



Department  
of Health &  
Social Care

# **DHSC support to EDCTP**

## **Annual Report/Review - 01 May 2020-30 April 2021**

Published 2024

**NIHR Global Health Research  
Portfolio**

## Contents

Annual reporting and review process.....	3
1. DSHC summary and overview .....	4
2. Summary of aims and activities.....	7
3. Outputs and outcomes .....	20
High quality policy/practice relevant research and innovation outputs.....	19
Informing policy, practice and individual/community behaviour in LMICs .....	25
LMIC and UK researchers trained and increased support staff capacity .....	26
LMIC institutional capacity strengthened .....	27
Equitable research partnerships and thematic networks established/strengthened .....	28
4. Value for money .....	31
5. Risk .....	36
6. Delivery, commercial and financial performance .....	39
7. Monitoring, evaluation and learning .....	39
Annex: Clearance checklist.....	<b>Error! Bookmark not defined.</b>

# Annual reporting and review process

This activity has been supported by the UK aid budget (Official Development Assistance, ODA) as part of the Department of Health and Social Care (DHSC) Global Health Research (GHR) portfolio.

The Annual Reporting and Annual Review templates are part of a continuous process of monitoring, review and improvement within NIHR'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 and will be used to provide accountability for the use of public money, meet Official Development Assistance transparency and compliance requirements. Within these common sections, sub-sections have been included to enable us to monitor progress against planned activities, test our portfolio Theory of Change using evidence collected on outputs and outcomes in accordance with the NIHR GHR portfolio results framework. There are also sections on value for money, risk management, financial reporting, monitoring, evaluation and learning updates.

The process for completing this template involves the following steps:

1. DHSC works with delivery partners to ensure that the relevant monitoring information is collected at the award level (as set out in the NIHR Global Health Research results framework). This information will be collected using existing reporting mechanisms wherever possible, before bespoke reporting is considered.
2. 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.
3. This report is then shared with DHSC for comment and feedback.
4. 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. Please write this summary with a public audience in mind, assuming no prior knowledge of the funding scheme.
5. 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 the clinical development of new or improved interventions to prevent or treat poverty related as well as emerging and re-emerging 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 phase II and III clinical trials. EDCTP runs its calls as part of annual work packages, and the Department of Health and Social Care (DHSC) has contributed to the 2016, 2017, 2018, and 2020 work packages. This annual review covers the reporting period April 2020 to April 2021.

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

DHSC is currently supporting eight EDCTP calls for proposals, EDCTP's [COVID-19 Emergency Funding Mechanism](#) as well as a Participating States Initiated Activity (PSIA) '[Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa](#)'.

-EDCTP calls for proposals:

-[Call RIA2016E: 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 projects under this call, with both of which experienced increased attention to COVID-19 in their activities resulting in further resources and time being required.

-[Call RIA2016MC on 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 projects, two of which received extensions.

-[Call RIA2017S: 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

PRDs. DHSC is funding one project under this call with the full impact of COVID-19 not yet understood at the time of the report.

[-Call RIA2017MC: Clinical trials to reduce health inequities in pregnant women, newborns and children](#) aims to accelerate the adaptation and/or optimisation of treatment and prevention products (excluding vaccines) in pregnant women, newborns and/or children in Sub-Saharan Africa. DHSC supports two projects under this call. One project reported to be significantly impacted by COVID-19 with the second project still reviewing timelines.

[-Call RIA2018D: Diagnostic tools for poverty-related diseases](#) aims to support implementation of new or improved diagnostic tools and technologies for the detection of any of the of poverty-related diseases (PRDs). DHSC provides funding to five projects under this call. In general the deliverables were reported to be behind schedule due to COVID-19. However, no major impact on the overall objectives or duration is currently expected.

[Call RIA2018CO: 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 with projects reporting to be behind schedule due to COVID-19 although the extent of the impact varies.

[Call RIA2018V: 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. The projects report moderate impacts on schedules due to COVID-19.

[-Call CSA2020E: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020](#) aims to establish an African cohort of epidemiologists by supporting institutions in sub-Saharan Africa and Europe that provide master's training in epidemiology and biostatistics, as part of the Africa CDC's framework for public health workforce development. DHSC is funding two projects under this call. The call is on track to contribute towards expected outcomes/impact of establishing an African cohort of epidemiologists by supporting institutions in sub-Saharan Africa and Europe that provide Master's training in epidemiology and biostatistics, as part of the Africa CDC's framework for public health workforce development.

Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020: aims to support research activities in sub-Saharan Africa to manage and/or prevent the spread of the current COVID-19. DHSC provides funding to five projects under this emergency funding mechanism which are all on track to deliver expected outcomes/impact.

[-Participating States Initiated Activity \(PSIA\) 'Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa'](#). DHSC provides funding to [four projects](#) under this call. The call is on track to contribute towards expected outcomes/impact of developing capacity in clinical research among female researchers. Four proposals were selected for funding and were in grant preparations at the time of the review.

### 1.3 Performance of delivery partners

EDCTP continue to be an important and valued delivery partner of the DHSC Global Health Research (GHR) team. EDCTP provide DHSC GHR with a well-regarded and respected mechanism to directly fund high-quality high-impact clinical research in sub-Saharan Africa. They also employ responsive risk management, share the same values of equitable partnership, community engagement, value for money, and the importance of monitoring, evaluation, and learning.

This annual report has been an informative insight into the EDCTP calls and projects DHSC GHR helps support. DHSC GHR 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 donor, and for continuing to be responsive to requests for information as and when they are needed by the DHSC GHR team.

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

EDCTP support clinical trials in sub-Saharan Africa through equitable partnerships and capacity strengthening. These activities are aligned to, and make a significant contribution to, relevant areas of the DHSC Global Health Research portfolio, and learning and lessons are shared accordingly.

## 2. Summary of aims and activities

### 2.1 Overview of award/funding call aims

DHSC is currently supporting eight EDCTP calls for proposals, EDCTP's [COVID-19 Emergency Funding Mechanism](#) as well as a Participating States Initiated Activity (PSIA) titled '[Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa](#)'.

-EDCTP calls for proposals:

-[Call RIA2016E: 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 projects under this call:

(1) [PANDORA-ID-NET - Pan-African Network For Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics](#) and (2) [ALERRT - African coalition for Epidemic Research, Response and Training](#)

-[Call RIA2016MC on 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 projects:

(1) [CHAPS - Combined HIV African Prevention Study: On demand Truvada and F/TAF Pre-exposure and Post exposure prophylaxis to protect adolescents from HIV](#); (2) [PROMISE-EPI - Prevention Of Mother-To-Child Transmission Of Hiv-1: Program Evaluation And Innovative Rescue Intervention Integrated In The Expanded Program Of Immunization](#); and (3) [LIFE Study - 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 6 weeks of age, on the uptake of ART and infant prophylaxis, and on rates of infant survival, morbidity and retention in care.](#)

-[Call RIA2017S: 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 PRDs.

DHSC is funding one project under this call: [PREVAC-UP - The Partnership for Research on Ebola Vaccinations-extended follow-UP and clinical research capacity build-UP](#).

-[Call RIA2017MC: 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 projects under this call: (1) [EMPIRICAL - Empirical treatment against cytomegalovirus and tuberculosis in severe pneumonia in HIV-infected infants: a randomized controlled clinical trial](#) and (2) [BabyGel - A cluster randomised trial to evaluate the effectiveness of household alcohol-based handrub for the prevention of sepsis, diarrhoea and pneumonia in Ugandan infants](#).

-[Call RIA2018D: Diagnostic tools for poverty-related diseases](#) aims to support implementation of new or improved diagnostic tools and technologies for the detection of any of the of poverty-related diseases (PRDs).

DHSC provides funding to five projects under this call:

(1) [Triage TB - Field evaluation of a point-of-care triage test for active tuberculosis](#); (2) [DIAGMAL - Phase 3 evaluation of an innovative simple molecular test for the diagnosis of malaria in different endemic and health settings in sub-Sahara Africa](#); (3) [LAMP4Yaws - Clinical evaluation of a Loop-mediated isothermal amplification test for Treponema pallidum pertenu: A Diagnostic tool to support Yaws Eradication](#); (4) [ERASE-TB Early risk assessment in TB contacts by new diagnostic tests](#); and (5) XACT III - A randomized control trial to evaluate a scalable active case-finding intervention for tuberculosis using a point-of-care molecular tool (Xpert Omni).

-[Call RIA2018CO: 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:

(1) [VITALITY - VITamin D for AdoLescents with HIV to reduce musculoskeletal morbidity and ImmunopaThology: an individually randomised, double-blinded placebo-controlled trial](#); (2) META TRIAL - 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; (3) [PROTID - Randomised Controlled Trial of Preventive Treatment of Latent Tuberculosis Infection in Patients with Diabetes Mellitus](#) and (4) [5FC HIV-Crypto - Improved flucytosine formulation for the treatment of meningitis in advanced HIV disease](#).



-[Call RIA2018V: 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: [PREPARE - Prevention of invasive Group B Streptococcus disease in young infants: a pathway for the evaluation & licensure of an investigational maternal GBS vaccine](#)

-[Call: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020](#) aims to establish an African cohort of epidemiologists by supporting institutions in sub-Saharan Africa and Europe that provide master's training in epidemiology and biostatistics, as part of the Africa CDC's framework for public health workforce development.

DHSC is funding 2 proposals under this call. All proposals are under grant agreement preparation: (1) IDEA Fellowship: Consortium for Development of Sustainable Research Based Fellowship Training on Infectious Disease Epidemiology and Biostatistics in Africa and (2) ENTRANT: East and Southern African Consortium for Outbreak Epidemiology Training

- [COVID-19 Emergency Funding Mechanism](#) aims to support research activities in sub-Saharan Africa to manage and/or prevent the spread of the current COVID-19.

DHSC provides funding to five projects under this emergency funding mechanism:

(1) [CSIGN: COVID Surveillance Intensification in Ghana Network](#); (2) MozCOVID: COVID-19 surveillance in rural Mozambique for prompt and effective response; (3) COVID-19 HCW: Surveillance among healthcare workers for SARS-Coronavirus-2-infection; (4) [ITAIL-COVID-19: Integrated testing approaches and intensive laboratory training as strategy against SARS-COV-2 spread in Brazzaville](#); (5) [periCOVID-Africa: Understanding COVID-19 infections in pregnant women and their babies in Uganda, Kenya, Malawi, The Gambia and Mozambique](#)

-[Participating States Initiated Activity \(PSIA\) 'Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa'](#).

DHSC provides funding to four projects\* under this call:

(1) TAGENDI: TESA addressing gender and diversity regional gaps in clinical research capacity; (2) CaFe-SEA: Capacity Building for Female Scientists in East Africa; (3) TALENT: Creating a gender sensitive platform for clinical research in WANETAM; (4) WISE: Strengthening gender capacity in clinical research within CANTAM network

\*All four proposals are currently in grant agreement preparation.

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?
<p><a href="#">Call RIA2016E: 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.</a></p>	<p>The projects are on track. However, there is an increased attention to COVID-19 in their activities in comparison to other epidemic diseases and expanded scope requiring additional resources to complete the projects.</p>	<p>For <a href="#">PANDORA-ID-NET</a> the significant increase in workload to respond to the pandemic means that additional time (minimum 8 months) and staffing are needed to complete activities.</p>
<p><a href="#">Call RIA2016MC on 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.</a></p>	<p>Project deliverables have been significantly impacted by COVID-19 outbreak, though the extent varies from project to project.</p> <p><a href="#">CHAPS</a> project comprises studies evaluating PrEP requirements in young people in sub-Saharan Africa. The project is conducting a social science study to identify barriers to PrEP medication adherence and a phase 2 clinical trial (<a href="#">NCT03986970</a>) to evaluate different doses and timing of oral PrEP. The social science study completed recruitment ahead of schedule and finalised the related data set. The phase II trial is running behind schedule due to slow regulatory approval</p>	<p><a href="#">CHAPS</a> was granted a 12-month no-cost extension to accomplish the planned deliverables and milestones.</p>

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?
	<p>in South Africa as well as COVID-19-related lockdowns in Uganda and South Africa. The study achieved enrolment completion in March 2021.</p> <p><a href="#">The PROMISE-EPI</a> trial on prevention of Mother-to-child transmission of HIV-1 (<a href="#">NCT03870438</a>) is recruiting in Burkina Faso and Zambia. In both countries the project initiated recruitment later than planned due to slow regulatory approvals in Zambia, delays caused by the COVID-19 outbreak as well as the security situation in Burkina Faso.</p> <p><a href="#">The LIFE study</a>, is a cluster-randomised controlled study conducted at maternity health facilities in Mozambique and Tanzania (<a href="#">NCT04032522</a>). Due to the COVID-19 pandemic, the recruitment in both countries was temporarily put on hold but resumed in July 2020. The trial is ongoing and estimated to complete in May 2023. It is not yet clear whether COVID-19 delays will require an extension of the project duration.</p>	<p><a href="#">The PROMISE-EPI</a> received an 18-month extension.</p> <p>n/a</p>
<p><a href="#">Call RIA2017S: Strategic actions supporting large-scale clinical trials – 2017</a></p>	<p>Minor/moderate impact of COVID-19 outbreak on project deliverables.</p> <p><a href="#">PREVAC-UP</a> project is involving a follow-up of 1,400 adults and 1,400 children taking part in a</p>	<p>Full extent of COVID-19 impact on project timelines in not yet determined.</p> <p>To be determined</p>

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?
	<p>previously conducted phase IIB trial (<a href="#">NCT02876328</a>) that evaluated safety and immunogenicity of three vaccine strategies for preventing Ebola virus in children and adults. Preparation for follow-up is ongoing. COVID-19 delays were reported, among others, in relation to planned workshops conducted under the project.</p>	
<p><a href="#">Call RIA2017MC: Clinical trials to reduce health inequities in pregnant women, newborns and children – 2017</a></p>	<p>Minor/moderate impact of COVID-19 outbreak on project deliverables.</p> <p><a href="#">EMPIRICAL</a> study on treatment against Cytomegalovirus and Tuberculosis in HIV-infected Infants With Severe Pneumonia (<a href="#">NCT03915366</a>) recruited its first patient in March 2020, in Malawi. Despite the COVID-19 pandemic causing temporary suspension of the study, other recruitment sites in Mozambique, Cote d'Ivoire and Zambia also initiated the recruitment in 2020. The trial is ongoing with 68 children recruited by the end of the second year of the project.</p> <p><a href="#">The Babygel study</a> - A cluster randomised trial to evaluate the effectiveness of household alcohol-based hand-rub for the prevention of sepsis, diarrhoea</p>	<p><a href="#">EMPIRICAL</a> trial is facing significant delays and the consortium will submit a request for extension of 18 months to complete recruitment, pushing back the new end date to July 2025. The delay is due in part to COVID-19 impact but also due to lower than expected recruitment in certain sites and countries. The project has responded by stopping recruitment at some clinical sites and opening recruitment at new sites.</p>

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?
	<p>and pneumonia in Ugandan infants  <a href="#">(PACTR202004705649428)</a>-initiated recruitment in Uganda in February 2021. Due to COVID-19 restrictions, the start of the study was delayed by 9 months. The project expects to reach 25% of the study sample by July/August 2021.</p>	<p><a href="#">The Babygel consortium</a> will review timelines to see if activities can be accomplished in the 60-month lifespan of the project or whether additional time is needed.</p>
<p><a href="#">Call RIA2018D: Diagnostic tools for poverty-related diseases – 2018</a></p>	<p>In general, deliverables behind schedule due to COVID-19. However, no major impact on the overall objectives or duration is currently expected.</p> <p><a href="#">Triage TB study</a>: Point-of-care Triage Test for Active Tuberculosis (<a href="#">NCT04232618</a>) is currently recruiting and progressing well, despite initial delays. The study was first put on hold due to the COVID-19 lockdown at all recruiting sites in the Gambia, South Africa and Uganda. Furthermore, the project modified study protocols to include COVID-19 testing (funded from complementary sources) requiring additional time for ethics approvals.</p> <p><a href="#">The DIAGMAL study</a> - a phase</p>	<p><a href="#">Triage TB</a> was granted a 6-month extension in order to successfully complete the study.</p> <p>n/a</p>

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?
	<p>III study evaluating an innovative simple molecular test for the diagnosis of malaria in five different malaria endemic settings in sub-Saharan Africa - is in preparation. The consortium is completing trial documents for ethical approvals in Burkina Faso, Ethiopia, Kenya, Namibia and Sudan, following which the trial will begin. The project so far did not report major delays to the implementation caused by the COVID-19 outbreak.</p> <p><a href="#">LAMP4Yaws study</a> on Clinical Evaluation of a Loop-mediated Isothermal Amplification Test for <i>Treponema Pallidum Pertenuis</i>: A Diagnostic Tool to Support Yaws Eradication (<a href="#">NCT04753788</a>) obtained ethical approval in all countries: Cote d'Ivoire, Cameroon and Ghana and recruited study teams as well as conducted initial staff training. The project planned to start recruitment in Cote d'Ivoire, Cameroon and Ghana in March 2021- a delay of 3 months due to the COVID-19 outbreak. The consortium reported that this delay would unlikely impact on the timely achievement of project deliverables.</p>	n/a

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?
	<p><a href="#">ERASE-TB</a> started 01 May 2020 and will submit its first progress report in July 2021.</p> <p>XACT III started on 01 April 2020 and is due to report in June 2021.</p>	<p>To be determined</p> <p>To be determined</p>
<p><a href="#">Call RIA2018CO: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities – 2018</a></p>	<p>In general, deliverables are behind schedule due to COVID-19. The extent varies from project to project. The full impact is yet to be determined.</p> <p><a href="#">The VITALITY trial</a>: VITamin D for AdoLescents with HIV to reduce musculoskeletal morbidity and ImmunopaThologY (<a href="#">PACTR202009897660297</a>) is conducted in Zimbabwe and Zambia. The project secured ethical and regulatory approvals, as well as recruited and trained study teams. Despite delays caused by the COVID-19 pandemic, the project initiated recruitment in Zambia and Zimbabwe in the first quarter of 2021. The 25% recruitment mark has been reached for Zimbabwe.</p> <p><a href="#">META Trial</a> project started on 1 April 2020 and is due to report at the end of May 2021.</p>	<p>To be determined</p> <p>The consortium has reported that the start of recruitment is delayed by 3-6 months due to COVID-</p>

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?
	<p><a href="#">PROTID</a> project is conducting a Randomized Double Blind Placebo Controlled Trial of Rifapentine and Isoniazid for Prevention of Tuberculosis in People With Diabetes in Tanzania and Uganda (<a href="#">NCT04600167</a>). The project reported delays in ethical and regulatory approvals clearance due to COVID-19 and its other deliverables such as staff training were also affected, thus delaying the start of the trial Furthermore, the availability of rifapentine is lower due to global shortage. The consortium has indicated that they expected that a 12-month extension will be needed.</p> <p><a href="#">5FC HIV-Crypto</a> project started on 1 July 2020 and will submit its first report in September 2021. Preparations to initiate the phase I studies are ongoing.</p>	<p>19. More details are expected in the report due in May 2021.</p> <p>To be determined</p> <p>To be determined</p>
<p><a href="#">Call RIA2018V: Vaccines for diarrhoeal diseases or lower respiratory tract infections – 2018</a></p>	<p>Moderate impact of the COVID-19 outbreak on project deliverables.</p> <p><a href="#">PREPARE</a> project is testing two experimental vaccines in separate trials against group B streptococci in women with and without HIV. The project is actively recruiting in order to establish the GBS disease</p>	<p>n/a</p>



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?
	<p>incidence rate in an urban Ugandan cohort. Furthermore, preparations for the main clinical trial in pregnant women with and without HIV are ongoing. COVID-19 related lockdown caused delays to the project but the consortium did not report that it would impact the overall objectives of the project. One of the vaccine trials (Minervax candidate) will start earlier than expected.</p>	
<p><a href="#">Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020</a></p>	<p>The call is on track to contribute towards expected outcomes/impact. All projects will submit their first progress reports in the second half of 2021.</p> <p>The <a href="#">CSIGN</a> project is conducting a multi component observational study to enhance COVID-19 surveillance in Ghana. Its preliminary findings are available <a href="#">here</a>. The consortium is in the process of requesting a 6-month extension of the project, in order to gather more surveillance data on vaccine roll-out and the emergence of new SARS-CoV-2 variants.</p> <p>Similarly, MozCOVID project is focusing on COVID-19 surveillance in rural Mozambique and the project is ongoing.</p>	<p>n/a</p> <p>n/a</p>

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?
	<p><a href="#">Covid-19 HCW</a> project is investigating the epidemiology of SARS-CoV-2 infection among different healthcare workers exposed to COVID-19 patients. The project is ongoing and its findings were submitted for publication in Clinical Infectious Diseases. The project has requested an extension of 12 months to continue collecting data.</p> <p><a href="#">PeriCOVID Africa</a> is describing the sero-epidemiology of COVID-19 among pregnant women to determine risk and routes of mother-to-child transmission. The project is ongoing.</p> <p><a href="#">ITAIL-COVID-19</a> is conducting research on COVID-19 infection epidemiology in Congo-Brazzaville in order to strengthen the country's national surveillance system. The project is ongoing.</p>	<p>n/a</p> <p>n/a</p> <p>n/a</p>
<p><a href="#">-Call CSA2020E: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020</a></p>	<p>The call is on track to contribute towards expected outcomes/impact. Two DHSC-supported proposals are under grant agreement preparation, one of which has been sent out for signature.</p>	<p>n/a</p>
<p><a href="#">PSIA2020AGDG: Addressing gender and</a></p>	<p>The call is on track to contribute towards expected</p>	<p>n/a</p>

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?
<a href="#">diversity gaps in clinical research capacity at the ECCTP Regional Networks of Excellence – 2020</a>	outcomes/impact. Four proposals were selected for funding and are in grant preparation.	

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). All EDCTP project proposals involving clinical studies are required to specify details concerning patient and community involvement during the development and conduct of clinical trials (see: [EDCTP Template for essential information to be provided for proposals including clinical trials and diagnostic studies.](#)) Furthermore, some projects include specific project objectives and related sets of deliverables that are oriented towards community engagement strategies.

[ALERRT - African coalition for Epidemic Research, Response and Training](#) has a dedicated project objective and related activities to set up systems of community engagement for clinical trials and outbreak responses and collect evidence of effective engagement. The project contributed to the [WHO Global Protocol](#) detailing a cross-sectional survey for health care workers during COVID-19 and utilised this tool to survey almost 10,000 healthcare workers in Ghana, Cameroon, Senegal and Uganda. It plans to publish the results in 2021. Furthermore, ALERRT carried out a scoping review of available literature on Community engagement activities, with a focus on sub-Saharan Africa, published in [BMC Public Health](#). The paper provides recommendations for facilitating the effectiveness of community engagement initiatives as essential elements of infectious diseases studies.

[BabyGel project - A cluster randomised trial to evaluate the effectiveness of household alcohol-based handrub for the prevention of sepsis, diarrhoea and pneumonia in Ugandan infants](#) recognises the crucial role of public engagement in ensuring relevance of research

to the needs of end-users and has a dedicated set of activities devoted to public engagement. In partnership with James Lind Alliance, the project is researching women's priorities - including matters concerning pregnancy, childbirth, and after childbirth among under-served populations in rural settings of Uganda. [The protocol](#) for the study was published in a peer-reviewed journal Research Involvement and Engagement. The consortium plans to share the research questions and results with relevant ministries in Uganda as well as the World Health Organization to encourage inclusion of women's priorities in research.

[PREVAC-UP - The Partnership for Research on Ebola Vaccinations-extended follow-UP and clinical research capacity build-UP](#) conducted ethnographic research in Guinea, Liberia, Mali and Sierra Leone to evaluate the acceptability of the PREVAC vaccine trial for the community and trial participants. The analysis was ongoing at the time of last reporting to EDCTP.

MozCOVID project on 'COVID-19 surveillance in rural Mozambique for a prompt and effective response' is conducting a community seroprevalence survey. It aims to raise awareness among the study population of the risk factors for transmission of COVID-19 and the importance of adherence to the prevention measures adopted by the government of Mozambique. The project will engage with the Community Advisory Board of the Centre for Health Research of Manhica (CISM) and local administrative authorities. Key COVID-19 prevention messages will be disseminated in health facilities during routine health talks. Moreover, community information will be intensified using radio channels, megaphones, and SMS services.

### 3. Outputs and outcomes

#### High quality policy/practice relevant research and innovation outputs

3.1 Aggregated number of outputs by output type.

Output type	Total number across all NIHR funded awards (cumulative number since funding began)
Assay/cell line/antibody/biomarker	Not quantified
Book chapter	0
Whole book	0
Checklists/scales	Not quantified
Cochrane review	0
Conference abstract	4
Conference poster	Not quantified
Database	Not quantified
Diagnostic test/ diagnostic studies	24
Vaccine studies	15
Therapeutic studies	20
Feature article	Not quantified
Journal article	21
Journal editorial	6

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.

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
<a href="#">Call RIA2016E : Poverty-related diseases Epidemics</a>	Zoonotic disease preparedness in sub-Saharan African countries	Linzy Elton, Najmul Haider, Richard Kock, Margaret J. Thomason, John Tembo, Liã Bárbara Arruda, Francine Ntoumi, Alimuddin Zumla, Timothy D. McHugh and the PANDORA-ID-NET consortium	22 March 2021	Peer-reviewed scientific article	<a href="https://doi.org/10.1186/s42522-021-00037-8">https://doi.org/10.1186/s42522-021-00037-8</a>
	How can community engagement in health research be strengthened for infectious disease outbreaks in Sub-Saharan Africa? A scoping review of the literature	Samantha Vanderslott, Manya Van Ryneveld, Mark Marchant, Shelley Lees, Sylvie Kwedi Nolna & Vicki Marsh	01 April 2021	Article	<a href="https://doi.org/10.1186/s12889-021-10348-0">https://doi.org/10.1186/s12889-021-10348-0</a>
	Perceptions of Healthcare Workers regarding local	Nina Gobat, Denise van Hout, Emily Chan, Anna	29 April 2020	Research protocol	n/a Available from: <a href="https://www.who.int/publications/">https://www.who.int/publications/</a>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	infection prevention and control procedures for COVID-19: Research protocol.	Levin, Maria Clara Padoveze Fonseca Barbosa, Yolanda Bayugo, Alice Simniceanu Alessandro Cassini, Benedetta Allegranzi			<a href="https://doi.org/10.1186/s13063-020-04760-19">m/item/perceptions-of-healthcare-workers-regarding-local-infection-prevention-and-control-procedures-for-covid-19-research-protocol</a>
<a href="#">Call RIA2016 M Maternal &amp; Child Health Saharan Africa.</a>	Combined HIV Adolescent Prevention Study (CHAPS): comparison of HIV pre-exposure prophylaxis regimens for adolescents in sub-Saharan Africa—study protocol for a mixed-methods study including a randomised controlled trial	S. Nash, J. Dietrich, A. S. Ssemata, C. Herrera, K. O’Hagan, L. Else, F. Chiodi, C. Kelly, R. Shattock, M. Chirenje, L. Lebina, S. Khoo, L-G Bekker, H. A. Weiss, C. Gray, L. Stranix-Chibanda, P. Kaleebu, J. Seeley, N. Martinson & J. Fox on behalf of the CHAPS team	30 October 2020	Article/Research protocol	<a href="https://doi.org/10.1186/s13063-020-04760-x">https://doi.org/10.1186/s13063-020-04760-x</a>
<a href="#">Call RIA2017 M Maternal &amp; Child Health</a>	Maternal and newborn health priority setting partnership in rural Uganda in association	James Ditai, Monicah Nakyazze, Deborah Andrinar Namutebi,	22 September 2020	Article/Research protocol	<a href="https://doi.org/10.1186/s40900-020-00231-4">https://doi.org/10.1186/s40900-020-00231-4</a>

<b>Award</b>	<b>Output title</b>	<b>Authors</b>	<b>Date</b>	<b>Output type (e.g. article, book chapter, policy brief etc)</b>	<b>DOI (where applicable )</b>
	with the James Lind Alliance: a study protocol	Proscovia Auma, Martin Chebet, Cynthia Nalumansi, Grace Martha Nabulo, Kenneth Mugabe, Toto Anne Gronlund, Anthony Mbonye & Andrew D. Weeks			

### 3.3 Lead/senior authorship

	<b>Total number across all NIHR funded awards (cumulative number since funding began)</b>	<b>% of total number of externally peer-reviewed research publications</b>
Number of externally peer-reviewed research publications with a lead or senior author whose home institution is in an LMIC*	13 out of 31	42%
Number of externally peer-reviewed research publications with a female lead or senior author**	21 out of 31	68%
Number of externally peer-reviewed research publications with a female lead or senior author whose home institution is in an	7 out of 31	23%



	<b>Total number across all NIHR funded awards (cumulative number since funding began)</b>	<b>% of total number of externally peer-reviewed research publications</b>
LMIC***		

\* Number of peer-reviewed publications with first or last author whose home institution is in sub-Saharan Africa (incl. South Africa)

\*\* Number of peer-reviewed publications with female first or last author

\*\*\* Number of peer-reviewed publications with female first or last author whose home institution is in sub-Saharan Africa (incl. South Africa)

## Informing policy, practice and individual/community behaviour in LMICs

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.

[PANDORA-ID-NET - Pan-African Network For Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics](#) has a dedicated project objective and set of activities on engaging policy makers and global public health bodies - led by Chatham House. To this end, the project has built up and maintained working relationships with the Africa Centres for Disease Control (CDC), Public Health England, the African Coalition of Epidemic Research, Response and Training (ALERT) and multiple Ministries of Health and National Public Health Institutes across the African continent. PANDORA-ID-NET has developed a strategic partnership with the Africa CDC and is providing input to its operations across the continent. The consortium supported the Africa CDC in developing policy around the role of social sciences during epidemics and drafting strategies for community engagement. Furthermore, the consortium contributed to the operationalisation of [One Health Approach](#) across Africa through inputs to Africa CDC's [One Health Framework for National Public Health Institutes](#). In addition, PANDORA-ID-NET is supporting the Africa CDC in their outbreak response model which includes a roster of responders from across African Union (AU) member states coordinated through their five regional coordinating centres. PANDORA-ID-NET offers training and capacity building to the rapid response teams from individual AU member states.

[ALERRT - African coalition for Epidemic Research, Response and Training](#) set up the COVID-19 clinical characterisation protocol (CCP) - work funded by the Wellcome Trust and the [UK Foreign, Commonwealth and Development Office](#) - and is working closely with the WHO/AFRO, Africa CDC and existing networks and structures across Africa and globally to adapt the CCP for implementation in Africa. It has been so far implemented in four countries (Ghana, Senegal, Cameroon and Uganda) and planning is underway to extend to other countries such as Guinea, Central African Republic and Democratic Republic of Congo.

Furthermore, in partnership with The African Academy of Sciences (AAS), Africa CDC, WHO/AFRO, The Alliance for Accelerating Excellence in Science in Africa (AESAs) and The African Union Development Agency (AUDA-NEPAD), ALERRT has disseminated emerging COVID-19 clinical management evidence through [interactive webinars](#).

## LMIC and UK researchers trained and increased support staff capacity

### 3.5 Aggregate level summary across awards of individual capacity strengthening supported by at least 25% NIHR award funding

Training level	Total number who are currently undertaking or have completed during the award period	% LMIC nationality*	% female
BSc	0	n/a	n/a
MSc	6	100%	100%
MD	0	n/a	n/a
Mphil	0	n/a	n/a
PhD	26	92%	54%
Postdoc	4	100%	100%
Professional training for non-research support staff (e.g. research manager, finance, admin, community engagement practitioners etc)	Not quantified	n/a	n/a
Other	5	40%	100%

\*All-Saharan African countries South Africa

## LMIC institutional capacity strengthened

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

In order to achieve both high quality collaborations and international standards studies, one of ECCTP's five specific objectives is to build the capacity of countries in sub-Saharan Africa where the research is conducted. Support for capacity development is either embedded within funding for clinical trials (staff trainings and long-term support to Master's, PhD students as well as post-doctoral researchers as described in section 3.5) or is in the form of standalone research capacity grants (fellowships, ethics and regulatory strengthening and formation or networks involved in interregional capacity building).

All the DHSC-supported clinical trial projects have elements of clinical trial capacity development as integral project activities. Trainings for researchers and clinical trial site staff - for example, nurses and clinical personnel - involves topics such as good clinical practice (GCP), pharmacovigilance, data management and statistics, just to name a few. In total, 1,049 individuals have so far received such trainings as part of UKDSHC-supported clinical trial projects, in addition to 41 researchers receiving degree-related trainings and other long-term trainings (section 3.5).

Another example of capacity strengthening is the provision of laboratory capacity required to support clinical studies. This is especially relevant in times of COVID-19 when infrastructure is supporting the public health response to COVID-19. In South Africa, laboratories used by the DHSC-funded [CHAPS](#) project have been repurposed for COVID-19 vaccine research. PANDORA's facilities at Kumasi Centre for Collaborative Research into Tropical Medicine (KCCR) are serving as a diagnostic centre for COVID-19 in central and northern Ghana and the consortium was instrumental in setting up another laboratory centre in Ghana at the Komfo Anokye Teaching Hospital.

In terms of standalone research grants, the objectives of [ALERTT](#) and [PANDORA-ID-NET](#) are fully focused on building the capacities of sub-Saharan African countries to respond to epidemic threats. Examples of their recent capacity development activities include four skills-sharing workshops delivered by ALERTT in partnership with other ECCTP-funded international research networks. The topics of the workshops included [laboratory quality control](#), [grant writing](#), [research in global health emergencies](#) and [research ethics during epidemics](#), with a total number of 1,303 people trained. PANDORA-ID-NET has supported capacity development through training of personnel in deployment of mobile labs, sequencing technologies such as MinION (Oxford Nanopore) and COVID-19 diagnostics and ethics. Furthermore, the DHSC-funded Participating States Initiated Activity (PSIA) ['Towards addressing gender and diversity capacity gaps in clinical research in sub-](#)

[Saharan Africa](#)' will provide training opportunities for female researchers, with four projects under grant agreement preparation. This activity responds to the findings and recommendations of the EDCTP-Africa CDC workshop on [Collaborating to improve gender-related and regional disparities in research funding](#).

3.7 Aggregated distribution of support staff (collected for the purposes of understanding how wider research support responsibilities are divided between LMIC and HIC institutions)

	<b>Total number of FTE support staff (research managers, finance, admin, community engagement practitioners, other) in post during the last 12 months - <i>note that this may not be a whole number depending on institutional employment policies*</i></b>
Employed in LMICs	This is not routinely collected though 3.10 Aggregated HIC/LMIC spend across all awards will show involvement of LMICs and HICs project partners will also indicate the extent of involvement in project activities
Employed in HICs	

*\*e.g. if an institution employs 5 support staff, of which 3 work full time for 12 months, 1 works full time but leaves after 6 months, and 1 works 1 day/week for 12 months, the total reported would be:  $3 + (1 \times 0.5) + 0.2 = 3.7$  FTE*

## Equitable research partnerships and thematic networks established/strengthened

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

DHSC supports through EDCTP two epidemic preparedness networks – [ALERRT](#) and [PANDORA-ID-NET](#). Both ALERRT and PANDORA-ID-NET are well-established, large international networks, comprising together 22 institutions from 15 African countries as well as 18 institutions from five European countries. They play a crucial role in generating evidence on strategies to prevent further COVID-19 transmission by providing laboratory skills training and sharing experience and data relevant to further pandemic control.

The two epidemic preparedness networks have also collaborated with the [EDCTP Regional Networks](#). For example, in December 2020, the network for the Southern African region (TESA) organised a workshop on 'Research ethics during epidemics' in collaboration with PANDORA-ID-NET and ALERRT. Another EDCTP Regional Network,

the Eastern Africa Consortium for Clinical Research (EACCR), is now also working with ALERRT and PANDORA-ID-NET to build capacity for research during epidemics.

### 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>47,563,456</b>	<b>51.47%</b>
United Kingdom	21,635,881	23.41%
France	11,733,093	12.70%
Germany	3,243,689	3.51%
Spain	2,190,883	2.37%
Netherlands, The	2,125,517	2.30%
Italy	1,886,857	2.04%
Switzerland	1,838,024	1.99%
Denmark	885,433	0.96%
Norway	789,982	0.85%
Belgium	616,771	0.67%
Sweden	343,805	0.37%
Portugal	273,520	0.30%
Luxembourg**	0	0.00%
New Zealand**	0	0.00%
North America**	0	0.00%
<b>LIMC</b>	<b>44,847,623</b>	<b>48.53%</b>
Uganda	9,102,386	9.85%
United Republic of Tanzania	6,538,690	7.08%
Zambia	4,632,490	5.01%
Sierra Leone	3,689,967	3.99%
South Africa	3,592,313	3.89%
Zimbabwe	2,956,827	3.20%

<b>Country</b>	<b>Total committed amount (GBP) allocated to:</b>	<b>% of total committed amount to all institutions:</b>
Mozambique	2,587,003	2.80%
Cameroon	1,904,740	2.06%
Republic of the Congo	1,785,675	1.93%
Cote D'Ivoire	1,729,703	1.87%
Senegal	1,295,777	1.40%
Ghana	1,129,296	1.22%
Burkina Faso	896,452	0.97%
Guinea	711,926	0.77%
Sudan	622,586	0.67%
Nigeria	411,907	0.45%
Kenya	295,378	0.32%
Ethiopia	252,746	0.27%
Namibia	223,308	0.24%
Malawi	218,819	0.24%
Madagascar	110,520	0.12%
Central Afrcian Republic	110,520	0.12%
The Democratic Republic of the Congo	48,595	0.05%
Gabon	0	0.00%
Mali	0	0.00%
Pakistan **	0	0.00%
<b>Total*</b>	<b>92,411,079</b>	<b>100.00%</b>

\*The total excludes Grant Agreement is under preparation.

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

## 4. 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.

### 4.1 Economy - how are you (the delivery partner) ensuring that funding is being spent on the best value inputs?

ECCTP uses different approaches to ensuring that ECCTP funds are used by beneficiaries in a cost-effective manner. These approaches include:

- Internal audits of beneficiaries: ECCTP has signed a memorandum of understanding with PWC Netherlands to conduct internal audits of ECCTP-funded projects.
- Site visits: ECCTP operation and finance teams conduct site visits to selected ECCTP-funded projects to perform technical and financial assessments, including reviewing the internal controls over procurement; segregation of duties over financial transactions; and the financial reports submitted to ECCTP to ensure that they agree with the underlying supporting documents.
- Thorough review of periodic financial reports: At the end of each reporting period, beneficiaries are required to submit financial reports to the ECCTP for review. These reviews include checking all reported financial transactions, including procurement of goods and services, and compliance with ECCTP financial guidelines.
- Effective follow-up on management letter points: The ECCTP Grant Finance Officers write to all the sites with a modified audit report requesting them to report on the actions taken or planned in respect of the observations and recommendation raised in the external auditors' management reports.

### 4.2 Enhanced efficiency - how are you (the delivery partner) maximising the outputs (research and innovation outputs, knowledge exchange, strengthened researcher and support staff capacity, strengthened partnerships/networks) for a given level of inputs?

ECCTP has increasingly been developing partnerships with other funders and key stakeholders such as product development partnerships. These have led to a number of joint calls, where ECCTP and other funders jointly organise calls for proposals, and co-funding initiatives, where funding is conditional on financial contributions from partners.

In addition, the programme has been undertaking a range of activities to facilitate high-quality clinical research and greater coordination of research efforts. These include support for the development of an [R&D roadmap for TB vaccine development](#), in close liaison with WHO, and the [launch](#) of the [EDCTP Knowledge Hub](#), an online platform with open-access resources for researchers conducting clinical research in low-resource settings.

In times of COVID-19, which has illustrated the importance of timely and coordinated responses, the programme has made efforts to reach out to like-minded organisations, to align activities and achieve synergies.

For example, in June 2020 EDCTP joined the [COVID-19 Clinical Research Coalition](#), which was launched in April 2020 to promote international research collaboration and coordination to support African, Latin American, Eastern European, and Asian countries to respond effectively to the pandemic and accelerate research in resource-limited settings. The Coalition's Steering Committee includes Professor Francine Ntoumi, a member of the PANDORA-ID-NET epidemic preparedness network.

EDCTP has also entered into a collaboration with the Africa-CDC to develop capacity for outbreak and epidemic responses in sub-Saharan Africa. Through this partnership, EDCTP funding of €7.47 million will be available to institutions in sub-Saharan Africa and Europe that provide master's-level training in epidemiology and biostatistics, as part of Africa CDC's framework for public health workforce development. DHSC is supporting two grants from this call.

Finally, EDCTP is a member of the [GloPID-R](#) funders network, an alliance of global research funding organisations set up to facilitate research into new or re-emerging infectious disease with epidemic and pandemic potential. GloPID-R is enabling funders to track COVID-19-related investments in research avoid duplications of effort, and identify key gaps in knowledge.

#### 4.3 Effectiveness - how are you (the delivery partner) assessing that the outputs deliver the intended outcomes?

In line with principles of results-based management, we monitor and evaluate the EDCTP2 programme to report on operational performance and results. EDCTP's monitoring and evaluation approach draws on a [theory of change](#) that maps out the route through which our funding generates immediate outputs (such as the published results from clinical trials), outcomes (such as changes in health policy and practice) and impact (improvements in health and wellbeing and economic gain). This approach helps collect and analyse information from our projects and other activities that is of strategic importance to realising EDCTP programme objectives. The theory of change model distinguishes different aspects of EDCTP's work –clinical research, capacity development,



and coordination and partnerships – and recognises that activities in these areas facilitate achievement of ECCTP’s strategic objectives.

Based on our theory of change we have developed a monitoring and evaluation framework which incorporates a set of key performance indicators spanning operational performance and expected outputs, outcomes, and impact. For example, tracking peer reviewed publications and their authorship trends, collecting evidence on contributions to evidence to guide national/international policies and clinical guidelines as well as examples of career progression and professional recognition.

Data and information from ongoing monitoring is regularly communicated in our annual progress report, funders' reports and during the biannual meetings of the General Assembly and the Scientific Advisory Committee.

#### 4.4 Equity

- Please summarise any activities that have taken place to ensure everyone is treated fairly as part of the application process and within funded research teams, regardless of gender, gender identity, disability, ethnic origin, religion or belief, sexual orientation, marital status, transgender status, age and nationality.

ECCTP projects 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, ECCTP 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.

With regards to monitoring diversity, ECCTP gender and geographical representation is tracked both at the application stage as well as during project implementation.

- How are you (the delivery partner) ensuring that the funded research benefits vulnerable groups to improve health outcomes of those left behind?

EDCTP's strategy and funding approach has a focus on populations often excluded from clinical studies but with major unmet medical needs, such as pregnant women, newborns, children, other vulnerable populations, and people with co-infections and co-morbidities. Such groups are often underrepresented or excluded from clinical trials and therefore have difficulty to benefit from new medical interventions and innovations. EDCTP-funded studies involve pregnant and lactating women and their children (10% of studies), newborns and infants (18%), children (31%) and adolescents (29%). Furthermore, studies also involve people living with HIV, the elderly, healthcare workers, as well as populations classified by WHO as key populations and vulnerable groups (e.g. sex workers).

- 4.5 List of any additional research awards secured **by LMIC partners** during the course of this NIHR funding - including value, funding source, lead institution and country, what % of additional funding allocated to LMIC partners, HRCS code. (leave blank if not applicable)

Cash cofunding to projects as well as additional research grants secured.

<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>HRCS code</b>
RIA2017 S-2014 PREVAC-UP	National Institute of Health (NIH), USA	10,530,191.29	Institut national de la santé et de la recherche médicale (INSERM), France	To be determined at the final closure of the project	3.4
RIA2016 E-1612-ALERRT	UK Foreign, Commonwealth and Development Office and Wellcome Trust	1,400,000	University of Oxford, United Kingdom	To be determined	3.4
RIA2018 D-2499-TriageTB	National Institutes of Health	5,556,375	Stellenbosch University, South Africa	To be determined	3.4
RIA2016 E-1609 PANDOR A-ID-NET	British Society for Microbial Chemistry	46,786	FCRM - Fondation Congolaise pour la recherche	To be determined	3.4

Award	Funding source	Amount (GBP)	Lead institution name and country	% of additional funding allocated to LMIC partners	HRCS code
			medicale, Congo		
RIA2020 EF-2926 periCOVI D-Africa	Wellcome Trust	329,372	St. George's Hospital Medical School	To be determined	3.4

## 5. Risk

5.1 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
There is uncertainty regarding the 2014, 2015, 2016, 2017, 2018, 2019 and 2020 Participating States' Initiated Activities (PSIAs) submitted to the EC in the annual progress reports because the EC has only provisionally accepted them as eligible.	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.	The status of this risk is open. The planned action is to monitor; immediate action is required.
EDCTP may exceed the 6% administrative budget ceiling as set out Art. 2 (3) of Decision 556/2014/EU.	<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>	The status of this risk is open. The planned action is to monitor; immediate action is required.
Failure by beneficiaries to refund EDCTP for ineligible expenses incurred due to non-compliance with provisions of the EDCTP Grant Agreement	<ul style="list-style-type: none"> <li>• Extensive review of annexes 1 and 2 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>	The status of this risk is open. The planned action is to monitor; no immediate action is required.
Financial shortfalls on projects due to delays caused by COVID-19 resulting in projects not being able to deliver on the objectives of the project.	Encourage EDCTP Participating States to provide supplementary funding. The EC has written to European Participating States encouraging them to provide funding support to projects that have financial shortfalls.	The status of this risk is open. The planned action is to monitor; immediate action is required.
COVID-19 is spreading very fast; many countries have now been affected. It is unclear when the situation will stabilise; there is no definitive end in sight. The	<ul style="list-style-type: none"> <li>• Close monitoring of the projects</li> <li>• Approving no-cost extensions</li> <li>• Brought it to attention of the EDCTP General Assembly and Board</li> <li>• This topic is going to be substantive agenda item at the next General</li> </ul>	The status of this risk is open. The planned action is to monitor.

Risk	How is the risk being managed/mitigated?	Current status
risks to EDCTP of this uncertainty include delay in EDCTP beneficiaries completing their projects on time; and successful implementation of their action activities.	Assembly meeting	

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

- their approach to handling accusations of fraud, corruption and bribery (if not covered in previous reports)
- any changes in the last year to the anti-corruption strategy applied to managing NIHR funded awards

EDCTP has a documented fraud response plan, which provides guidance to EDCTP directors, managers, and staff on how to deal with detected or suspected cases of fraud. The EDCTP Fraud Response plan clearly defines roles and responsibilities; and reporting and responding to suspected incidents of fraud.

There has been no changes to the EDCTP anti-fraud strategy.

- Aggregated credible allegations

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

5.3 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.

EDCTP continues to require all DHSC-funded beneficiaries to read and confirm agreement with safeguarding principles as part of the enhanced due diligence procedure conducted prior to grant agreement signature. For all DHSC-funded beneficiaries where the due diligence process had already been completed and grant agreements signed prior to implementing the enhanced due diligence form on safeguarding, EDCTP has sent a letter outlining EDCTP's safeguarding principles and highlighting their importance.

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

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

5.4 Please summarise any 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 section 4.4). Moreover, due to COVID-19 outbreak all EDCTP2 evaluation procedures and ethics checks in 2020 and 2021 were conducted online as well as the meetings of the Scientific Advisory Committee and the General Assembly. Further, the [Tenth EDCTP forum](#) on 17-20 October 2021 will have a hybrid format (virtual and live from Maputo, Mozambique). EDCTP grantees also conducted many of their activities online, including meetings and trainings. The programme will be taking stock of lessons learnt from these new ways of working to inform its operations post COVID-19 pandemic.

## 6. Delivery, commercial and financial performance

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

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

### 6.2 Transparency - this question applies to funding schemes which include transparency obligations within their contracts..

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

ECCTP has not yet taken action in relation to IATI reporting as this is pending further guidance from DHSC. It was previously agreed that the DHSC lead on transparency will outline DHSC's expectations here and provide clearer guidance and agree a reasonable timeline for ECCTP to work towards. Beyond IATI reporting, ECCTP continues to require 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 ECCTP Model Grant Agreement). As per the Memorandum of Understanding (MoU) between ECCTP and DHSC, ECCTP publishes information about all funded projects (once grant agreements are signed) on the ECCTP website and all project summaries can also be accessed through the [public portal](#) of the ECCTP grants system. Furthermore, ECCTP regularly updates the ECCTP2 online project portfolio with [case studies](#) of signed grants, including those funded by DHSC. On an annual basis, ECCTP reports 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. ECCTP is in the process of joining Europe PubMed Central which will facilitate open access compliance by beneficiaries.

# 7. Monitoring, evaluation and learning

## 7.1 Monitoring

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

A key focus in 2020 and 2021 for the EDCTP Secretariat has been on monitoring the impact of COVID-19 on project implementation and its implications on project duration. The implementation of EDCTP2 projects has been adversely affected by the COVID-19 pandemic, with many research projects having had to suspend their activities and/or having experienced delays to the planned activities. The EDCTP Secretariat is monitoring all disruptions and currently dealing with the most urgent amendment requests from projects that are due to end imminently and must be extended. For other projects, the full extent of the delays and disruption due to COVID-19 is to be determined. Grant-holders have been advised to hold off with submitting amendment requests until there is greater clarity and more information will be coming through future periodic reports.

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

In 2020, EDCTP published [a report](#) from an independent evaluation concerning the support of Swedish Development and has been implementing an action plan in response to the recommendations of the First Interim Evaluation of EDCTP2 programme (2017). One of the activities implemented in 2020 is funded by DHSC - a Participating States Initiated Activity (PSIA) on [Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence](#) that aims at achieving more equitable distribution of activities and funding across countries.

Furthermore, in 2020 independent oversight committees reviewed EDCTP investments in malaria vaccines and malaria drugs and a meeting to review EDCTP investments in TB is planned on 19 May 2021. The oversight committees provided advice to EDCTP on the progress and performance of EDCTP2 projects, including reviewing risk monitoring plans, major study deviations and amendment requests, where applicable.

## 7.3 Learning

The programme is taking stock of lessons learnt from working during COVID-19 pandemics which is affecting EDCTP operations.



7.4 Key milestones/deliverables for the awards for the coming year

Award	Key milestones/deliverables for coming year
<p><a href="#">Call RIA2016E: 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.</a></p>	<p><a href="#">ALERRT</a>: Implementation of nested study focused on COVID-19 pandemic</p>
<p><a href="#">Call RIA2016MC on 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.</a></p>	<p>Completion of the following clinical trials:</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>
<p><a href="#">Call RIA2017S: Strategic actions supporting large-scale clinical trials – 2017</a></p>	<p>Progression of PREVAC trial: <a href="#">NCT02876328</a></p>
<p><a href="#">Call RIA2017MC: Clinical trials to reduce health inequities in pregnant women, newborns and children – 2017</a></p>	<p>Progression of the following trials:</p> <p>EMPIRICAL: <a href="#">NCT03915366</a></p> <p>The Babygel study: <a href="#">PACTR202004705649428</a></p>
<p><a href="#">Call RIA2018D: Diagnostic tools for poverty-related diseases – 2018</a></p>	<p>Start/ progression of the following trials:</p> <p>Triage TB study: <a href="#">NCT04232618</a></p> <p><a href="#">The DIAGMAL study</a></p> <p>LAMP4Yaws study: <a href="#">NCT04753788</a></p> <p><a href="#">ERASE-TB</a> study</p> <p>XACT III study</p>
<p><a href="#">Call RIA2018CO: Advances in product</a></p>	<p>Start/ progression of the following trials:</p>

Award	Key milestones/deliverables for coming year
<a href="#">development for effective prevention, treatment and management of co-infections and co-morbidities – 2018</a>	The VITALITY trial: <a href="#">PACTR202009897660297</a> META Trial PROTID trial: <a href="#">NCT04600167</a> <a href="#">5FC HIV-Crypto</a> trial
<a href="#">Call RIA2018V: Vaccines for diarrhoeal diseases or lower respiratory tract infections – 2018</a>	Start of one of the two planned vaccine trials in the <a href="#">PREPARE project</a>
<a href="#">Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020</a>	Progression of studies Publication of outputs
<a href="#">PSIA2020AGDG: Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence – 2020</a>	Signing of four grant agreements and start of the projects.
Call CSA2020E: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020	Signing of two grant agreements and start of the projects.

7.5 Any other comments/feedback/issues to flag to NIHR/DHSC? This could include any suggestions on anything the delivery partner could do to improve its support for award holders, or on anything that DHSC could do to better support the delivery partner.

As indicated elsewhere in the report, almost all projects have reported suspensions and delays to implementation, requiring extensions in time. Some projects have indicated that they will have financial shortfalls which puts project delivery at risk.

© Crown copyright 2018

Published to GOV.UK in pdf format only.

[Directorate/Division/Branch]

[www.gov.uk/dhsc](http://www.gov.uk/dhsc)

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit [nationalarchives.gov.uk/doc/open-government-licence/version/3](http://nationalarchives.gov.uk/doc/open-government-licence/version/3)

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

