



Department
of Health &
Social Care

DHSC support to EDCTP

Annual Report/Review - 01 May 2021-30 April 2022

NIHR Global Health Research Portfolio

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Contents

Annual reporting and review process.....	3
1. DSHC summary and overview	4
2. Summary of aims and activities.....	7
3. Outputs and outcomes	27
High quality policy/practice relevant research and innovation outputs.....	27
Informing policy, practice and individual/community behaviour in LMICs	37
LMIC and UK researchers trained and increased support staff capacity	38
LMIC institutional capacity strengthened	38
Equitable research partnerships and thematic networks established/strengthened	40
4. Value for money	43
5. Risk	48
6. Delivery, commercial and financial performance	52
7. Monitoring, evaluation and learning	53
Annex: Clearance checklist.....	Error! Bookmark not defined.

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. DSHC 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 2021 to April 2022.

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. DHSC also supports 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](#)'. Furthermore, in 2022 DHSC is providing funding to support strengthening GloPID-R's work with funders and researchers on clinical trial coordination.

-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 projects requesting 12 month extensions.

-[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, all 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, reporting minor/moderate impacts due to the COVID-19 outbreak. The project was also granted a 6-month extension.

-[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 both of which were significantly impacted by COVID-19.

-[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.

[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: 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.

- [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 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 projects concluded grant agreement preparation in the third quarter of 2021 and at the time of the annual review these four were yet to submit their progress reports to EDCTP.

The Global Research Collaboration for Infectious Disease Preparedness - Improving our preparedness capabilities for global response-GloPID-R. This project was under grant agreement preparations at the time of the report.

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. DHSC also supports 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](#)'. Furthermore, in 2022 DHSC is providing funding to support strengthening GloPID-R's work with funders and researchers on clinical trial coordination.

-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 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: (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 pertenuis: 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 two projects under this call: (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.

Through its current contribution of £1.8 million, DHSC is supporting the training of 20 female PhD candidates at the four EDCTP Regional Networks of Excellence (five PhD candidates/network). In order to maximise the impact of this initiative, it was proposed that this contribution is increased by £1 million to allow up to 12 additional female PhD students to be supported from the list of reserve candidates (three additional PhD candidates per network).

- The Global Research Collaboration for Infectious Disease Preparedness - Improving our preparedness capabilities for global response-GloPID-R

GloPID-R grant with a funding of EUR 709,966.75 EUR from the UK Department of Health and Social Care seeks to strengthen GloPID-R's capabilities (building on the existing core funding from the European Commission) to respond to emerging threats through three core components.

1. LMIC geographical nodes - Pilot phase for the African Regional hub: Mapping of the infectious disease research funding landscape and surveying funders to increase regional engagement and membership. Undertaking a launch meeting for the new hub to bring together local stakeholders.
2. Research funding tracking for pandemic preparedness - kick-starting the new tool: Producing a full business plan for the research funding tracking tool for epidemic and pandemic preparedness, fundraising for the build phase and project management.
3. Clinical trials group - Developing a funders framework for coordination of clinical trials (strengthening GloPID-R's work with funders and researchers on clinical trial coordination).

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?
Call RIA2016E: Research and clinical management of patients in poverty-	The projects are ongoing and generally on track towards achieving the objectives of the	

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>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.</p>	<p>call. 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>ALERRT project revised the protocol of its FISSA study (Febrile Illness in Sub-Saharan Africa) to include a research response component in the event of a declaration of a Public Health Emergency by national or international health authorities in the countries participating in the FISSA study. In December 2021, ALERRT stopped recruitment into the FISSA study after enrolment of 8867 participants from 16 healthcare centres in sub-Saharan Africa. The sample size of this observational study is the largest of any fever study to-date. Analysis is ongoing, and results are expected in Q2 of 2022.</p> <p>With complementary funding from the Wellcome Trust and the UK Foreign, Commonwealth and Development Office working closely with the WHO/AFRO, Africa CDC and existing networks and structures across Africa, ALERRT set up the COVID-19 clinical</p>	<p>ALERRT project will request a 12-month no-cost extension to ensure completion of activities.</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>characterisation protocol (CCP), a study nested within the FISSA study. This study aims to investigate risk factors and outcomes for Covid with a particular focus on co-morbidities in an African context (anaemia, helminth infections, malaria, HIV, TB and hepatitis)</p> <p>PANDORA-ID-NET consortium has undertaken ad hoc studies to support the African response to COVID-19. The PANDORA-ID-NET project and members of the PANDORA consortium have published more than 120 articles on COVID-19. They organised online workshops on laboratory quality control), infection prevention and control, and research ethics during epidemics. The consortium also documented how the indirect effects of the COVID-19 pandemic may undermine the health care system in sub-Saharan Africa as the incidence of malaria, tuberculosis (TB), and HIV infection increases.</p>	<p>PANDORA-ID-NET received a 12 month extension of project duration to allow successful completion of project activities. PANDORA-ID-NET has also received a supplement of EUR 1M from Germany (DLR-PT).</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>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.</p>	<p>Project deliverables have been significantly impacted by COVID-19 outbreak, though the extent varies from project to project.</p> <p>CHAPS 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 (NCT03986970) to evaluate different doses and timing of oral PrEP among adolescents. The first three articles from the social science study were published in 2021. The phase II trial ran behind schedule due to slow regulatory approval process and COVID-19-related lockdowns; however, the study completed enrolment in March 2021 and follow-up in April 2021. Laboratory studies relating to the primary and secondary endpoints continued after the trial. Results are expected in Q2 2022.</p> <p>The PROMISE-EPI trial on prevention of Mother-to-child transmission of HIV-1 (NCT03870438) recruited in Burkina Faso and Zambia. In</p>	<p>CHAPS was granted a 12-month no-cost extension to accomplish the planned deliverables and milestones.</p> <p>The PROMISE-EPI received an 18-month extension.</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>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. A publication in 2021 documented the trial design and challenges of conducting this large HIV-prevention study. The trial completed recruitment by end of 2021 and there is a 12-month follow up period. An additional extension is required to complete.</p> <p>The LIFE study, is a cluster-randomised controlled study conducted at maternity health facilities in Mozambique and Tanzania (NCT04032522). COVID-19 pandemic led to temporary suspension of recruitment, and hindered study monitoring procedures e.g. external monitoring visits by the study sponsor were not possible due to travel restrictions.</p> <p>The trial is ongoing, with recruitment completing end of 2021/Q1 2022. An extension of 6-12 months will be needed to complete all study outcomes, including virological parameters at month 18 post recruitment. Current end date is May 2023, likely extended to Q4 2023.</p>	<p>Remote monitoring was established that included regular biweekly zoom meetings, continuous remote data monitoring and cleaning, harmonization of external and internal monitoring procedures, repeated remote and on-site training sessions.</p>
Call RIA2017S: Strategic	Minor/moderate impact of	

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?
actions supporting large-scale clinical trials – 2017	<p>COVID-19 outbreak on project deliverables.</p> <p>PREVAC-UP project is involving a follow-up of 1,400 adults and 1,400 children taking part in a previously conducted phase IIB trial (NCT02876328) that evaluated safety and immunogenicity of three vaccine strategies for preventing Ebola virus in children and adults. The project reported COVID-19 related delays and was granted a 6 month extension of the duration. The study was estimated to complete in December 2023, however an additional extension of 6-9 months may be required due to prolonged disruption caused by COVID-19.</p>	<p>6 month extension of duration was granted.</p>
Call RIA2017MC: Clinical trials to reduce health inequities in pregnant women, newborns and children – 2017	<p>Significant impact of COVID-19 outbreak on project deliverables.</p> <p>EMPIRICAL study on treatment against Cytomegalovirus and Tuberculosis in HIV-infected Infants With Severe Pneumonia (NCT03915366) recruited its first patient in March 2020, in Malawi. The trial was facing significant delays due in part to COVID-19 but also due to lower than expected recruitment in certain sites and countries and is expected to reach 50% of the recruitment rate reached around</p>	<p>EMPIRICAL trial received an extension of 18 months in order to complete recruitment by January 2025.</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>July 2022.</p> <p>The Babygel study - 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 (PACTR202004705649428)-initiated recruitment in January 2021 with the remaining sites that followed in March 2021 and May 2021. Due to COVID-19 restrictions, the start of the study was delayed by 9 months, and recruitment was suspended because of lockdown restrictions in Uganda. Recruitment has re-started and has reached 50% of the target. Recruitment is expected to complete by mid 2023 and an extension of 6-12 months will be needed to complete the activities. EDCTP conducted a site visit of the project in February 2022.</p>	<p>The Babygel consortium has initiated discussions on the possibility to receive an extension of the project duration.</p>
<p>Call RIA2018D: Diagnostic tools for poverty-related diseases – 2018</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>Triage TB study: Point-of-care Triage Test for Active Tuberculosis (NCT04232618) is recruiting. The study was first put on hold due to the COVID-19</p>	<p>Triage TB adjusted recruitment targets for study phases-to 50 participants in phase 1 and 250 participants in phase 2</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>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. Due to delays in start of the recruitment, the phase 1 recruitment target was reduced to half and the phase 2 target increased. The study is estimated to complete in March 2024.</p> <p>The DIAGMAL study is a phase III study evaluating an innovative simple molecular test for the diagnosis of malaria in five different malaria endemic settings in sub-Saharan Africa. At the time of reporting to EDCTP, the consortium finalised the the development of the study protocols (trial and health economics), secured most ethical clearances, pending only approvals from Sudan. The study sites in Burkina Faso, Ethiopia, Kenya, and Namibia had the study initiation visit in Q4-2021. Enrolment of the first subject occurred in Burkina Faso in November 2021, followed up by the sites in Kenya and Namibia in December 2021. A manuscript to publish the study protocol is in preparation.</p>	<p>to prevent further delays in the study which could affect the overall timeline.</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>In the reporting period the consortium has strengthened its engagement with the African Health Observatory Platform on Health Systems and Policies to collaborate on the diagnostic health systems analysis, hosted by the WHO Regional Office for Africa (WHO AFRO).</p> <p>LAMP4Yaws study on Clinical Evaluation of a Loop-mediated Isothermal Amplification Test for Treponema Pallidum Pertenu: A Diagnostic Tool to Support Yaws Eradication (NCT04753788) Initiated recruitment in Cote d'Ivoire, Cameroon and Ghana and recruited study teams as well as conducted initial staff training. Although the recruitment was delayed due to COVID-19 restrictions, the consortium does not expect this to impact on achieving the desired study sample.</p> <p>ERASE-TB study (NCT04781257) is evaluating a number of newly developed diagnostic tests in Tanzania, Mozambique and Zimbabwe, to see which of those will be able to predict TB in persons at risk, and therefore initiate preventive</p>	<p>n/a</p> <p>Trainings on study protocol and informed consent as well as clinical, laboratory and data management procedures and monitoring activities have been implemented virtually to minimise delays. The consortium</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?
	treatment. The study started recruiting in March 2021 in Zimbabwe and experienced some delays in Mozambique and Tanzania due to slow regulatory approval, coupled with COVID-19 restrictions.	may consider applying for additional time to complete field activities
Call RIA2018CO: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities – 2018	<p>In general, deliverables are behind schedule due to COVID-19.</p> <p>The VITALITY trial: VITamin D for AdoLescents with HIV to reduce musculoskeletal morbidity and ImmunopaThologY (PACTR202009897660297) is conducted in Zimbabwe and Zambia. Participant recruitment in Zimbabwe began on the in February 2021 and in March 2021 in Zambia. Despite the limitations imposed by the COVID19 pandemic, recruitment of 820 participants was achieved in 2021 and the project has met all its planned milestones. The study is expected to run until December 2024.</p> <p>META Trial (ISRCTN77382043) aims to identify a low-cost intervention for preventing and delaying the development of diabetes among HIV-infected persons on antiretroviral therapy (ART) and is the largest trial of</p>	<p>n/a</p> <p>The consortium has reported they are confident they could make up for the time lost due to COVID-19, owing robust recruitment plans in place. However, it is likely that an extension</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>its kind in Africa. The recruitment for the trial is ongoing. COVID-19 has caused delays in the implementation of the trial, including long ethics review and regulatory approval. The restrictions in travel have also limited the ability of researchers and the sponsor to travel to the site for study preparation and review.</p> <p>PROTID 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 (NCT04600167). The protocol of the trial was published in Contemp Clin Trials. 2021 Apr 17;105:106402. 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. Overall, there is a delay of around 20 months in the timeline of activities.</p> <p>5FC HIV-Crypto project aims to advance the development of sustained-release flucytosine to simplify inpatient and outpatient treatment of cryptococcal infections. Preparations for the</p>	<p>will be required to complete the trial.</p> <p>EDCTP is supporting the project to understand what support is required.</p> <p>The project partners are currently discussing mitigation measures such as optimising the time</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>Phase I trial continued through 2021 and the study began at FARMOVS in South Africa in early 2022. Phase II studies in Tanzania and Malawi will take place in subsequent years. Project activities have been delayed due to technical challenges on the development of investigational medicinal product by the manufacturer and the significant impact of COVID-19 hindering progress on pharmaceutical development and manufacturing activities.</p>	<p>between different study phases by employing a more efficient data cleaning process as well as a quicker analysis of the results and enabling a flexible protocol amendment to avoid any further delays.</p>
<p>Call RIA2018V: Vaccines for diarrhoeal diseases or lower respiratory tract infections – 2018</p>	<p>Moderate impact of the COVID-19 outbreak on project deliverables.</p> <p>PREPARE project is testing two experimental vaccines in separate trials against group B streptococci in women with and without HIV. The preparatory study recruiting a cohort of pregnant women (NCT04653948) initiated recruitment in September 2020. 3423 women have been recruited and recruitment is complete. The clinical trial of the Minervax vaccine began earlier than scheduled and recruitment has been completed. NCT04596878. Overall, activities are delayed due to COVID-19 lockdowns and an</p>	<p>Extension will be required.</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?
	extension will be required.	
<p>Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020</p>	<p>The call is on track to contribute towards expected outcomes/impact.</p> <p>The CSIGN project aims to strengthen surveillance for COVID-19 in Ghana. Its preliminary findings are available here. The consortium received a 12-month extension of the project duration, in order to gather more surveillance data on vaccine roll-out and the emergence of new SARS-CoV-2 variants.</p> <p>MozCOVID project involves an observational study (NCT05228639) aiming to understand the epidemiology and natural history of COVID-19 in a rural area in Southern Mozambique. The study is currently recruiting and estimated to be completed in August 2022. The project has been extended from 12 to 21 months in order to cover delays experienced in approval processes.</p> <p>Covid-19 HCW project was investigating the epidemiology of SARS-CoV-2 infection among different healthcare workers exposed to COVID-19 patients at the Chris Hani Baragwanath Academic Hospital in South Africa, Africa's largest tertiary</p>	<p>n/a</p> <p>The project has been extended from 12 to 21 months in order to cover delays experienced in approval processes.</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>Hospital. The study found that overall, 166 (41.9%) HCWs had evidence of SARS-CoV-2 infection- a higher rate than those previously described in Europe and North America due to poor ventilation and crowded wards that contributed to HCWs being at greater risk of SARS-CoV-2 infection. Furthermore, the rates elsewhere on the continent are likely to be higher than in South Africa, a relatively well-resourced African country.</p> <p>PeriCOVID Africa is describing the sero-epidemiology of COVID-19 among pregnant women to determine risk and routes of mother-to-child transmission. More than 3,000 women out of a target of 5,000 have been recruited to date in periCOVID Africa. In the course of study, researchers in Uganda have reported that the response to COVID-19 in Uganda (lockdown restrictions) negatively impacted maternal, child and neonatal health, with an increase seen in pregnancy complications and foetal and infant outcomes, likely due to delayed care-seeking behaviour. Furthermore, decreased vaccination clinic attendance leaves a cohort of infants unprotected, affecting all vaccine-preventable diseases. During the COVID-19 crisis, all</p>	<p>The project received 8 month extension of project duration to allow sites to complete the laboratory and data analysis of all the samples.</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>transportation (import and export of samples) was withheld, so, the partners could not begin with the laboratory and data analysis as planned. This is now resumed and most of the samples have been shipped for analysis.</p> <p>ITAIL-COVID-19 is conducting research on COVID-19 infection epidemiology in Congo-Brazzaville in order to strengthen the country's national surveillance system. The project completed in October 2021. The study findings demonstrated a significant number of undiagnosed SARS-CoV-2 infections in Brazzaville. By determining the proportion of the population with antibodies, the study findings might contribute to future prevention strategies involving use of limited resources. In addition, the project collected data on circulating strains in Congo-Brazzaville. Genomic data has been submitted to the GSAID repository. Publications are pending.</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?
-Call CSA2020E: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020	<p>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.</p> <p>Two DHSC-supported projects have concluded grant agreements in the second and third quarter of 2021 and are yet to submit their progress reports to EDCTP. For IDEA Fellowship fellows recruitment is in progress. For ENTRANT project the first batch of Fellows was recruited in 2021 while the second batch will be recruited by August 2022.</p>	n/a
PSIA2020AGDG: Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence – 2020	<p>The call is on track to contribute towards expected outcomes/impact of developing capacity in clinical research among female researchers .</p> <p>Four projects concluded grant agreement preparation in the third quarter of 2021 and are yet to submit their progress reports to EDCTP. Agreements for the additional funding are under preparation.</p>	n/a
GloPID-R - "The Global Research Collaboration for Infectious Disease	The project is under grant agreement preparation.	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?
Preparedness - Improving our preparedness capabilities for global response".		

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.

Community engagement in clinical research is a dynamic and interactive relationship between researchers, policy-makers and the community. EDCTP encourages this engagement; the projects it funds are often oriented towards building interactive engagement with end-users of research results. DHSC supported [ALERT - 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. ALERT 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.

Community engagement as key to the pandemic response has also formed an important component of many of the projects under the Emergency funding mechanism. Among others, under the DHSC's funded project MozCOVID: 'COVID-19 surveillance in rural Mozambique for a prompt and effective response'. The project is conducting a community seroprevalence survey while also aiming 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 is engaging with the Community Advisory Board of the Centre for Health Research of Manhica (CISM) and local administrative authorities.

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	36
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)
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.	<p>The Critical Need for Pooled Data on COVID-19 in African Children: An AFREhealth Call for Action through Multi-Country Research Collaboration</p>	<p>Sam-Agudu NA, Rabie H, Pipo MT, Byamungu LN, Masekela R, van der Zalm MM, Redfern A, Dramowski A, Mukalay A, Gachuno OW, Mongweli N, Kinuthia J, Ishoso DK, Amoako E, Agyare E, Agbeno EK, Jibril AM, Abdullahi AM, Amadi O, Umar UM, Ayele BT, Machezano RN, Nyasulu PS, Hermans MP, Otshudiema JO, Bongo-Pasi Nswe C, Kayembe JN, Mbala-Kingebeni P, Muyembe-Tamfum JJ, Aanyu HT, Musoke P, Fowler MG, Sewankambo N, Suleman F, Adejumo P, Tsegaye</p>	<p>15 November 2021</p>	<p>Article</p>	<p>https://doi.org/10.1093/cid/ciab142</p>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	From Easing Lockdowns to Scaling Up Community-based Coronavirus Disease 2019 Screening, Testing, and Contact	A, Mteta A, Noormahomed EV, Deckelbaum RJ, Zumla A, Mavungu Landu DJ, Tshilolo L, Zigabe S, Goga A, Mills EJ, Umar LW, Kruger M, Mofenson LM, Nachege JB; for investigators in the AFREhealth COVID-19 Research Collaboration on Children and Adolescents Nachege JB, Grimwood A, Mahomed H, Fatti G, Preiser W, Kallay O, Mbala PK, Muyembe JT, Rwagasore E, Nsanzimana S, Ngamije D, Condo J,	27 January 2021	Article	10.1093/cid/ciaa695

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	<p>Tracing in Africa-Shared Approaches, Innovations, and Challenges to Minimize Morbidity and Mortality</p> <p>How can community engagement in health research be strengthened for infectious disease outbreaks in Sub-Saharan Africa? A scoping review of the literature</p>	<p>Sidat M, Noormahomed EV, Reid M, Lukeni B, Suleman F, Mteta A, Zumla A</p> <p>Samantha Vanderslott, Manya Van Ryneveld, Mark Marchant, Shelley Lees, Sylvie Kwedi Nolna & Vicki Marsh</p>	<p>01 April 2021</p>	<p>Article</p>	<p>10.1186/s12889-021-10348-0</p>
<p>Call RIA2016MC on Clinical trials and operational research studies aims to optimise the use of products (new or improved products or combination of</p>	<p>The potential effect of pre-exposure prophylaxis (PrEP) roll-out on sexual-risk behaviour among adolescents and young people in East and southern Africa</p>	<p>Andrew Sentoogo Ssemata, Richard Muhumuza, Lynda Stranix-Chibanda, Teacler Nematadzira, Nadia Ahmed, Stefanie</p>	<p>01 Apr 2022</p>	<p>Article</p>	<p>https://doi.org/10.2989/16085906.2022.2032218</p>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
products) for poverty-related diseases in mothers, newborns, children and/or adolescents in Sub-Saharan Africa.	<p>Women at high risk of HIV-infection in Kampala, Uganda, and their candidacy for PrEP</p> <p>Design and challenges of a large HIV prevention clinical study on mother-to-child transmission: ANRS 12397 PROMISE-EPI study in Zambia and</p>	<p>Hornschuh, Janan Janine Dietrich, Gugulethu Tshabalala, Millicent Atujuna, Denis Ndekezi, Phiona Nalubega, Esther Awino, Helen A Weiss, Julie Fox & Janet Seeley</p> <p>Rachel Kawuma, Andrew Sentoogo Ssemata, Sarah Bernays, Janet Seeley</p> <p>Mennecier A, Kankasa C, Fao P, Moles JP, Eymard-Duvernay S, Mwiya M, Kania D, Chunda-Liyoka C, Sakana L, Rutagwera D, Tassebedo S, Wilfred-Tonga MM,</p>	<p>March 2021</p> <p>June 2021</p>	<p>Article</p> <p>Article</p>	<p>https://doi.org/10.1016/j.ssmph.2021.100746</p> <p>10.1016/j.cct.2021.106402</p>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	Burkina Faso	Mosqueira B, Tylleskär T, Nagot N, Van de Perre P			
Call RIA2017M Maternal & Child Health	Maternal and newborn health priority setting partnership in rural Uganda in association with the James Lind Alliance: a study protocol	James Ditai, Monicah Nakyazze, Deborah Andrinar Namutebi, Proscovia Auma, Martin Chebet, Cynthia Nalumansi, Grace Martha Nabulo, Kenneth Mugabe, Toto Anne Gronlund, Anthony Mbonye & Andrew D. Weeks	22 September 2020	Article	https://doi.org/10.1186/s40900-020-00231-4
Call RIA2018D: Diagnostic tools for poverty-related diseases – 2018	Diagnostic accuracy of the Cepheid 3-gene host response fingerstick blood test in a prospective, multi-site study: interim results.	Sutherland JS, van der Spuy G, Gindeh A, Thuong NT, Namuganga AR, Owolabi O, Mayanja-Kizza H, Nsereko M, Thwaites G, Winter J, Dockrell HM, Scriba TJ,	22 September 2021	Article	10.1093/cid/ciab839

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	Global phylogeny of <i>Treponema pallidum</i> lineages reveals recent expansion and spread of contemporary syphilis	<p>Geluk A, Corstjens P, Stanley K, Richardson T, Shaw JA, Smith B, Malherbe ST, Walzl G; TrENDx-TB consortium</p> <p>Beale MA, Marks M, Cole MJ, Lee MK, Pitt R, Ruis C, Balla E, Crucitti T, Ewens M, Fernández-Naval C, Grankvist A, Guiver M, Kenyon CR, Khairullin R, Kularatne R, Arando M, Molini BJ, Obukhov A, Page EE, Petrovay F, Rietmeijer C, Rowley D, Shokoples S, Smit E, Sweeney EL, Taiaroa G, Vera JH, Wennerås C,</p>	24 November 2021	Article	10.1038/s41564-021-01000-z

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
		<p>Whiley DM, Williamson DA, Hughes G, Naidu P, Unemo M, Krajden M, Lukehart SA, Morshed MG, Fifer H, Thomson NR</p>			
<p>Call RIA2018CO: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities – 2018</p>	<p>Tuberculosis preventive therapy for people with diabetes mellitus</p>	<p>Olomi W, Biraro IA, Kilonzo K, Te Brake L, Kibirige D, Chamba N, Ntinginya NE, Sabi I, Critchley J, Sharples K, Hill PC, Van Crevel R, PROTID Consortium</p>	<p>15 April 2022</p>	<p>Article</p>	<p>https://doi.org/10.1093/cid/ciab755</p>
<p>Call RIA2018V: Vaccines for diarrhoeal diseases or lower respiratory tract infections – 2018</p>	<p>The Italian arm of the PREPARE study: an international project to evaluate and license a maternal vaccine against group B streptococcus</p>	<p>Berardi A, Cassetti T, Creti R, Vocale C, Ambretti S, Sarti M, Facchinetti F, Cose S</p>	<p>28 October 2020</p>	<p>Article</p>	<p>10.1186/s13052-020-00923-3</p>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	"Maternal Vaccination in Uganda: Exploring Pregnant Women, Community Leaders and Healthcare Workers' Perceptions, "	Nalubega P, Karafillakis E, Atuhaire L, Akite P, Zalwango F, Chantler T, Cochet M, Seely J, Le Doare K	25 May 2021	Article	10.3390/vaccines9060552
Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020	<p>SARS-CoV-2 antibodies protect against reinfection for at least 6 months in a multicentre seroepidemiological workplace cohort</p> <p>Effectiveness of infection prevention and control interventions, excluding personal protective equipment, to prevent nosocomial transmission of SARS-CoV-2:</p>	<p>Finch E, Lowe R, Fischinger S, de St Aubin M, Siddiqui SM, Dayal D, et al</p> <p>Jafari, Y., Yin, M., Lim, C., Pople, D., Evans, S., Stimson, J., Pham, T. M., LSHTM CMMID COVID-19 working group, Read, J. M., Robotham, J.</p>	<p>10 February 2022</p> <p>01 March 2022</p>	<p>Article</p> <p>Article</p>	<p>https://doi.org/10.1371/journal.pbio.3001531</p> <p>https://doi.org/10.1016/j.infpip.2021.100192</p>

Award	Output title	Authors	Date	Output type (e.g. article, book chapter, policy brief etc)	DOI (where applicable)
	a systematic review and call for action	V., Cooper, B. S., & Knight, G. M			
	Severe Acute Respiratory Syndrome Coronavirus 2 Infection Among Healthcare Workers in South Africa: A Longitudinal Cohort Study	Nunes MC, Baillie VL, Kwatra G, Bhikha S, Verwey C, Menezes C, Cutland CL, Moore DP, Dangor Z, Adam Y, Mathivha R, Velaphi SC, Tsitsi M, Aguas R, Madhi SA, Bara HCW Study Group	05 May 2021	Article	10.1093/cid/ciab398

3.3 Lead/senior authorship

	Total number across all NIHR funded awards (cumulative number since funding began)	% 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	22 out of 46	48%

	Total number across all NIHR funded awards (cumulative number since funding began)	% of total number of externally peer-reviewed research publications
Number of externally peer-reviewed research publications with a female lead or senior author	29 out of 46	63%
Number of externally peer-reviewed research publications with a female lead or senior author whose home institution is in an LMIC	11 out of 46	23%

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. The consortium 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 (ALERRT) 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. Among others the network played a critical supportive role in the drafting, consultation and final publishing of the [Africa CDC framework for One Health practice](#) in national public health institutions. This is a guiding document supporting One Health implementation that the Africa CDC is utilising to advise and support African Member States.

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	1	0%	100%
MSc	18	89%	83%
MD	0	0%	0%
Mphil	0	0%	0%
PhD	56	89%	50%
Postdoc	11	91%	36%
Professional training for non-research support staff (e.g. research manager, finance, admin, community engagement practitioners etc)	Not quantified	n/a	n/a
Other (internships, diplomas)	10	60%	90%

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 EDCTP'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 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, 1,878 individuals have so far received such trainings as part of DSHC-supported clinical trial projects, in addition to 96 researchers receiving degree-related trainings and other long-term trainings (section 3.5).

In terms of standalone research grants, the objectives of [ALERRT](#) and [PANDORA-ID-NET](#) are fully focused on building the capacities of sub-Saharan African countries to respond to epidemic threats. PANDORA has carried out online workshops focusing on laboratory quality control in LMICs as well as infection prevention and control and research ethics during epidemics. In partnership with The Global Health Network (TGHN), the consortium developed a [PANDORA hub on TGHN website](#), making available training materials and other relevant resources. In partnership with Delta State and Edo State in Nigeria as well as the Nigeria Center for Disease Control (NCDC) and the the Federal Ministry of Health of Germany, PANDORA deployed Mobile Laboratory in Nigeria for diagnostic of SARS-CoV-2/COVID-19. ALERRT has collaborated with [EACCR: East African Consortium for Clinical Research](#) on several workshops including Research in Global Health Emergencies. Jointly with [Central African Network on Tuberculosis, HIV/AIDS and Malaria \(CANTAM3\)](#) and PANDORA-ID-NET, ALERRT has organised several workshops including on: PCR diagnosis of infectious disease through the novel Co-primers technology (June 2021) and Implementation of novel laboratory diagnostics for emerging infectious diseases (May 2021).

DHSC funding is also supporting the capacities of female African researchers ([Participating States Initiated Activity \(PSIA\) 'Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa'](#)) as well establishing an African cohort of epidemiologists through master's training in epidemiology and biostatistics ([Call: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020](#)).

- 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)

	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>
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 provides support to 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 are collaborating with the [EDCTP Regional Networks](#). ALERRT has a close interaction with the Eastern Africa Consortium for Clinical Research (EACCR). The Uganda Virus Research Institute of EACCR is participating in both the [FISSA study](#) (Febrile Illness in Sub-Saharan Africa) and in [the COVID-19 clinical characterisation protocol \(CCP\)](#), ALERRT has also collaborated with EACCR on several workshops including Research in Global Health Emergencies. Jointly with Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM3) and PANDORA-ID-NET, ALERRT has organised several workshops including on: PCR diagnosis of infectious disease through the novel Co-primers technology (June 2021) and Implementation of novel laboratory diagnostics for emerging infectious diseases (May 2021).

- 3.9 Aggregated HIC/LMIC spend across all awards

Country	Total committed amount (GBP) allocated to:	% of total committed amount to all institutions:
HIC	46,529,226	50%
United Kingdom	22,243,620	24%
France	10,105,149	11%
Germany	3,463,928	4%
Spain	2,189,151	2%
The Netherlands	2,174,665	2%
Italy	1,885,511	2%
Switzerland	1,836,572	2%
Denmark	884,733	1%
Belgium	616,284	1%
Norway	512,775	1%
Sweden	343,533	0%
Portugal	273,303	0%
Luxembourg*	-	0%
New Zealand*	-	0%
North America*	-	0%
LIMC	45,749,037	50%
Uganda	9,858,746	11%
United Republic of Tanzania	6,735,482	7%
Zambia	3,945,644	4%
Sierra Leone	3,793,839	4%
South Africa	3,596,850	4%
Mozambique	2,983,097	3%
Zimbabwe	2,959,100	3%
Republic of the Congo	2,362,123	3%
Cote D'Ivoire	1,728,336	2%
Senegal	1,376,959	1%

Country	Total committed amount (GBP) allocated to:	% of total committed amount to all institutions:
Cameroon	1,334,421	1%
Ghana	1,207,098	1%
Burkina Faso	895,744	1%
Sudan	627,603	1%
Nigeria	490,605	1%
Kenya	380,293	0%
Gambia, The	278,119	0%
Ethiopia	252,546	0%
Namibia	223,132	0%
Malawi	218,646	0%
Central Afrcian Republic	110,432	0%
Madagascar	110,432	0%
Guinea	87,804	0%
Rwanda	85,148	0%
Gabon	54,329	0%
The Democratic Republic of the Congo	48,557	0%
Botswana	3,951	0%
Angola**	-	0%
Mali**	-	0%
Eswatini, Kingdom of**	-	0%
Pakistan**	-	0%
Total*	92,278,263	100%

*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?

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

- *Internal audits of beneficiaries: EDCTP has signed a memorandum of understanding with PWC Netherlands to conduct internal audits of EDCTP-funded projects.*
- *Site visits: EDCTP operation and finance teams conduct site visits to selected EDCTP-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 EDCTP 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 EDCTP for review. These reviews include checking all reported financial transactions, including procurement of goods and services, and compliance with EDCTP financial guidelines.*
- *Effective follow-up on management letter points: The EDCTP 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?

EDCTP2 has a strategic focus on building collaboration with industry, like-minded organisations, product development partnerships (PDPs), research funders and development cooperation agencies. These collaborations range from leveraging resources and establishing jointly funded initiatives (calls and other activities) to programmatic collaborations that promote an uptake of EDCTP results into policy and practice, as well as partnerships that can provide high visibility to EDCTP in the global health landscape.

Joint and coordinated calls involve mutual priority setting and allocation of funding to activities of common interest. Joint fellowship calls, for example, have been organised with Novartis and Fondation Botnar as well as GlaxoSmithKline (GSK).

EDCTP2's main vehicle to establish co-funded research activities has been the so-called "strategic RIAs". Calls for "strategic RIAs" have been included in the EDCTP2 work plans since 2015. In these calls EDCTP2 provides up to 50% of the total funding for a specific project 'large-scale action' and the remaining part is mobilised through co-funding. Strategic Actions aim to support trials, which provide evidence to support the product approval process and/or influence policy and practice, are often large in scale, complex and expensive, beyond the resources of a single funder. Coordination and collaboration between partners and funders are needed to leverage the expertise, resources and investments to accelerate the development of new or improved products for PRDs and maximise the impact of research funding investments. EDCTP2's Portfolio Funding also falls under this Strategic Actions mechanism, where evaluation and comparison of products, development of criteria for early selection/deselection of candidates and speeding up development through phase I-III through innovative trial designs to reduce subject numbers and generate rapid results. Through the strategic projects, EDCTP has established strategic partnerships with major funders such as the National Institute of Health (NIHR) and Bill and Melinda Gates Foundation, as well as pharmaceutical companies such as Merck KGaA, and GlaxoSmithKline (GSK) and PDPs including IAVI and MMV, amongst others. Strategic calls have also resulted in long-term strategic funding partnerships, such as with the Global Health Innovative Technology (GHIT) Fund in Japan, which has co-invested with EDCTP in the Pediatric Praziquantel Consortium's treatment access programme for schistosomiasis in preschool-aged children through two Strategic RIA grants, PZQ4PSAC and ADOPT. Alongside the Strategic Actions, there are many RIA projects that receive cofunding from external partners, often in the form of products supplied for clinical trials (for example Gilead, Merck, Viiv, Novavax, Serum Institute of India), support for capacity building at specific sites (INSERM/ANRS), support for additional arms in trials (Janssen). Some studies, including TMAs, are embedded in larger-scale projects that provide the platform (infrastructure, subjects, samples) to make it possible to conduct the EDCTP2-funded activity.

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

The M&E approach of EDCTP draws on a 'theory of change' that maps out the route through which EDCTP 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 helps collect and analyse information from EDCTP projects and other activities that is of strategic importance to realising programme objectives. Based on EDCTP theory of change we have developed a

programme-wide monitoring and evaluation framework (aka Results Framework). The framework incorporates a set of key performance indicators spanning operational performance and expected outputs, outcomes and impact. We are using this framework as basis for collecting programme data, preparing analyses and reporting- formal reports to funders, updates to constituencies, and to general audience. More information about M&E at EDCTP can be found on [EDCTP website](#).

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.

EDCTP 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 participants 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.

With regards to monitoring diversity, EDCTP 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 (12% of studies), newborns and infants (25%), children (33%) and adolescents (33%). 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.

Award	Funding source	Amount (GBP)	Lead institution name and country	% of additional funding allocated to LMIC partners	HRCS code
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- ALERT	UK Foreign, Commonwealth and Development Office and Wellcome Trust, EDCTP, University of British Columbia	8,907,239.37	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 medicale, Congo	To be determined	3.4
RIA2020 EF-2926 periCOVI	Wellcome Trust	329,372	St. George's Hospital Medical	To be determined	3.4

Award	Funding source	Amount (GBP)	Lead institution name and country	% of additional funding allocated to LMIC partners	HRCS code
D-Africa			School		

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, 2020 and 2021 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"> • Comparing of actual expenditure against budget • Encouraging more Participating States to provide funding for administrative support • Tight control of administrative expenditure 	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"> • Extensive review of annexes 1 and 2 by both EDCTP Project Officers and Grant Finance Officers to ensure no ineligible items are included • Organising regular project and financial trainings • Conducting site visits and operational audits. 	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. Several countries have provided additional funding.	The status of this risk is open. The planned action is to monitor; immediate action is required.
EDCTP received on 11 October 2021 a whistleblower notification against an EDCTP beneficiary (UZCRC) that:	- Two additional tasks have been included in the terms of reference for the external audit of one of the EDCTP funded projects that has recently closed. These are:	The status of this risk is open. The planned action is to monitor; immediate action

Risk	How is the risk being managed/mitigated?	Current status
<p>health insurance premiums and pensions deducted from employees' wages by UZCRC are not timely paid to the relevant third parties; pensions deducted from employees' wages are higher than normal; and UZCRC has been breaking national labour laws by keeping staff on yearly contracts for more than 15 years.</p>	<p>a) To perform tests to confirm statutory deductions (income tax – PAYE, national social security deductions, etc.) are accurate. b) To performs tests, including reviewing bank statements, to confirm that all payroll deductions are paid over to appropriate third parties.</p> <p>- An EDCTP site visit to the beneficiary will take place in the first week of July 2022.</p>	<p>is required.</p>
<p>Internal control failures were identified at SAfRI, in Uganda. SAfRI is one of the beneficiaries of the EDCTP funded Babygel project (RIA2017MC-2029). A total of UGX 136,335,600 (EUR 32,955) of procurements were made from companies that were owned by SAfRI staff or their relatives without adherence to the Institute's conflict of interest policy.</p>	<p>- Site visit to the site was conducted in February 2022. - Rejection of all ineligible costs associated with these procurements; EDCTP and University of Liverpool (the Coordinator of Babygel project) have agreed to temporary transfer the financial management of this project to Mbale Hospital (another beneficiary). EDCTP has regular meetings with the project coordinator at University of Liverpool to follow up on the agreed actions from the site visit.</p>	<p>The status of this risk is open. The planned action is to monitor.</p>

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 have been no changes to the EDCTP anti-fraud strategy.

As described above for the Babygel project, expenses relating to procurements have been declared ineligible.

- Aggregated credible allegations

	Total number of credible allegations:
Made against any NIHR funded awards	1
Made against any NIHR funded awards and investigated by delivery partner	1
Made against NIHR funded awards and reported to NIHR/DHSC	1*

*Babygel project as described above.

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.

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

	Total number of safeguarding issues
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 between 2020 and 2022 all EDCTP2 evaluation procedures and ethics checks 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 had a hybrid format (virtual and live from Maputo, Mozambique). EDCTP grantees also conducted many of their activities online, including meetings and trainings. The programme is 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 EDCTP 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.

EDCTP 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 EDCTP to work towards. Beyond IATI reporting, EDCTP 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 EDCTP Model Grant Agreement). As per the Memorandum of Understanding (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 public portal of the EDCTP grants system. Furthermore, EDCTP regularly updates the EDCTP2 online project portfolio with case studies of signed grants, including those funded by DHSC. On an annual basis, EDCTP 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. EDCTP is now a member of Europe PMC (PubMed Central), an open science platform that maintains a worldwide collection of scientific articles and research outputs. This enables EDCTP-funded researchers to share their publications via one central location, facilitating open access compliance by EDCTP beneficiaries.

7. Monitoring, evaluation and learning

7.1 Monitoring

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

In addition to ongoing monitoring of projects and programme by EDCTP Secretariat, four independent oversight committee meetings took place in 2021 that reviewed the progress of EDCTP-funded projects on TB drugs, TB vaccines, malaria drugs and malaria vaccines and provided operational and scientific recommendations- including related to extensions of project durations. In addition the Scientific Advisory Committee (SAC) participated in a review of the Epidemic Preparedness Consortia at their meeting in October 2021 as well as EDCTP Regional Networks in April 2022.

EDCTP has established the oversight mechanism for overseeing projects with high budgets and those considered high-risk due to the complexity of the study design, implementation plan, and target populations.

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

In December 2021 the European Commission has launched the Second Interim Evaluation of EDCTP2 programme as part of Evaluation study of the European Framework Programmes for Research and Innovation for a Resilient Europe. The evaluation involves various data collection and analysis methods such as interviews and case studies and analysis of clinical trials data, among others. The study is currently in data collection phase with the final report expected towards the end of 2022.

7.3 Learning

Nearly all projects have reported delays and disruption due to COVID-19 involving shutdown and delays to clinical trial milestones (ethics approvals, shipping of essential equipment, patients recruitment, disruptions of laboratory activities, dissemination events). Following the guidance under Horizon 2020, requests for extensions of six months are approved speedily. However, many projects are experiencing delays of more than six months.

The latest end date for all EDCTP2 projects has been set by the Secretariat as 31 December 2025 to align with the EDCTP2 programme closure in 2026. Assuming a six-month extension to all projects 260 projects will be active in the final years of the

programme 2024-2026, compared to 163 active projects in the scenario without this extension. Review of project reports, audits and final payments to these projects would need to be concluded by end of 2026, followed by activities in 2026-2027 to close the EDCTP2 programme, such as monitoring and final reporting, external evaluation and audits, among others.

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

<p><u>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.</u></p>	<p><u>ALERRT</u>: Publication of the FISSA study results.</p>
<p><u>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.</u></p>	<p>Completion or publishing of the results from the following clinical trials:</p> <p>CHAPS <u>NCT03986970</u> expected publication of results PROMISE-EPI trial: <u>NCT03870438</u> follow up of enrolled mothers and babies The LIFE study: <u>NCT04032522 progression of study and analysis of primary endpoint.</u></p>
<p><u>Call RIA2017S: Strategic actions supporting large-scale clinical trials – 2017</u></p>	<p>Progression of PREVAC trial: <u>NCT02876328</u></p>
<p><u>Call RIA2017MC: Clinical trials to reduce health inequities in pregnant women, newborns and children – 2017</u></p>	<p>Progression of the following trials:</p> <p>EMPIRICAL: <u>NCT03915366 - completion of recruitment</u> The Babygel study: <u>PACTR202004705649428 - completion of recruitment</u></p>
<p><u>Call RIA2018D: Diagnostic tools for poverty-related diseases – 2018</u></p>	<p>Progression of the following trials:</p>

	<p>Triage TB study: NCT04232618 The DIAGMAL study LAMP4Yaws study: NCT04753788 ERASE-TB study XACT III study</p>
<p>Call RIA2018CO: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities – 2018</p>	<p>Progression of the following trials:</p> <p>The VITALITY trial: PACTR202009897660297 META Trial NCT04600167 PROTID trial: NCT04600167 5FC HIV-Crypto trial</p>
<p>Call RIA2018V: Vaccines for diarrhoeal diseases or lower respiratory tract infections – 2018</p>	<p>PREPARE project: Analysis of cohort study NCT04653948 Results from vaccine trial NCT04596878</p>
<p>Call RIA2020EF: Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020</p>	<p>Publication of outputs from projects</p>
<p>PSIA2020AGDG: Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence – 2020</p>	<p>Recruitment and progression of all PhD students.</p>
<p>Call CSA2020E: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC – 2020</p>	<p>Recruitment of fellows.</p>

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.

n/a

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