



Department  
of Health &  
Social Care

# **DHSC contribution to EDCTP Annual Review - 1 Jan 2018 to 30 Apr 2020**

**NIHR Global Health Research Portfolio**

Published December 2020

## Contents

Annual reporting and review process.....	3
1. DHSC summary and overview .....	4
2. Summary of aims and activities.....	9
3. Outputs and outcomes .....	20
4. Theory of Change and progress towards longer term impacts.....	38
5. Value for money .....	40
6. Risk .....	44
7. Delivery, commercial and financial performance.....	47
8. Monitoring, evaluation and learning.....	49
9. Diversity and environmental sustainability.....	53

# Annual reporting and review process

The Annual Reporting and Annual Review templates are part of a continuous process of review and improvement within DHSC's Global Health Research portfolio. These are an opportunity for DHSC and partners responsible for delivering a funding scheme to reflect critically on the performance and ongoing relevance of awards.

The main sections of the template have been developed in accordance with cross-funder common reporting practice. Within these common sections, sub-sections have been included to enable us to test our portfolio Theory of Change using evidence collected in accordance with the DHSC GHR portfolio results framework.

The process for completing this template involves the following steps:

- DHSC works with partners responsible for delivering a funding scheme to ensure that the relevant monitoring information is collected at the award level (as set out in the DHSC Global Health Research results framework). This information will be collected using existing reporting mechanisms wherever possible, before bespoke reporting is considered.
- Delivery partners collate a synthesis of the award level monitoring information and present aggregated funding scheme level findings (and award level wherever specified) within this template. Any findings or views on performance should be clearly linked to the evidence base.
- This report is then shared with DHSC for comment and feedback.
- DHSC will then use the annual report and additional information gathered through meetings, field visits and any other documentation to complete the annual review template - **relevant sections are highlighted with green boxes**. This will include an assessment of overall funding scheme performance over the last 12 months, identify lessons learnt, time-bound recommendations for action consistent with key findings and will be used as an evidence base for future funding decisions.
- Annual review signed off and published.

# 1. DHSC summary and overview

## 1.1 Brief description of funding scheme

The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to support collaborative research that accelerates new or improved ways to diagnose, prevent or treat infectious diseases affecting sub-Saharan Africa. EDCTP especially aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related infectious diseases, with a focus on large late-stage clinical trials that help further assess safety. EDCTP funds clinical trials/research projects as part of competitive research funding calls around specific themes with clear aims. Each year, a series of calls forms part of that years' Scientific Advisory Committee and General Assembly-approved EDCTP work plan. The Department of Health and Social Care (DHSC) has contributed to the 2016, 2017, 2018, and most recently the 2020 EDCTP work plan. DHSC also contributes to programme activities costs, which support the EDCTP secretariat.

This annual review covers the reporting period January 2018 (the start of DHSC contributions to EDCTP) to April 2020.

## 1.2 Summary of funding scheme performance over the last 12 months (general progress on activities, early outputs, outcomes, impacts across all awards)

### General progress -

As of May 2020 when the report was submitted, DHSC was supporting 17 projects, as well as one awarded proposal under grant agreement preparation, as part of seven EDCTP research calls within its 2016-2018 work plans. These are summarised in more detail below. In short, all projects have been impacted by COVID-19, the full extent of which is yet to be determined and will require follow-up by DHSC.

(1) Call: Research and clinical management of patients in poverty-related disease epidemics in sub-Saharan Africa

DHSC is funding two projects under this call: (1) Pan-African network for rapid research, response, relief and preparedness for infectious diseases epidemics (PANDORA-ID NET), and (2) African coalition for epidemic research, response and training (ALERT).

The two projects are on track, have actively responded to disease outbreaks in the region (Lassa fever, Ebola, plague, monkeypox, Chikungunya) and notably are now active in the COVID-19 response.

(2) Call: Clinical trials to reduce health inequities in pregnant women, newborns and children

Under this call, DHSC supports three ongoing projects: (1) Combined HIV African prevention study: on demand pre-exposure and post exposure prophylaxis to protect adolescents from HIV (CHAPS); (2) Prevention of mother-to-child transmission of HIV-1: program evaluation and innovative rescue intervention integrated in the expanded program of immunisation (PROMISE-EPI); and (3) Neonatal HIV early infant diagnosis (EID) versus standard of care EID – impact on infant health: a feasibility study of point-of care testing at birth versus at six weeks of age, on the uptake of anti-retroviral therapy and infant prophylaxis, and on rates of infant survival, morbidity and retention in care (LIFE Study).

All three studies began participant recruitment between October and December 2019; however, COVID-19 has delayed progress, with full impact yet to be determined.

(3) Call: Strategic actions supporting large-scale clinical trials

DHSC is funding one ongoing project under this call, namely: The partnership for research on Ebola vaccinations-extended follow-up and clinical research capacity build-up (PREVAC-UP).

A parasitological survey and early community engagement work has been completed; however planned capacity development workshops have been postponed due to COVID-19.

(4) Call: Clinical trials to reduce health inequities in pregnant women, newborns and children

DHSC supports two ongoing projects under this call: (1) Empirical treatment against cytomegalovirus and tuberculosis in severe pneumonia in HIV-infected infants: a randomised controlled clinical trial (EMPIRICAL), and (2) A cluster randomised trial to evaluate the effectiveness of household alcohol-based hand rub for the prevention of sepsis, diarrhoea and pneumonia in Ugandan infants (BabyGel).

The trial activities for both projects have been suspended due to COVID-19, however the BabyGel team is assessing the implications of the COVID-19 pandemic on their study design, given that the intervention under study is the use of an alcohol-based hand rub.

(5) Call: Diagnostic tools for poverty-related diseases

DHSC provides funding to four ongoing projects under this call, namely: (1) Field evaluation of a point-of-care triage test for active tuberculosis (Triage TB); (2) Phase III evaluation of an innovative simple molecular test for the diagnosis of malaria in different

endemic and health settings in sub-Saharan Africa (DIAGMAL); (3) Clinical evaluation of a loop-mediated isothermal amplification test for *Treponema pallidum pertenuis*: a diagnostic tool to support Yaws eradication (LAMP4Yaws), and (4) Early risk assessment in tuberculosis contacts by new diagnostic tests (ERASE-TB).

In addition, one more DHSC supported project is in grant agreement preparation: A randomised control trial to evaluate a scalable active case-finding intervention for tuberculosis using a point-of-care molecular tool, Xpert Omni (XACT III).

With the exception of the XACT III study, all projects have formally begun and had their initial meetings in late 2019/early 2020. First progress reports from these projects to EDCTP are due in the next six months (late 2020/early 2021); however, delays in milestones due to COVID-19 are expected, with full impact yet to be determined.

(6) Call: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

DHSC is providing funding to four projects under this call, namely: (1) Vitamin D for adolescents with HIV to reduce musculoskeletal morbidity and immunopathology: an individually randomised, double-blinded placebo-controlled trial (VITALITY); (2) Preventing and delaying the development of diabetes in Africa: a randomised placebo-controlled double-blind phase III trial of metformin in HIV-infected persons with pre-diabetes (META TRIAL); (3) Randomised controlled trial of preventive treatment of latent tuberculosis infection in patients with diabetes mellitus (PROTID), and (4) Improved flucytosine formulation for the treatment of meningitis in advanced HIV disease (5FC HIV-Crypto).

All projects began on schedule in early 2020, with first progress reports due to EDCTP in early 2021. However, delays in project milestones due to COVID-19 are expected, with full impact yet to be determined.

(7) Call: Vaccines for diarrhoeal diseases or lower respiratory tract infections

DHSC is funding one project under this call: Prevention of invasive Group B *Streptococcus* (GBS) disease in young infants: a pathway for the evaluation and licensure of an investigational maternal GBS vaccine (PREPARE).

The project has begun recruitment in order to establish the GBS disease incidence rate in an urban Ugandan cohort and its second annual meeting will take place virtually in October 2020, followed shortly after by its first progress report to EDCTP; delays in project milestones due to COVID-19 are expected.

---

Early inputs and outputs from EDCTP to highlight -

(1) EDCTP calls encourage patient and community engagement, and in the case of clinical studies, require it. An example is the BabyGel team, who aim to inclusively include women and members of the public at each stage of the BabyGel trial. The project brought together local women from Mbale Regional Referral hospital, and villages around Mbale who provided opinions, helped shape the design of BabyGel logo and a BabyGel trial poster.

(2) EDCTP is a European-African partnership, which embodies equitable partnership and strives to promote gender equity at all levels. Each Participating State (14 European and 16 African countries) contributes to EDCTP governance with equal voting rights and involvement in planning and decision making. During the evaluation procedures, proposals are assessed not only on scientific excellence but on contributions to research capacity strengthening, appropriateness of the allocation of tasks and resources, and the involvement of African researchers in the scientific leadership of the studies.

(3) DHSC-funded awards have published 22 peer-reviewed articles to date, 55% (12 of 22) with a female lead or senior author, and 36% (8 of 22) with a lead or senior author based in an LMIC. DHSC funding had also contributed to the training of 19 individuals (including 10 PhDs), the majority of whom are LMIC-based and female, as part of EDCTP's broader research capacity strengthening efforts.

(4) Thanks to their prompt response to COVID-19, the DHSC-funded epidemic consortia, PANDORA-ID NET and ALERRT, have been highlighted as examples of Global EU response to the coronavirus pandemic and attracted international media citations as a result.

### 1.3 Performance of delivery partners

EDCTP is an important DHSC delivery partner. EDCTP is a well-regarded mechanism which directly funds high-quality, high-impact clinical research in sub-Saharan Africa. They also employ responsive risk management, and share the same values of equitable partnership, community engagement, value for money, and the importance of monitoring, evaluation and learning.

This first annual review has been an informative insight into the EDCTP calls and projects DHSC helps support. Some project-level information was not included due to the timing of this report, and there are expected delays to almost all projects as a result of COVID-19. DHSC will follow-up on these as part of its routine monitoring.

DHSC thanks the EDCTP secretariat for their efforts to summarise a diverse portfolio via this report, for continuing to engage with the UK as a General Assembly member and DHSC as a funder, and for continuing to be responsive to requests for information as and when they are needed by the DHSC team.

1.4 What are the key lessons identified over the past year for wider DHSC/NIHR global health research

EDCTP is unique within the DHSC portfolio in terms of its size, structure, and ways of working, and therefore it is difficult to draw lessons that would apply to the rest of the DHSC portfolio. The main lesson, not unique to EDCTP, is the importance of regular communication outside of formal meetings (such as the General Assembly), particularly this year where projects and research teams have been impacted by COVID-19.

1.5 DHSC to summarise key recommendations/actions for the year ahead, with ownership and timelines for action

Recommendation	Owner	Timeline
Follow up with EDCTP regarding any updates on COVID-19 related impact, including for those nine projects that had not submitted their own reports to EDCTP in time for inclusion in this report	DHSC	October 2020 (annual reporting period mid-point)
Follow up with DHSC transparency lead for an update on International Aid Transparency Initiative (IATI) guidance for partners including EDCTP	DHSC	September 2020, to update EDCTP in October.
Follow up with EDCTP re: 2020 Work Plan	DHSC	ongoing
Continue to monitor progress and plans for EDCTP3	DHSC	ongoing
Consider PANDORA-ID NET and ALERRT projects as possible impact case studies	DHSC	ongoing
Work with EDCTP to potentially build on and more closely complement research capacity strengthening and research uptake areas of work (DHSC priority areas)	DHSC	ongoing



## 2. Summary of aims and activities

### 2.1 Overview of award/funding call aims

DHSC is currently supporting seven EDCTP calls for proposals and the resulting 17 ongoing projects, as well as one awarded proposal under grant agreement preparation.

(1) Call: [Research and clinical management of patients in poverty-related disease epidemics in sub-Saharan Africa](#) aims to accelerate evidence for the optimal clinical management of patients and for guiding the public health response in case of epidemic outbreaks.

DHSC is funding two ongoing projects under this call: (1) [PANDORA-ID-NET](#) and (2) [ALERRT](#)

(2) Call : [Clinical trials and operational research studies aims to optimise the use of products \(new or improved products or combination of products\) for poverty-related diseases in mothers, newborns, children and/or adolescents in Sub-Saharan Africa.](#)

Under this call, DHSC supports three ongoing projects: (1) [CHAPS](#); (2) [PROMISE-EPI](#); and (3) [LIFE Study](#)

(3) Call: [Strategic actions supporting large-scale clinical trials](#) aims to support strategic actions (clinical research activities), notably phase III studies, which are part of a large-scale clinical trial with the potential to achieve rapid advances in the clinical development of medical interventions (drugs, diagnostics, vaccines, microbicides) for poverty-related diseases.

DHSC is funding one ongoing project under this call, namely: [PREVAC-UP](#)

(4) Call: [Clinical trials to reduce health inequities in pregnant women, newborns and children](#) aims to accelerate the adaption and/or optimisation of treatment and prevention products (excluding vaccines) in pregnant women, newborns and/or children in Sub-Saharan Africa.

DHSC supports two ongoing projects under this call: (1) [EMPIRICAL](#), and (2) [BabyGel](#)

(5) Call: [Diagnostic tools for poverty-related diseases](#) aims to support validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies. These should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response with a significant impact on clinical decision and health outcomes.

DHSC provides funding to four ongoing projects under this call, namely: (1) Triage TB; (2) [DIAGMAL](#); (3) LAMP4Yaws , and (4) ERASE-TB

Furthermore, one more DHSC supported project is in grant agreement preparation, namely: XACT III.

(6) Call: [Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities](#) aims to fund improvements in the prevention, treatment and/or clinical management of co-infections and co-morbidities in sub-Saharan Africa.

DHSC is providing funding to four projects under this call, namely: (1) VITALITY; (2) META TRIAL; (3) [PROTID](#) ,and (4) 5FC HIV-Crypto.

(7) Call: [Vaccines for diarrhoeal diseases or lower respiratory tract infections](#) aims to accelerate the development of vaccines for diarrhoeal infections and lower respiratory tract infections in sub-Saharan Africa.

DHSC is funding one project under this call, namely [PREPARE](#).

## 2.2 Delivery partner's assessment of progress against milestones/deliverables

Award	Current status of progress against milestones/deliverables	If the award is not on track to contribute to expected outcomes and impacts, why not? What are the potential impacts of this and how have plans been revised to accommodate this?
RIA2016E (PRD Epidemics)	<p>The call is on track to contribute towards expected outcomes/impact.</p> <p>The two funded projects - ALERRT and PANDORA-ID-NET - have actively responded to disease outbreaks in the region (Lassa fever, Ebola, plague, monkeypox, Chikungunya) and notably are now active in the COVID-19 response. For example, ALERRT has revised its <a href="#">FISSA study</a> (Febrile Illness in Sub-Saharan Africa) protocol to include a research response component in the event of a Public Health Emergency (COVID-19 for now) declaration by national or international health authorities in countries participating in the FISSA study.</p> <p>PANDORA-ID-NET has adapted the WHO "First Few X (FFX) Cases and contact investigation protocol for COVID-19" (see <a href="#">FFX protocol</a>) to the African context, to identify transmission dynamics (asymptomatic patients). The projects will</p>	n/a

	<p>remain largely unaffected by COVID-19 outbreak because their focus is on addressing epidemic threats. However, there is likely to be an increased attention to COVID-19 in future project activities in comparison to other epidemic diseases.</p>	
RIA2016MC (Maternal & Child Health)	<p>The call was on track to contribute towards expected outcomes/impact. However, the projects are now likely to be affected by COVID-19 outbreak.</p> <p>CHAPS project comprises three studies evaluating PrEP requirements in young people in sub Saharan Africa: study 1 is a social science study with the aim of identifying barriers to medication adherence; phase 2 is a clinical trial registered under <a href="#">NCT03986970</a> which evaluates different doses and timing of oral PrEP. The trial began recruitment in November 2019. Study 3 will look at post-exposure administration of drugs.</p> <p>The PROMISE-EPI trial, registered under <a href="#">NCT03870438</a>, initiated recruitment in Zambia in December 2019, following preparation phase: purchasing supplies and study medication and performing training at the selected sites as well as obtaining ethics and regulatory approvals.</p> <p>The LIFE study, registered under <a href="#">NCT04032522</a>, initiated recruitment in</p>	<p>Delays and suspensions related to COVID-19 are very likely. The extent of COVID-19 impact is yet to be determined.</p>

	<p>October 2019, following preparation phase: obtaining approvals and organising trainings for each country's study team as well as for nurses and midwives.</p>	
RIA2017S (Strategic Actions)	<p>The call is on track to contribute towards expected outcomes/impact. However, delays in project milestones due to COVID-19 have been reported.</p> <p>PREVAC-UP will provide data regarding long-term immunogenicity and safety of three different Ebola vaccine regimens, as well as the impact of co-infections on the persistence on the antibody response. Most project activities to date have focused on the preparation of the PREVAC-UP trial (follow-on to PREVAC trial: <a href="#">NCT02876328</a>.) In order to evaluate the impact of malaria and other parasitic infections on the persistence of the antibody response to two Ebola vaccines, a parasitological survey was conducted in Sierra Leone. Extensive community engagement work has been carried out alongside the trial in each site. Several capacity building activities have been initiated, including collaboration on setting up a new university degree in Global Health and Emerging diseases in Guinea.</p>	<p>The consortium reported postponement of capacity development workshops due to COVID-19.</p>
RIA2017MC (Maternal & Child Health)	<p>The call was on track to contribute</p>	

	<p>towards expected outcomes/impacts. However, the projects are now put on hold due to COVID-19 outbreak.</p> <p>EMPIRICAL study is registered under <a href="#">NCT03915366</a>. The consortium reported to EDCTP that it was ready to begin recruitment but the trial has been put on hold due to the COVID-19 outbreak.</p> <p>The Babygel study received its final ethical approval. Training took place in Uganda in January 2020 and the team was ready to start the study in April 2020. However, COVID-19 halted all study activities in Uganda from March onwards and the team is currently assessing the implications of the COVID-19 pandemic on their study design, given that the intervention is the use of an alcohol-based hand rub.</p>	<p>Delays to EMPIRICAL study are expected due to COVID-19. The consortium reported that the EMPIRICAL Executive Committee are working on an emergency plan. They are weighing up the risk/benefit at all the sites and remain in communication. Under the guidance of the trial steering committee and DSMB, the executive committee will decide whether activities (and which ones) need to be put on hold.</p> <p>The Babygel project reported to EDCTP that all organisations involved in the Babygel study are working remotely in accordance with Governments' instructions on limiting the spread of COVID-19. Meetings are taking place online. Contingency arrangements are being put in place to ensure that once the COVID-19 restrictions are lifted the study can move forward as quickly as possible.</p>
RIA2018D (Diagnostics)	<p>The call was on track to contribute towards expected outcomes/impacts. However, delays in project milestones due to COVID-19 are expected.</p>	<p>The first progress reports are due in Q4 2020 (Triage TB) or in Q1 and Q2 2021 (remaining projects). Delays in project milestones due to COVID-19 are expected.</p>

Triage TB project started on 1 October 2019. Study preparations are slightly delayed due to COVID-19 related restrictions, but study documents have been submitted for ethical approval. A project website was created and can be found under <https://www.triagetb.com/>.

The DIAGMAL grant started on 1 December 2019 and had its kick-off meeting in January 2020. In June 2020, the consortium finalised the generic study protocol and the respective study sites submitted the protocol for ethical approval in July 2020. The consortium has also carried out two (virtual) investigators meetings in February and May 2020. Project website is available at <http://malariadx.org/index.html>

LAMP4Yaws started on 1 January 2020 and the protocol was submitted for ethical approval. The consortium plans to begin recruitment as originally planned in 2021, however it is dependent on COVID-19 outbreak. Project website is available on <https://www.lshtm.ac.uk/research/centres-projects-groups/lamp4yaws>.

ERASE-TB started in May 2020 and is at the preparation stage.

RIA2018CO (Co-infections and Co-morbidities)

The call was on track to contribute towards expected outcomes/impacts. However, delays in project milestones due to COVID-19 are expected.

VITALITY started 1 January 2020 and held a kick-off meeting in January in Harare, Zimbabwe. Trial preparations are ongoing and include finalising the study protocol and submitting study documents for ethics and regulatory approval.

META Trial project started on 1 April 2020 and held its virtual meeting in June 2020 in order to kick off a phase 3 randomised placebo-controlled double-blind trial of metformin in HIV-infected persons with pre-diabetes.

PROTID started on 1 January 2020 and its kick-off meeting took place in January in Mbeya, Tanzania. Study preparations are ongoing but slightly delayed due to current restrictions. A project website was created and can be found under <https://www.protid-africa.com/>.

5FC HIV-Crypto started 1 July 2020 and held a virtual kick-off meeting in June. Preparatory work regarding study protocols and pharmaceutical development activities with the industrial partner is ongoing.

All DHSC supported projects will submit their first progress reports in 2021. Delays due to COVID-19 are expected. Exact details are yet to be determined.



RIA2018V (Vaccines)

The call was on track to contribute towards expected outcomes/impacts. However, delays in project milestones due to COVID-19 are expected.

PREPARE started on 1 October 2019. Its kick-off meeting took place in London, UK in October 2019 and its second annual meeting is scheduled for 1 October 2020 (remotely). Study proceedings of PREPARE are tightly linked to another project that was recently awarded via the EDCTP emergency funding mechanism. PREPARE is actively recruiting in order to establish the GBS disease incidence rate in an urban Ugandan cohort. A project website was created and can be found under <https://gbsprepare.org/>.

The project will submit its progress report to EDCTP in the last quarter of 2020. Delays in project milestones due to COVID-19 are expected.

2.3 Delivery partner's assessment of how individuals/communities (including any relevant sub-groups) have been engaged and their needs reflected in identifying research priorities, design/planning, implementation, analysis, and reporting and dissemination

EDCTP encourages community engagement in research as an interactive relationship between researchers, policy makers and local communities (in line with WHO's broad understanding of community engagement that involves various end users of research results<sup>1</sup>). A number of EDCTP calls have either explicitly required or encouraged submission of project proposals involving community engagement strategies concerning both local community members as well as policy makers. Examples include the 2014

<sup>1</sup> See for example <https://www.who.int/hiv/pub/6.pdf>

call on [Maximising the impact of EDCTP research: translation of research results into policy and practice](#), the 2020 call on [Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives](#) and the [2020 Regional Networks](#) call. Moreover, all EDCTP projects involving clinical studies are required to specify details concerning patient and community involvement. Please see the [EDCTP Template for essential information to be provided for proposals including clinical trials and diagnostic studies](#).

In the DHSC-supported projects there are several examples of activities and deliverables oriented towards building interactive engagement with end users of research results:

ALERRT has a dedicated set of activities aiming to set up systems of community engagement for clinical trials and outbreak responses and conduct social science research in order to collect evidence of effective engagement. The project has used the NIH/EDCTP/DHSC-supported [PREVAC](#) vaccine trial in Sierra Leone as a case study to determine best practices in engaging communities around biomedical research. Findings from the trial review are presented in the paper [Lessons learned from engaging communities for Ebola vaccine trials in Sierra Leone: reciprocity, relatability, relationships and respect \(the four R's\)](#). ALERRT teams have also partnered with the Nuffield Council on Bioethics, Wellcome Centre for Ethics and Humanities (WEH) and Ethox Centre at the University of Oxford to host a two-day international consultative workshop of 40 stakeholders in Dakar, Senegal (March 2019) under a theme '[Community engagement in and for ethical research in outbreaks of infectious disease and other humanitarian crises](#)'. In the [FISSA study](#) (Febrile Illness in Sub-Saharan Africa) ALERRT will seek input from social experts to explore social aspects and their implications on patients and care givers.

PANDORA ID NET aims to engage policymakers, global public health bodies and communities on ethical, administrative, regulatory and operational obstacles during outbreaks. Within this context, the consortium member Chatham House organised with SciDev.Net a media training for public health officials in order to promote provision of appropriate, evidence-based information and advice to the public during outbreaks. The training took place on 15 March 2019 and involved 30 Public Health officials working in Africa.

The LIFE Study is assessing whether the use of new rapid diagnostic tests for HIV leads to quicker and better treatment of infants with HIV. The LIFE Study has a strong focus on implementation research of most recent paediatric HIV test & treat strategies, including a component for cost-effectiveness, socio-economic and operational feasibilities. These concepts were introduced to the local, regional/provincial and national HIV health authorities and HIV programme coordinators in Mozambique and Tanzania to encourage considerations beyond the study phase and thus concerning sustained services provision.

EMPIRICAL project aims to communicate and disseminate study results to the community, scientists and policymakers. The project issued press releases to various media outlets (trade press, journals, web portals) to ensure that industry, civil society organisations, policy-making authorities, and the wider community are aware and supportive of the project, its objectives and, later in the project, its outcomes.

BabyGel recognises public involvement as an important part of its research and aims to include women and members of the public at each stage of the BabyGel trial. For example, the project brought together local women from Mbale Regional Referral hospital, and villages around Mbale who provided opinions and helped shape the design of BabyGel logo and a BabyGel trial poster. The project also organised meetings in the Mbale, Budaka, Butebo, and Bukedea districts of Uganda, where village members met with their leaders and confirmed boundaries for numerous villages in Budaka and Busiu Hubs.

### 3. Outputs and outcomes

#### 3.1 Aggregated number of outputs by output type.

The following represent figures from all DHSC supported calls with at least 22% of DHSC's funding.

<b>Output type</b>	<b>Total number across all DHSC funded awards (cumulative number since funding began)</b>
Assay/cell line/antibody/biomarker	Not quantified
Book chapter	0
Whole book	0
Checklists/scales	Not quantified
Cochrane review	0
Conference abstract/conference publication	4
Conference poster	Not quantified
Database	Not quantified
Diagnostic test/diagnostic studies*	14
Peer reviewed articles	22
Vaccine studies*	8
Drug (prevention and treatment studies)*	13

\*all figures concern ongoing studies as well as planned (in preparation) studies

EDCTP's monitoring system has identified several key outputs that are expected across the entire portfolio and are therefore systematically collected, quantified and reported. These include, for example, scientific outputs such as clinical studies, scientific publications, capacity development-related outputs (trainees and trainings) as well as outputs/outcomes related to IP rights and policies (patent applications/patent granted, policies influenced e.g. citations in clinical reviews, clinical guidelines, systematic reviews or other policy documents issued by national, regional or international policymaking bodies). We are reporting these in sections 3.1-3.3 (publications, clinical studies) as well as 3.6 (trainees). Regarding policy influencing, we are not quantifying this at output level, e.g. no. of policy decision makers reached, number of outreach events, only at outcome level (results of engagement in terms of contributions to policy change).

3.2 List of research and innovation outputs produced that are considered **by award holders** to be most significant in contributing towards high quality applied global health knowledge with strong potential to address the needs of people living in low- and middle-income countries. This list should include up to 3 outputs per award.

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	Digital Object Identifier (where applicable)
RIA2016E (PRD Epidemics)	<a href="#">Preparedness and vulnerability of African countries against importations of COVID-19: a modelling study</a>	Marius Gilbert, Giulia Pullano, Francesco Pinotti, Eugenio Valdano, Chiara Poletto, Prof Pierre-Yves Boëlle, Eric D'Ortenzio, Prof Yazdan Yazdanpanah, Serge Paul Eholie, Mathias Altmann, Bernardo Gutierrez,	February 20, 2020	Article (The Lancet)	10.1016/S0140-6736(20)30411-6

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	Digital Object Identifier (where applicable)
	<a href="#">Is Africa prepared for tackling the COVID-19 (SARS-CoV-2) epidemic? Lessons from past outbreaks, ongoing pan-African public health efforts, and implications for the future</a>	<p>Moritz U G Kraemer, Vittoria Colizza</p> <p>Nathan Kapata Chikwe Ihekweazu Francine Ntoumi Tajudeen Raji Pascalina Chanda-Kapata Peter Mwaba Victor Mukonka Matthew Bates John Tembo Victor Corman Sayoki Mfinanga Danny Asogun Linzy Elton Liã Bárbara Arruda Margaret J. Thomason Leonard Mboera Alexei Yavlinsky Najmul Haider David Simons Lara Hollmann Swaib A. Lule</p>	February 28, 2020	Editorial (International Journal of Infectious Diseases)	10.1016/j.ijid.2020.02.049

EDCTP Annual Review (covering 1 Jan. 2018 to 30 Apr. 2020)

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	Digital Object Identifier (where applicable)
	<a href="#">PANDORA &amp; ALERRT Data Sharing Principles</a>	Francisco Veas Muzamil Mahdi Abdel Hamid Osman Dar Sarah Edwards Francesco Vairo Timothy D. McHugh Christian Drosten Richard Kock Giuseppe Ippolito Alimuddin Zumla  Members of ALERRT and PANDORA-ID-NET consortia	19 March 2019	Best practice Guidelines	
RIA2016MC (Maternal & Child Health)	Developing attributes and attribute-levels for a Discrete Choice Experiment on oral Pre-Exposure Prophylaxis (PrEP) delivery among young people in Cape Town and Johannesburg, South Africa	Stefanie Hornshuh, Andrew Ssemata, Teacler Nematadzira, Nadia Ahmed, Millicent Atunjuna, Richard Muhumuza, Nash S, Lynda Stranix-Chibanda, Neil Martinson, Janet Seeley, Linda-Gai	29 July 2019	Conference Publication (AIDSImpact conference 2019)	

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	Digital Object Identifier (where applicable)
	"People will Think I am Infected with HIV": Exploring Barriers and Facilitators of PrEP Uptake Among Young People in Uganda, Zimbabwe and South Africa	Bekker, Helen Weiss, Janan Dietrich, Julie Fox.  Richard Muhumuza, Andrew Ssemata, Steffi Hornschuh, Teacler Nematadzira, Nash S, Linda-Gail Bekker, Janan Dietrich, Lynda Stranix-Chibanda, Janet Seeley and Julie Fox	29 July 2019	Conference Publication (AIDSImpact conference 2019)	
RIA2018CO (Co-infections and Co-morbidities)	<a href="#">Having diabetes and being underweight in Asia: a potent risk factor for tuberculosis</a>	R van Crevel, I Andia-Biraro, N E Ntinginya, N Chamba, J Critchley, L Te Brake, D Kibirige, C K Manyama, K Kilonzo, M Pennington, K Sharples, P C Hill	1 June 2020	Response (International Journal of Tuberculosis and Lung Disease)	<a href="https://doi.org/10.5588/ijtld.20.0033">10.5588/ijtld.20.0033</a>

3.3 Lead/senior authorship



The following represent figures from all DHSC supported calls where at least 22% of funding comes from DHSC.

	No.	% of total number of externally peer-reviewed research publications
Number of externally peer-reviewed research publications with a lead or senior author whose home institution is in an LMIC*	8 out of 22	36%
Number of externally peer-reviewed research publications with a female lead or senior author**	12 out of 22	55%
Number of externally peer-reviewed research publications with a female lead or senior author whose home institution is in an LMIC***	2 out of 22	9%

\* We are calculating the number of peer-reviewed publications with first or last author whose home institution is in sub-Saharan Africa (this includes South Africa)

\*\* We are calculating the number of peer-reviewed publications with female first or last author

\*\*\* We are calculating the number of peer-reviewed publications with female first or last author whose home institution is in sub-Saharan Africa (this includes South Africa)

### 3.4 Delivery partner's summary of the most significant outcomes of any award level engagement and/or influence of policy makers, practitioners and individual/community behaviour

Thanks to their prompt response to COVID-19, the EDCTP epidemic-preparedness consortia, namely PANDORA-ID NET and ALERRT, have been highlighted as examples of Global EU response to the coronavirus pandemic and attracted international media citations as a result:

[Q&A: Global EU response to the coronavirus pandemic](#) (EC)

[Explainer: Global EU response to the coronavirus pandemic](#) (Global Diplomacy)

[União Europeia apoia países africanos na luta contra o coronavírus](#) (TV Europa)

[Ερωτήσεις και απαντήσεις: Η σφαιρική ανταπόκριση της ΕΕ στην πανδημία του κορονοϊού](#) (Live Media News)

[Οδηγίες για τον επαναπατρισμό επιβατών κρουαζιερόπλοιων και την προστασία πληρωμάτων πλοίων Πηγή](#) (Pagasitikos News)

[The EU's Global Response To Coronavirus: "Supporting Our Partner Countries – The Gambia Included](#) (The Voice)

### 3.5 Aggregate level summary across awards of individual capacity strengthening supported by at least 22% DHSC award funding

<b>Training level</b>	<b>Total number who are currently undertaking or have completed during the award period</b>	<b>% LMIC nationality*</b>	<b>% female</b>
BSc	0	n/a	n/a
MSc	1	100%	100%
MD	0	n/a	n/a
Mphil	0	n/a	n/a
PhD	10	90%	70%
Postdoc	3	100%	33%
Professional training for non-research support staff (e.g. research manager, finance, admin, community engagement practitioners etc)	Not quantified	Not quantified	Not quantified
Other (long-term training for researchers-internships, diplomas etc.)	5	60%	80%

Training level	Total number who are currently undertaking or have completed during the award period	% LMIC nationality*	% female
Grand total	19		

\*We included all sub-Saharan African countries (incl. one trainee from South Africa) in LMIC category.

3.6 Delivery partner's summary of evidence of activities and outcomes from across awards demonstrating how DHSC funding has helped to strengthen LMIC institutional capacity to contribute to and lead high quality research and training.

EDCTP aims to strengthen the research-enabling environment in sub-Saharan Africa. This is done through investments in a comprehensive fellowship programme, in projects addressing ethics and regulatory issues, and in collaborative research networks. Moreover, the majority of EDCTP-funded clinical studies include a capacity-building work package that supports long- and short-term training, including PhDs and Master's degrees, in addition to improving site infrastructure and equipment. Importantly, intensive capacity development is also carried out both in preparation and during the conduct of multi-site and multi-country clinical studies. Furthermore, projects include various engagement activities to involve end users (communities, policymakers) and secure their support, in addition to supporting the application of medical interventions in health policy and practice.

Between 2014 and 2019, EDCTP awarded 126 fellowship grants to support the career development of current and aspiring African scientific leaders. These fellows comprise 47 (37 %) females and 79 (62%) males representing 20 sub-Saharan African countries. Profiles of current and former EDCTP fellows are available on the [EDCTP Alumni Network platform](#). Furthermore, 172 trainees were supported in EDCTP-funded research projects between 2014 and 2019. These training courses aim at academic degrees (146 or 85%, including 85 PhDs); post-doctoral training (9 or 5%); other qualifications such as certificates and leadership programmes (17 or 10%). The trainees come from 26 different countries in sub-Saharan Africa; 80 trainees are women (47%). The majority of trainees for academic degrees (106 out of 146 or 73%) are registered at institutions in sub-Saharan Africa. Most EDCTP-funded research projects also support workshops to improve the capacity to conduct clinical trials. Between 2014 and 2019, EDCTP beneficiaries reported 318 such training courses with a total number of 7,488 participants. Ethics training is part of several larger research projects or fellowships, but EDCTP support in this area is mainly given through the 'Ethics and regulatory capacities' calls, currently benefiting 27 countries in sub-Saharan Africa. EDCTP invests in the training of staff of ethics committees and regulatory

organisations, the coordination of activities between ethics committees and regulatory bodies, the harmonisation of regional approaches, and the development of online tools for improving the efficiency of ethics review processes. To address disparities between countries in sub-Saharan Africa in terms of clinical research capacity and to improve epidemics preparedness across the regions in sub-Saharan Africa, EDCTP invests in four Regional Networks of Excellence and the DHSCC-supported consortia for epidemic preparedness (ALERRT and PANDORA-ID-NET).

With regards to DHSCC-funded projects and capacity development investments, there are a number of notable examples of activities, outputs and outcomes concerning human capital and infrastructure development:

ALERRT launched the Fever In Sub Saharan Africa ([FISSA](#)) study in 2019, an observational study taking place in 16 care centres in sub-Saharan Africa and looking to recruit 10,000 participants, including adults and children. To this end, the project organised a series of trainings for FISSA Study Regional Coordinators and the staff of 13 sites were also trained - 132 people in total. The FISSA training has built research capacity in all sites, not just for FISSA but for future clinical studies as well.

ALERRT also reports several examples of professional achievements by researchers involved in the project, and the use of their newly acquired skills. In Cameroon, a researcher was promoted to Full Professor while two became second grade Senior Lecturers within the University of Yaounde, and another researcher was admitted by the President of the Republic of Cameroon into the ranks of Senior Lecturers integrated into the public service registry. Likewise, in Cameroon a researcher was admitted to the World Bank Monitoring and Evaluation course in Washington DC, having previously attended a similar course in Italy. In the United Kingdom, an ALERRT member from the London School of Hygiene and Tropical Medicine (LSHTM) participated in a one-day training at University College London (UCL) on rapid research methods in complex health emergencies and applied their knowledge in the planning of community engagement strategies and social science methods across ALERRT. With regards to research infrastructure, ALERRT introduced a Rotation Classroom at Faculty of Science, University of Yaounde-1, Cameroon, designed as a facility to deliver and support the implementation of online training activities and other future resources.

PANDORA-ID-NET conducted jointly with the African Centres for Disease Control (CDC) a workshop on clinical management of ill travellers in the context of the COVID-19 outbreak (March 2020). A total of 33 participants from 20 countries attended the workshop. The lectures and accompanying presentations from the workshop are available on the [PANDORA YouTube](#) channel.

CHAPS project members have been working on skills and leadership building for designing, implementing and analysing pharmacokinetic/pharmacodynamic clinical trials run at African sites. Knowledge transfer and expertise provided by King's College London (KCL), has shaped the development of the study protocol and associated study documents for the clinical trial by Perinatal HIV Research Unit (PHRU) in Johannesburg. To enable efficient recruitment in the social science study part of the CHAPS project, staff at all the sites underwent protocol training to ensure that they fully understood the objectives of the study, the study design, and procedures for recruitment. The project trained clinical staff on key messages for trial participants and on informed consent and eligibility criteria. This training has enabled staff at the clinical sites to successfully carry out the qualitative interviews of the social science study and start the survey.

PROMISE-EPI project engages in clinical trial capacity development as an integral part of the project. Research sites received training on good clinical practice (GCP) and study protocol as well as Xpert PCR testing, followed by receipt of relevant diplomas. Four of the study sites in Zambia have been upgraded following the installation of air conditioners and generators, locking systems for additional security and internet connection, among others.

The EMPIRICAL project encouraged each site to include young researchers in the EMPIRICAL activities, providing support in grant writing and online training, as well as supervision by a senior principal investigator (PI). As a result, three young researchers have applied for competitive fellowships (two for EDCTP fellowships and one for a [CIPHER](#) fellowship, which is a leadership fellowship granted by the International AIDS Society). Furthermore, all EMPIRICAL research team members involved in the clinical trial have undertaken the good clinical practice (GCP) course and received their corresponding certificates.

BabyGel project provided a 10-module training for 53 midwives and nurses and started renovation of one of the offices at the Sanyu African Research Institute (SAfRI), BabyGel's project partner in Uganda, which will act as the project headquarters. In addition, central hub offices have been identified in each of the hubs near to the central health centre. These will house the research midwives and data clerks at each site. Furthermore, a heavy-duty photocopier was installed in the SAfRI offices. Having the copier in place will preserve confidentiality of documentation reproduction as the usual channels are to purchase copying from one of a number of public outlets in Mbale. SAfRI has also invested in teleconferencing facilities to enable group virtual communication with other partners.

3.7 Delivery partner's assessment of the extent to which this DHSC funding has contributed towards building or strengthening equitable research partnerships/collaborations and thematic networks (where applicable, including engagement with communities).

EDCTP is a European-African partnership, which operates as a 'partnership of equals' with input from African countries at all levels. EDCTP membership currently includes 14 European and 16 African countries (known as Participating States in EDCTP's by-laws). Each Participating State contributes to EDCTP governance with equal voting rights, and hence can be equally involved in planning, decision making and shaping the policies and agenda of the programme.

During the evaluation procedures, proposals are assessed not only on scientific excellence but also on other criteria such as:

- Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials (Impact)
- Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role (Implementation)
- Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial (Implementation)

In the projects supported by DHSC, 52% of total funding is allocated to European institutions, while 48% of the funding is allocated to sub-Saharan African partners (see section 3.10). Therefore, funding is relatively balanced between the European and African partners. There is a similar trend across the entire EDCTP portfolio, though allocations for the sub-Saharan African partners are even higher. As of now, the funding to European and sub-Saharan African institutions represents 45% and 55% respectively of the signed grant value (excluding non-consortia fellowship funding that is always provided to sub-Saharan African institutions).

The DHSC-supported epidemic-preparedness consortia, namely ALERRT and PANDORA-ID-NET, represent two large thematic networks, which span sub-Saharan Africa, with ALERRT comprising 21 partner organisations from 13 countries (9 African and 4 European) and PANDORA-ID-NET comprising 22 partner organisations from 14 countries (10 African and 4 European). The governance and management structures are organised to ensure equitable partnership in decision-making and in the execution of the trial.

ALERTT and PANDORA-ID-NET are also actively promoting equity in their activities and deliverables. For example, PANDORA-ID-NET is actively promoting gender equity in science and the two consortia published jointly [PANDORA & ALERTT Data Sharing Principles](#) (March 2019) underpinned by the principle of equity.

Likewise, other DHSC-funded projects are promoting equity. EMPIRICAL project has advocated for fostering gender balance, in order to address the gaps in the participation of women in research at all levels. There are two independent committees in EMPIRICAL study: The Data and Safety Monitoring Board and the Trial Steering Committee, both of which are chaired by females. The consortium has been established in a way to optimise the participation of women by giving direct leadership to women in four out of the six work packages (project objectives). EMPIRICAL has also involved at least one or more female Co-PIs or Trial Coordinators at recruiting sites. One of the four researchers involved in the project is a female as well.

EMPIRICAL has ensured gender balance in the management of their clinical study - one or more Co-PIs or Trial Coordinators at recruiting sites are females.

3.8 Please complete the table of partners (including lead institution and downstream partners) and contracted amounts.

Call type	Award Project reference (Acronym)	Coordinating institution (Lead Applicant)	Country	Total contracted amount (GBP)	Funded by others (GBP)	Funded by UK DHSC (GBP)
RIA - 2016 - Epidemics	RIA2016E-1609 (PANDORA-ID-NET)	Fondation Congolaise pour la Recherche Médicale (FCRM), (Professor Francine Ntoumi)	Republic of the Congo	8,772,968	4,385,388	4,387,580
RIA - 2016 - Epidemics	RIA2016E-1612 (ALERTT)	The Chancellor, the Masters and the Scholars of the University of Oxford (UOXF), (Professor Peter Horby)	United Kingdom	8,774,629	4,387,048	4,387,581
Total RIA 2016 Epidemics				17,547,597	8,772,436	8,775,161

<b>Call type</b>	<b>Award Project reference (Acronym)</b>	<b>Coordinating institution (Lead Applicant)</b>	<b>Country</b>	<b>Total contracted amount (GBP)</b>	<b>Funded by others (GBP)</b>	<b>Funded by UK DHSC (GBP)</b>
RIA - 2016 - Maternal and child health	RIA2016MC-1615 (LIFE Study)	Instituto Nacional de Saúde (INS), (Dr Ilesh Jani)	Mozambique	2,602,479	-	2,602,479
RIA - 2016 - Maternal and child health	RIA2016MC-1616 (CHAPS)	King's College London, (Dr Julie Fox)	United Kingdom	2,632,547	-	2,632,547
RIA - 2016 - Maternal and child health	RIA2016MC-1617 (PROMISE-EPI)	l'Institut national de la santé et de la recherche médicale (INSERM), (Professor Philippe Van de Perre)	France	2,632,227	-	2,632,227
<b>Total RIA 2016 Maternal and Child Health</b>				<b>7,867,253</b>	<b>-</b>	<b>7,867,253</b>
RIA - 2017 - Maternal and child health	RIA2017MC-2013 (EMPIRICAL)	Servicio Madrileño de Salud (SERMAS), (Dr Pablo Rojo)	Spain	6,739,867	175,503	6,564,364
RIA - 2017 - Maternal and child health	RIA2017MC-2029 (BabyGel)	University of Liverpool, (Professor Andrew Weeks)	United Kingdom	5,245,176	928,340	4,316,836
<b>Total RIA 2017 Maternal and Child Health</b>				<b>11,985,043</b>	<b>1,103,843</b>	<b>10,881,200</b>
RIA - 2017 - Strategic	RIA2017S-2014 (PREVAC-UP)	l'Institut national de la santé et de la recherche médicale (INSERM), (Professor	France	13,938,612	1,565,635	12,372,977



EDCTP Annual Review (covering 1 Jan. 2018 to 30 Apr. 2020)

Call type	Award Project reference (Acronym)	Coordinating institution (Lead Applicant)	Country	Total contracted amount (GBP)	Funded by others (GBP)	Funded by UK DHSC (GBP)
		Yazdan Yazdanpanah)				
Total RIA 2017 Strategic call				13,938,612	1,565,635	12,372,977
RIA - 2018 - Co-infections and co-morbidities	RIA2018CO-2512 (VITALITY)	London School of Hygiene and Tropical Medicine (LSHTM), (Prof Dr Rashida Ferrand)	United Kingdom	3,460,908	-	3,460,908
RIA - 2018 - Co-infections and co-morbidities	RIA2018CO-2513 (META TRIAL)	Liverpool School of Tropical Medicine (LSTM), (Professor Shabbar Jaffar)	United Kingdom	3,503,899	-	3,503,899
RIA - 2018 - Co-infections and co-morbidities	RIA2018CO-2514 (PROTID)	Stichting Katholieke Universiteit- Radboudumc (RUMC), (Professor Reinout van Crevel)	The Netherlands	4,251,302	-	4,251,302
RIA - 2018 - Co-infections and co-morbidities	RIA2018CO-2516 (5FC HIV-Crypto)	Drugs for Neglected Diseases initiative (DNDi), (Dr Isabela Ribeiro)	Switzerland	3,103,774	-	3,103,774
Total RIA-2018 Co-infections and co-morbidities				14,319,883	-	14,319,883
RIA - 2018 -	RIA2018D-2495	London School of Hygiene	United Kingdom	2,551,704	-	2,551,704

<b>Call type</b>	<b>Award Project reference (Acronym)</b>	<b>Coordinating institution (Lead Applicant)</b>	<b>Country</b>	<b>Total contracted amount (GBP)</b>	<b>Funded by others (GBP)</b>	<b>Funded by UK DHSC (GBP)</b>
Diagnostics	(LAMP4Yaws)	and Tropical Medicine (LSHTM), (Dr Michael Marks)				
RIA - 2018 - Diagnostics	RIA2018D-2496 (DIAGMAL)	Academisch Medisch Centrum bij de Universiteit van Amsterdam (AMC), (Dr Henk Schallig)	The Netherlands	2,632,065	87,752	2,544,313
RIA - 2018 - Diagnostics	RIA2018D-2499 (Triage TB)	Stellenbosch University, (Professor Gerhard Walzl)	South Africa	2,888,555	-	2,888,555
RIA - 2018 - Diagnostics	RIA2018D-2508 (ERASE-TB)	Ludwig-Maximilians-Universitaet Muenchen (LMU), (Dr Norbert Heinrich)	Germany	2,917,476	-	2,917,476
RIA - 2018 - Vaccines	RIA2018V-2304 (PREPARE)	St George's Hospital Medical School (aka SGUL), (Dr Kirsty Le Doare)	United Kingdom	8,771,426	-	8,771,426
RIA - 2018 - Diagnostics	RIA2018D-2505 (XACT III)*	The University of Cape Town Lung Institute (Pty) Ltd (Professor Keertan Dheda )	South Africa	662,327	616,736	45,591
Total RIA-2018 Diagnostics				20,423,552	704,487	19,719,065
Total grant value				86,081,940	12,146,401	73,935,539

\*RIA2018D-2505 (XACT III) - the Grant Agreement is under preparation.

## 3.9 Aggregated HIC/LMIC spend across all awards

<b>Country</b>	<b>Total committed amount (GBP) allocated to:</b>	<b>% of total committed amount to all institutions:</b>
<b>HIC</b>	<b>44,738,090.06</b>	<b>52.37%</b>
United Kingdom	21,137,875.63	24.75%
France	10,002,919.05	11.71%
Germany	3,243,084.85	3.80%
Netherlands, The	2,122,569.84	2.48%
Spain	2,072,889.83	2.43%
Switzerland	1,835,475.63	2.15%
Italy	1,738,092.17	2.03%
Denmark	884,204.96	1.04%
Belgium	572,040.28	0.67%
Norway	512,469.40	0.60%
Sweden	343,328.17	0.40%
Portugal	273,140.27	0.32%
Luxembourg**	-	0.00%
United States**	-	0.00%
New Zealand**	-	0.00%

<b>Country</b>	<b>Total committed amount (GBP) allocated to:</b>	<b>% of total committed amount to all institutions:</b>
<b>LIMC</b>	<b>40,681,522.73</b>	<b>47.63%</b>
Uganda	9,003,969.98	10.54%
United Republic of Tanzania	6,529,623.21	7.64%
Zambia	3,778,754.90	4.42%
Sierra Leone	3,684,850.50	4.31%
South Africa	3,010,570.95	3.52%
Zimbabwe	2,630,091.68	3.08%
Mozambique	2,147,623.87	2.51%
Cote D'Ivoire	1,727,304.47	2.02%
Republic of the Congo	1,494,111.82	1.75%
Senegal	1,293,979.75	1.51%
Cameroon	1,265,617.33	1.48%
Burkina Faso	895,209.01	1.05%
Ghana	840,866.62	0.98%
Sudan	621,722.34	0.73%
Nigeria	411,335.67	0.48%
Kenya	294,968.81	0.35%
Ethiopia	252,395.57	0.30%
Namibia	222,998.78	0.26%

EDCTP Annual Review (covering 1 Jan. 2018 to 30 Apr. 2020)

<b>Country</b>	<b>Total committed amount (GBP) allocated to:</b>	<b>% of total committed amount to all institutions:</b>
Malawi	218,515.50	0.26%
Central African Republic	110,366.30	0.13%
Madagascar	110,366.30	0.13%
Guinea	87,751.61	0.10%
The Democratic Republic of the Congo	48,527.75	0.06%
Gabon**	-	0.00%
Mali**	-	0.00%
Grand Total*	85,419,612.79	100.00%

\*The total excludes RIA2018D-2505 (XACT III); the Grant Agreement is under preparation.

\*\*Some countries collaborated in project but requested zero funding from EDCTP.

## 4. Theory of Change and progress towards longer term impacts

### 4.1 Progress towards long term impacts

a) Accelerated evidence and improved capacities for effective health system response to epidemics in sub-Saharan Africa and reducing the public health and socio-economic impact of emerging and epidemic-prone infectious diseases.

Two DHSC-supported projects - ALERRT and PANDORA-ID-NET - will help ensure that African regions are better prepared to prevent, respond and minimise the impact of infectious disease outbreaks, including the current COVID-19 outbreak, by building a sustainable clinical and laboratory research preparedness and response network.

b) Optimised use of medical interventions for better treatment and prevention of poverty-related diseases in population with major unmet needs (mothers, newborns, children and adolescents) and reduction of health inequities in sub-Saharan Africa.

CHAPS project is the first to undertake research into attitudes to on-demand PrEP among adolescents in sub-Saharan Africa and the first multi-country study to investigate optimal dosing for on-demand PrEP. Its findings will play a key role in shaping the design of trials of on-demand PrEP in a group where more effective prevention is urgently required.

PROMISE-EPI project is aiming to identify and treat missed infant HIV cases, and to prevent transmission from previously undiagnosed HIV-infected mothers. The study could therefore identify a readily implementable strategy to further reduce infant infection rates, and a catch-up strategy to identify those who have been infected but were initially undetected.

The EMPIRICAL study will determine whether empirical treatment of TB and cytomegalovirus reduces pneumonia mortality in young HIV-infected infants, who currently have the worst survival of all age groups.

The LIFE study is assessing whether use of new rapid diagnostic tests for HIV leads to quicker and better treatment of infants with HIV.

The BabyGel study is examining whether giving mothers an alcohol-based hand rub can reduce severe infections in newborns.

c) Rapid progression of the clinical development of medical interventions (drugs, diagnostics, vaccines, microbicides) for making needed medical interventions available to people in sub-Saharan Africa

The PREVAC-UP study will generate long-term data on immune responses generated by two of the most advanced Ebola vaccines, in children as well as in adults. It will provide key evidence on the likelihood that individuals remain protected against Ebola infection in the years after vaccination. In particular, the study will provide data on responses in children, who were particularly vulnerable to Ebola in the 2014–16 outbreak and for whom little evidence on vaccine responses is currently available.

d) Better diagnostic tools and technologies for improving clinical decision and health outcomes in sub-Saharan Africa.

The LAMP4YAWS project aims to validate a rapid and simple LAMP test for yaws diagnosis in endemic countries (Ghana, Cote d'Ivoire and Cameroon).

e) Improved prevention, treatment and clinical management of co-infections and co-morbidities resulting in the reduction of the number of such cases in sub-Saharan Africa.

PROTID (Preventive Treatment of Latent Tuberculosis Infection in people with Diabetes Mellitus) study aims to establish the first empiric evidence for latent TB infection (LTBI) management among people with diabetes. Once complete, this study will provide crucial information to guide policy and practice regarding prevention and management of combined TB and diabetes.

## 5. Value for money

- Delivery partner's summary of evidence from across awards demonstrating activities during the past year to ensure value for money in how the research is being undertaken.

5.1 Economy: the degree to which inputs are being purchased in the right quantity and at the right price.

Paragraph seven (bullet vii) of article 6.1 (general conditions for costs to be eligible) of the Grant Agreement that EDCTP signs with coordinating institutions relates to economy and effectiveness. This paragraph reads: “For costs to be eligible, they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency”. To ascertain whether beneficiaries are implementing EDCTP-funded projects with due regard to value for money (economically, efficiently and effectively), and in compliance with [Horizon 2020](#) rules, particularly the Grant Agreement signed between them and EDCTP, EDCTP has signed an agreement with PricewaterhouseCoopers Netherlands for them to perform operational audits on EDCTP’s behalf. The main objectives of conducting the operational audits are to:

- Obtain understanding of the internal control environment and control activities of beneficiaries, including identifying beneficiaries with weak accounting and internal control systems, and provide recommendations on how to improve the systems;
- Detect operational inefficiencies and wasteful spending; and
- Review compliance with the Grant Agreement.

5.2 Enhanced efficiency: how efficiently the project is delivering its outputs, considering the rate at which intervention inputs are converted to outputs and its cost-efficiency.

EDCTP has a dedicated call mechanism to facilitate acceleration of Research and Development (R&D) in clinical studies of high potential to bring rapid advancements. As these research opportunities are often complex and resource-intensive, they require partnerships and joint resources to harness synergies and maximise on their R&D potential.

EDCTP’s main vehicle to establish co-funded activities - [EDCTP strategic calls for proposals](#) - have been part of the EDCTP work plans since 2015. In strategic projects, EDCTP typically provides up to 50% of the total funding for a specific project ‘large-scale action’, whereas the remaining budget must be mobilised from third-party funders.



Currently, EDCTP expects to mobilise EUR 323.87 million in project funding through its strategic grant schemes (EUR 228.39 million in cash and EUR 95.47 million in in-kind contributions). The partners contributing the highest co-funding are: National Institutes of Health (NIH), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Bill & Melinda Gates Foundation (BMGF), jointly accounting for EUR 204.65 million (63.20% of total contributions).

The DHSC currently supports one such project under strategic calls for proposals, namely RIA2017S-2014 (PREVAC-UP). PREVAC-UP, on top of its EDCTP budget of EUR 15,884,166.90, has secured EUR 12,000,000 from the National Institute of Allergy and Infectious Diseases (NIAID) / NIH as a direct cash contribution.

EDCTP has also launched a series of calls for proposals dedicated to maximising the impact of research results by supporting (strategic) actions that will facilitate the translation of research results of medical interventions into policies and practices, often in cooperation with development assistance initiatives. Four such calls have been launched to date: (1) [Maximising the impact of EDCTP research: translation of research results into policy and practice](#); (2) [Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives](#); (3) 2018 call on [Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems](#); (4) 2020 call on [Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives](#). Although none of these calls have been supported to date by DHSC, it is important to note that they are well-aligned with Official Development Assistance (ODA) funding priorities and receive co-funding from development assistance partners such as the Swedish International Development Cooperation Agency (Sida) and the U.S. Agency for International Development (USAID).

5.3 Effectiveness: the quality of the intervention's work by assessing the rate at which outputs are converted into outcomes and impacts, and the cost-effectiveness of this conversion.

EDCTP developed a Theory of Change with defined programme outputs, outcomes and corresponding indicators that form the basis for EDCTP's monitoring system. We track and analyse these, including establishing logical links between programme outputs (what the programme has delivered) and outcomes (the success the programme attained/desires to attain).

5.4 Equity: degree to which the results of the intervention are equitably distributed.

The needs of vulnerable populations are considered central to the EDCTP programme, with newborns, infants, children, adolescents and pregnant women recognised as

populations with major unmet needs due to frequent exclusion from clinical studies. Several EDCTP calls, including those supported by DHSC, have been dedicated to meeting the needs of these vulnerable populations. EDCTP's portfolio of clinical studies include pregnant and lactating women and their children (in 10% of studies), newborns and infants (in 17% of studies), children (in 31% of studies), and adolescents (in 29% of studies). Studies also frequently include people living with HIV. Several of the studies targeting unmet needs in special populations are large scale trials involving 5,000 patients or more.

5.5 List of any additional research and infrastructure grants secured **by LMIC partners** during the course of this DHSC funding - including value, funding source, lead institution and country, what % of additional funding allocated to LMIC partners, Health Research Classification System (HRCS) code.

The below numbers represent co-funding figures leveraged through EDCTP Strategic Calls (see section 5.2) and concern the entire DHSC supported call RIA2017S. Please note, however, that only one project in this call is supported with DHSC funds.

<b>Award</b>	<b>Funding source</b>	<b>Amount (GBP)</b>	<b>Lead institution name and country</b>	<b>% of additional funding allocated to LMIC partners</b>	<b>Health Research Classification System code</b>
RIA2017 S-2014 PREVAC-UP*	National Institute of Health (NIH), USA	12,000,000.00 EUR (cash) which is 10,530,191.29 GBP	Institut national de la santé et de la recherche médicale (INSERM), France	To be determined at the final closure of the project	3.4
RIA2017 S-2008 CAP012 SAMBA Trial	South African Medical Research Council (MRC), South Africa	3,250,000.00 EUR (in kind) which is 2,851,926.807 GBP	Centre for the Aids Programme of Research in South Africa (CAPRISA), South Africa	To be determined at the final closure of the project	3.4
RIA2017 S-2007 CAP-TB	Centro de Investigacao em Saude de Manhica	127,393.00 EUR (in kind) which is 111,789.3882 GBP	Foundation for Innovative New Diagnostics	To be determined at the final closure of	4.3

Award	Funding source	Amount (GBP)	Lead institution name and country	% of additional funding allocated to LMIC partners	Health Research Classification System code
	(CISM), Mozambique		(FIND), Switzerland	the project	
RIA2017 S-2024 ETEC Vaccine Efficacy	Scandinavian Biopharma, Sweden	5,108,641.00 EUR in total (2,340,000 EUR cash and 2,768,641 EUR in kind) which is 4,482,913.913 GBP in total	Scandinavian Biopharma Holding AB (SBH), Sweden	To be determined at the final closure of the project	3.4
RIA2017 S-2027 THECA	Bill & Melinda Gates Foundation, United States	40,835,800.00 EUR (cash) which is 35,834,065.45 GBP	The Chancellor, Masters and Scholars of the University of Cambridge, United Kingdom	To be determined at the final closure of the project	3.4

\*Project supported with DHSC funds

## 6. Risk

6.1 Delivery partner to summarise the five most significant risks (both in terms of potential impact and likelihood) across awards within the last year.

Risk	How is the risk being managed/mitigated?	Current status
<p>1) Delays in EDCTP submitting progress or other ad-hoc reports to the European Commission (EC), which can lead to suspension of pre-financing payments by EC.</p>	<ul style="list-style-type: none"> <li>• The costing features of Access Dimensions, the computerised accounting systems, have been set-up to allow easy generation of final reports.</li> <li>• With the help of CC Technology, the reporting features of the grant management system have been enhanced to allow easy preparation of technical progress reports.</li> <li>• The management committee, chaired by the Executive Director, comprising representatives from all EDCTP departments, is responsible for ensuring that all risks are identified and managed appropriately. At each management meeting, risk management is included as an agenda item and all open risks are reviewed.</li> </ul>	<p>The status of this risk is open. The planned action is to monitor; no action is required.</p>
<p>2) EDCTP may exceed 6% administrative budget ceiling as set out Art. 2 (3) of Decision 556/2014/EU.</p>	<ul style="list-style-type: none"> <li>• Comparing of actual expenditure against budget</li> <li>• Encouraging more Participating States to provide funding for administrative support</li> <li>• Tight control of administrative expenditure</li> </ul>	<p>The status of this risk is open. The planned action is to monitor; immediate action is required.</p>
<p>3) Delay in EDCTP beneficiaries completing their projects within the duration specified in article 3 of the Grant Agreement due to COVID19.</p>	<ul style="list-style-type: none"> <li>• Have sent an email to all EDCTP beneficiaries informing them that they can request an amendment of article 3 of the Grant Agreement once they know the full impact of COVID-19 on their project timelines.</li> </ul>	<p>The status of this risk is open. The planned action is to monitor; immediate action is required.</p>
<p>4) Inability of beneficiaries to refund EDCTP for ineligible expenses incurred due to non-compliance with Grant Agreement</p>	<ul style="list-style-type: none"> <li>• Extensive review of project progress and financial reports by both EDCTP Project Officers and Grant Finance Officers to ensure no ineligible items are included</li> <li>• Organising regular project and financial trainings</li> <li>• Conducting site visits and operational audits.</li> </ul>	<p>The status of this risk is open. The planned action is to monitor; no immediate action is required.</p>

Risk	How is the risk being managed/mitigated?	Current status
5) There is uncertainty regarding the 2014, 2015, 2016, 2017 and 2018 Participating States' Initiated Activities (PSIAs) submitted to the EC in the annual progress reports because the EC has only provisionally accepted them as eligible.	<ul style="list-style-type: none"> <li>Developed a reporting template which was approved by EC. PSIA is a new concept and the EC does not have written rules on PSIAs. The issue has been raised at all of the recent EDCTP General Assembly meetings, where the EC has been represented.</li> </ul>	The status of this risk is open. The planned action is to monitor; immediate action is required.

6.2 Fraud, corruption and bribery. Delivery partner to summarise:

- any changes in the last year to the anti-corruption strategy applied to managing DHSC funded awards

There been no changes to the EDCTP [anti-fraud](#) strategy.

- Aggregated credible allegations

	Total number of credible allegations:
Made against any DHSC funded awards	0
Made against any DHSC funded awards and investigated by delivery partner	0
Made against DHSC funded awards and reported to DHSC	0

6.3 Safeguarding

- Please detail and highlight any changes or improvements you (the delivery partner) have made in the past year to ensure safeguarding policies and processes are in place in your project and your downstream partners.

For all DHSC-funded beneficiaries for which the due diligence process had not yet been finalised by December 2019, EDCTP required them to read and confirm agreement with safeguarding principles as part of the due diligence procedure conducted prior to grant agreement signature. For this purpose, EDCTP developed an enhanced due diligence on safeguarding for external partners. In this form, EDCTP outline their safeguarding principles and request EDCTP beneficiaries to specify what safeguards and policies they already have in place on safeguarding responsibilities, including their ability to apply effective safeguards in their work, in particular to safeguard children and vulnerable adults from sexual exploitation and abuse, and to report all allegations of sexual harassment or abuse and ensure robust investigations and victim support. The form also covers issues such as whistleblowing, HR recruitment and selection, risk management, and code of conduct. Reference is made to Article 17 (2) of the EDCTP Model Grant Agreement (triggering the obligation for beneficiaries to immediately inform EDCTP) with respect to the requirement to report any and all allegations of sexual exploitation, abuse, harassment, and/or bullying. The enhanced due diligence form has been completed by the beneficiaries for the following projects for which due diligence had not yet been completed:

- ERASE TB (RIA2018D-2508)
- META TRIA (RIA2018CO-2513)
- HIV-Crypto (RIA2018CO-2516)

For all DHSC-funded beneficiaries where the due diligence process had already been completed and grant agreements were already signed or under signature, EDCTP will be sending the beneficiaries a statement on DHSC/EDCTP safeguarding principles and highlighting their importance to the funders by December 2020.

- Aggregate summary of safeguarding issues that have arisen during the reporting year

	<b>Total number of safeguarding issues</b>
Raised against any DHSC funded awards	0
Raised against any DHSC funded awards and investigated by delivery partner	0
Raised against DHSC funded awards and reported to DHSC	0

## 7. Delivery, commercial and financial performance

### 7.1 Performance of awards on delivery, commercial and financial issues

There were no major deviations. It is not possible for EDCTP projects to exceed the maximum budget set out in the Grant Agreement; there is no scope for supplementary allocations.

### 7.2 Have DHSC funded awards continued to meet ODA funding eligibility:

Yes

### 7.3 Transparency.

- Delivery partner to confirm whether or not International Aid Transparency Initiative (IATI) obligations have been met (<https://iatistandard.org/en/iati-standard/>). No
- If these are not yet met, please outline the reasons why.

EDCTP has not yet taken action in relation to IATI reporting. EDCTP agreed in the Memorandum of Understanding (MoU) with DHSC to provide all information and data necessary for the transparent, accurate, timely and comprehensive publishing of all data on the DHSC website, in addition to having given their consent for DHSC to use such data for the purposes of publishing on the IATI registry. However, as part of the due diligence procedure for the latest contribution from DHSC, it was clarified DHSC would require EDCTP to publish details of the downstream utilisation of DHSC funding to the IATI register. It has been agreed that the DHSC lead on transparency will outline DHSC's expectations here and provide clearer guidance and agree a reasonable timeline for EDCTP to work towards.

Beyond IATI reporting, EDCTP requires its beneficiaries to ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results (as outlined in the EDCTP Model Grant Agreement). As per the MoU between EDCTP and DHSC, EDCTP publishes information about all funded projects (once grant agreements are signed) on the EDCTP website and all project summaries can also be accessed through the EDCTP public portal. EDCTP also reports on an annual basis about expenditure of funds to G-FINDER, the World RePORT, the UNAIDS/IAVI/AVAC annual

resource tracking survey and the Treatment Action Group (TAG) Report on Tuberculosis Research Funding Trends, amongst others.



## 8. Monitoring, evaluation and learning

### 8.1 Monitoring activities throughout the review period and how these have informed programming decisions.

EDCTP's monitoring system is built on the concept of Theory of Change with identified programme outputs and outcomes. This helps focus their data collection and reporting in order to analyse and convey information from the projects and other activities that is of strategic importance to their programme objectives and the programme's overall mission and vision, i.e. illustrate how EDCTP's work is connected to programme objectives and broad goals. They are actively refining this model in conversation with their funders, drawing on lessons learnt from the outside, notably independent evaluations as well as in the context of emerging research priorities (e.g. ongoing discussions on the prospective EDCTP3/Global Health Partnership programme).

In the monitoring process, multiple efforts across the programme are taking place, including EDCTP's beneficiary monitoring and reporting to EDCTP, as well as the EDCTP Secretariat's efforts in collecting and synthesising project specific data in order to keep EDCTP management as well as their multiple funders and general audience up to date on the programme's progress. There is an intensive interaction between EDCTP Project and Finance Officers (regular communication, annual reports review and site visits, serving as observers on the major project advisory committees, such as trial steering committees) and the beneficiaries. Together with the grantees, they jointly oversee project progress and communicate regarding changes or improvements as well as facilitate formal amendments where needed. This takes place often in consideration of the changing context. A recent example of such change has been in the DHSC-supported ALERRT. The project has revised its [FISSA study](#) (Febrile Illness in Sub-Saharan Africa) protocol to allow inclusion of a research response component in the event of a Public Health Emergency (COVID-19 for now) declaration by national or international health authorities in countries participating in the FISSA study.

There are numerous examples of how monitoring data (incl. feedback from beneficiaries) is utilised in the programming decisions of EDCTP: through investing in new activities to improve participation of countries and regions which are underrepresented in EDCTP, or supporting gender equity, as well as answering the needs of populations with major unmet medical needs. The programme has made strategic decisions to launch calls dedicated to these topics and to organise a number of activities to improve indicators of gender and nationality representation in EDCTP, as well as in the wider context of sub-Saharan African participation in science, including women in science. Recent examples of such calls and activities include:

a) Workshop enhancing networking among African and European scientists to close regional and gender disparities experienced in EDCTP1 and EDCTP2 funded health research capacity activities in sub-Saharan Africa

b) Launch of Senior Fellowships Plus 2019 call aimed to engage less resourced African countries

c) Three grant writing workshops (targeting Portuguese-speaking and French speaking scientists) for young African scientists.

- Evaluation plans and activities that have taken place across awards throughout the review period.

EDCTP combines its monitoring efforts with independent evidence through independent oversight committees and external evaluations both concerning individual investments or schemes as well as programme level evaluations (for example, linked to support of a particular EDCTP funder). In 2019 EDCTP commissioned two evaluations - one on the EDCTP Regional Networks and the other concerning Sida's contributions to EDCTP (unlike DHSC funding, Sida funding is not earmarked for specific calls or projects). Both evaluations are now in the follow-up/dissemination phase after approvals by EDCTP of independent experts' reports. EDCTP is therefore taking into consideration the recommendations arising from these evaluations to inform its daily work as well as future funding decisions.

Lessons learnt from the Sida support evaluation should be of particular relevance to DHSC, as two projects in the scope of the Sida support evaluation are also supported by DHSC, namely: ALERRT and PANDORA- ID NET.

The Sida support evaluation has been designed and carried out in line with common OECD DAC evaluation standards and principles endorsed by funders such as Sida, EU and DFID, to name a few. The experts panel comprised global health/international development professionals with extensive experience in carrying out research/research capacity development evaluations in the donor funded environment. Key deliverables of the evaluation included an inception report as well as a draft and final report. A reference group coordinated by EDCTP was attached to this evaluation to review draft deliverables and provide stakeholders feedback. The reference group consisted of representatives from EDCTP and Sida with two meetings taking place in 2019: an inception meeting and a feedback session on draft final report.

One of the key conclusions that arose from this evaluation was "the need for further discussion on how to match EDCTP's vision, mission, objectives and activities funded" and therefore the evaluation recommended reflecting on the criteria used to assess and communicate the programme's successes. EDCTP has been taking stock of this

recommendation since and invited members of the EDCTP Scientific Advisory Committee, amongst others, to provide input (April 2020).

## 8.2 Learning

EDCTP has various informal and formal mechanisms for taking stock of the lessons learnt. This includes dissemination and publication of independent reports to engage stakeholders in discussions on lessons learnt as well as EDCTP management response to the recommendations of independent evaluations which is being updated in regular intervals as a follow-up phase to the evaluation.

## 8.3 Outline key milestones/deliverables for the awards for the coming year

Award	Key milestones/deliverables for coming year
RIA2016E (PRD Epidemics)	<p>Progression of <a href="#">FISSA study</a> that will incorporate caring of individuals and collection of coronavirus-relevant data. FISSA teams will work with social science experts to explore social aspects with implications on patients and care givers (formal and informal).</p> <p>Preparation of a coronavirus-19 healthcare worker preparedness survey - a joint deliverable between ALERRT consortia and The International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC),</p>
RIA2016MC (Maternal & Child Health)	<p>Progression of the following clinical studies:</p> <p>CHAPS: <a href="#">NCT03986970</a>.</p> <p>PROMISE-EPI trial: <a href="#">NCT03870438</a></p> <p>The LIFE study: <a href="#">NCT04032522</a></p>
RIA2017S (Strategic Actions)	<p>Start/progression of the PREVAC-UP (follow-on to PREVAC) trial: <a href="#">NCT02876328</a></p>
RIA2017MC (Maternal & Child Health)	<p>Start of BabyGel study (including possible changes to design due to COVID -19)</p> <p>Start of EMPIRICAL study <a href="#">NCT03915366</a></p>
RIA2018D (Diagnostics)	<p>Start/progression of the following clinical studies:</p> <p>LAMP4YAWS</p> <p>DIAGMAL</p> <p>TriageTB</p>

Award	Key milestones/deliverables for coming year
	ERASE-TB
RIA2018CO (Co-infections and Co-morbidities)	Start/progression of the following clinical studies: VITALITY The META trial PROTID 5FC HIV-Crypto
RIA2018V (Vaccines)	Start/Progression of the following clinical study: PREPARE

8.4 Any other comments/feedback/issues to flag to DHSC?

N/A

## 9. Diversity and environmental sustainability

9.1 Summary of activities that have taken place to ensure everyone is treated fairly, regardless of gender, gender identity, disability, ethnic origin, religion or belief, sexual orientation, marital status, transgender status, age and nationality, across this funding call.

EDCTP clinical study projects (RIAs) and many of the Fellowships (TMAs) are subject to an independent ethics evaluation, in parallel to or immediately following the technical evaluation, and before conclusion of grant agreement preparation. This is to ensure that all research activities are conducted in compliance with fundamental ethical principles and relevant national, EU and international legislation. The main areas that are addressed during the ethics evaluation include:

- Human subjects protection (in particular for study participants and researchers)
- Animal protection and welfare, where applicable
- Data protection and privacy
- Environment protection

The projects also undergo ethics review in the countries where the studies are conducted. Moreover, EDCTP and its beneficiaries have undertaken various activities to involve groups which are underrepresented in the studies, as well as to promote principles of equity and equal participation which are described in sections 3.8 and 8.1 of this report.

9.2 Summary of activities that have taken place to minimise carbon emissions and impact on the environment across this funding call.

Environment protection is one of the topics which is addressed as part of ethics checks (see 9.1).