2018 – 30 June 2019	Mekelle University, Ethiopia
263	PERIODIC REPORT of the ACTION	Evaluate 4mTB	1 April 2018 to 31 March 2019]	Stellenbosch University, South Africa
264	PERIODIC REPORT of the ACTION	HATUA -KENYA	1stApril 2018- 31stMarch 2019	Medical Research Institute (KEMRI), Kenya

No.	Туре	Title/ Project	Period (if applicable)	Author/ Coordinator
265	PERIODIC REPORT of the ACTION	MEPIE STUDY	1stMay 2018- 31stMay2019	Mbale Regional Referral Hospital, Uganda
266	PERIODIC REPORT of the ACTION	MIDAS	01 July 2018 - 30 June 2019	The Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa
267	PERIODIC REPORT of the ACTION	MMVC	1st April 2018 – 31st March 2019	The Chancellor, Masters and Scholars of the University of Oxford (UOXF), United Kingdom
268	PERIODIC REPORT of the ACTION	МуТВ	20March 2018 -31 March 2019	Stellenbosch University (SU), Stellenbosch, South Africa
269	PERIODIC REPORT of the ACTION	PANDORA-ID-NET	March1st 2018 to February 28th 2019	Fondation Congolaise pour la Recherche Médicale (FCRM), Congo
270	PERIODIC REPORT of the ACTION	PRACE	March1st 2018 to February 28th 2019	African Institute of Biomedical Science and Technology, Zimbabwe
271	PERIODIC REPORT of the ACTION	REECAO	April 01, 2018to March 31, 2019	Ministère de la santé et de l'hygiène publique, Mali
272	Grant Application	IMPROVE-2	2019	Liverpool School of Tropical Medicine (LSTM), United Kingdom
273	Email	Copy of EDCTP Award 68453 10-09-19	12 of September 2019	EDCTP
274	Minutes	EDCTP Audit Committee meeting held by teleconference	12 March 2018	EDCTP
275	Minutes	EDCTP Audit Committee (AC)	7 May 2018	EDCTP
276	Minutes	EDCTP Audit Committee meeting held by teleconference	22 November 2018	EDCTP
277	Minutes	EDCTP Audit Committee meeting held by teleconference	12 March 2019	EDCTP
278	Minutes	EDCTP Audit Committee (AC)	20 May 2019	EDCTP

### ANNEX 5: LIST OF INTERVIEWEES

	Name	Organisation
1	Norbert Heinrich	Ludwig-Maximilians-Universitaet Muenchen
2	Francine Ntoumi	Fondation Congolaise pour la Recherche Médicale
3	Akwaowo Christie	University of Uyo Teaching Hospital
4	Alo Chihurumnanya	Ebonyi State University
5	Dawit Wolday	Mekelle University
6	Collen Masimirembwa	African Institute of Biomedical Science and Technology (Private) Limited (AiBST)
7	Jonas Lexow	Medical Research Council Unit The Gambia/ London School of Hygiene & Tropical Medicine
8	Joseph Jarvis	London School of Hygiene and Tropical Medicine
9	Nelita Du Plessis	Stellenbosch University
10	Richard Mwaiswelo	Tropical Pesticides Research Institute (TPRI)
11	Roma Chilengi	Centre for Infectious Disease Research in Zambia Limited (CIDRZ)
12	Winfred B Nazziwa	Uganda National Council for Science and Technology
13	Jenny Hill	Liverpool School of Tropical Medicine
14	Michael Makanga	EDCTP
15	Evelyne Ombati	Kenya Medical Research Institute
16	Garry Aslanyan	WHO TDR
17	Grace Waititu	Kenya Medical Research Institute
18	Hannah Akuffo	Sida
19	Inmaculada Penas Jimenez	European Commission
20	Kevin McCarthy	European Commission
21	Melese Addisu	Bahir Dar University
22	Björn Sjöstrand	Scandinavian Biopharma Holding AB
23	Nuraan Fakier	EDCTP
24	Okedo-Alex Ijeoma Nkem	Ebonyi State University
25	Pires Germano	Mozambique Ministry of Health
26	Eleni Aklillu	Karolinska Institutet
27	Catherine Hankins	McGill University
28	Feiko ter Kuile	Liverpool School of Tropical Medicine
29	Salim S. Abdool Karim	Centre for the Aids Programme of Research in South Africa
30	Uneke Chigozie Jesse	Ebonyi State University