

GLOBAL HEALTH EDCTP3 PORTFOLIO
2022-2026



Global Health
EDCTP3

Science, partnership, impact

EUROPEAN PARTNERSHIP



Funded by
the European Union

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Who we are

Global Health European & Developing Countries Clinical Trials Partnership 3 (Global Health EDCTP3) is a **unique European-African partnership** working to improve health through research. Backed by the European Union and more than 45 countries, we focus on infectious diseases that continue to affect millions of people across sub-Saharan Africa.

We fund **clinical trials and studies**, train researchers and strengthen Africa's clinical research ecosystem. By bringing together partners across sectors and continents, we help develop, evaluate and deliver solutions where they are most needed, while contributing to stronger **global health security**.

Our mission is to reduce mortality and morbidity from infectious diseases in sub-Saharan Africa by supporting **collaborative research**, strengthening **research capacity**, and accelerating the development, evaluation and implementation of solutions to prevent, detect, treat and monitor infectious diseases.

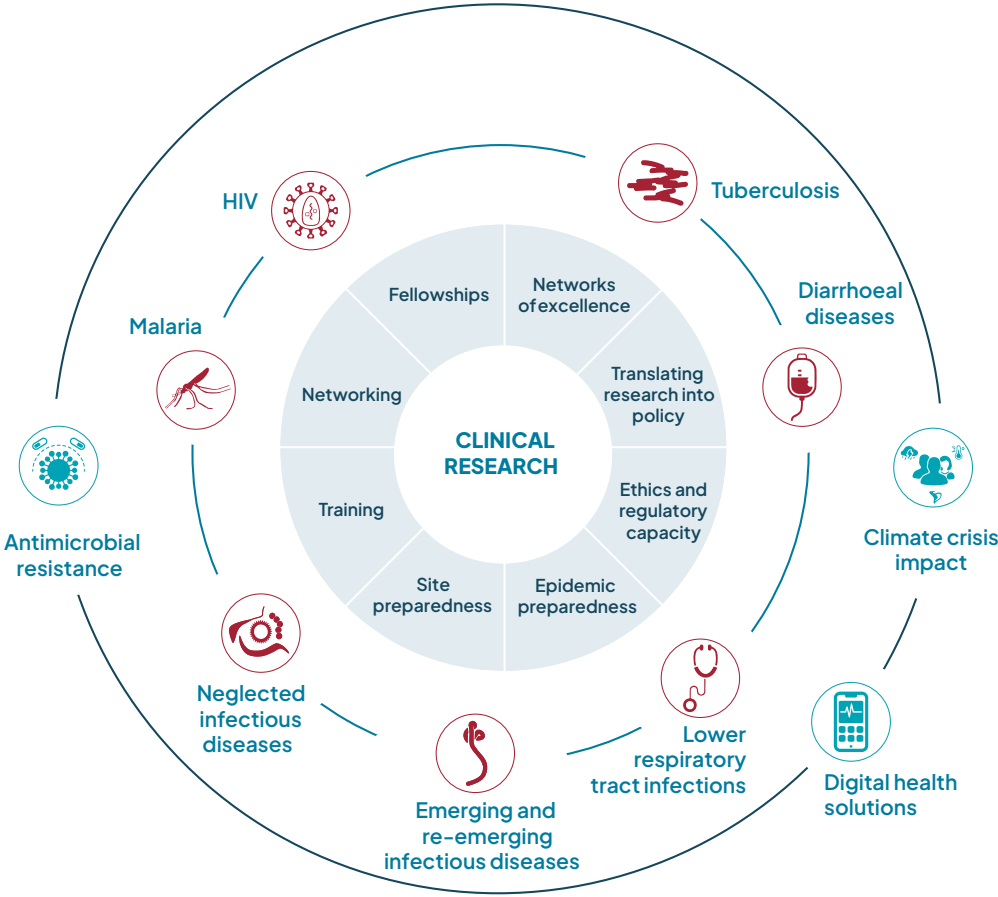
Global Health EDCTP3 contributes to the EU's priorities for health research in Africa and supports the Sustainable Development Goals on infectious diseases. It also contributes to the implementation of the **EU Global Health Strategy**, the **Global Health Resilience Initiative** and shared African Union-EU priorities on health and innovation.

We fund projects through **Horizon Europe**, the EU's research and innovation framework. Projects are selected through open calls for proposals and bring together partners from Africa, Europe and beyond.

The EDCTP programme was established in 2003 and has evolved through three successive programmes over more than 20 years. Global Health EDCTP3, the third iteration, runs from 2021 to 2031, with an expected **budget of €1.84 billion**.

Our scope

We focus on the **major infectious disease** threats facing sub-Saharan Africa. We tackle all stages of clinical evaluation but particularly **later-stage studies** with a special focus on vulnerable population groups. We strengthen and build **research capacities** in sub-Saharan Africa.



Foreword



Dear colleagues, partners and friends,

It is my great pleasure to share this portfolio showcasing the **159 projects** funded by Global Health EDCTP3 since 2022, when the third EDCTP iteration was launched.

Behind every collaboration presented in our portfolio are scientists, institutions, communities and partners working together to **turn science into impactful global health solutions**. Their collective efforts are helping to develop new tools and diagnostics, strengthen research capacity, and generate evidence that can improve health outcomes for some of the most vulnerable populations in sub-Saharan Africa and beyond.

These initiatives illustrate the **scale, diversity and ambition** of our Africa-Europe partnership. They are the result of the first five Global Health EDCTP3 annual work programmes and 14 highly competitive calls for proposals, which have attracted more than 1,800 applicants.

Today, **513 organisations from 69 countries** are involved in implementing these projects, spanning education and research organisations, small and medium-sized enterprises, product development partnerships and private sector organisations.

Global Health EDCTP3 has awarded **€722 million** to this portfolio of projects. An amount that has been complemented by additional funds from the EDCTP Association member countries, Contributing Partners, public institutions from EDCTP Association member states, and from other sources.

The portfolio addresses **all priority disease areas** identified in our [Strategic Research and Innovation Agenda](#), with the largest shares dedicated to malaria, emerging/re-emerging infectious diseases, neglected infectious diseases, tuberculosis, and HIV.

At the heart of the portfolio are **119 Research and Innovation Actions (RIAs)** for a total budget of €611 million, supporting clinical trials and other clinical research activities. A further **40 Coordination and Support Actions** with a total budget of €111 million, strengthen coordination, networks and institutional capacities, helping to create the enabling environment needed for sustainable clinical research.

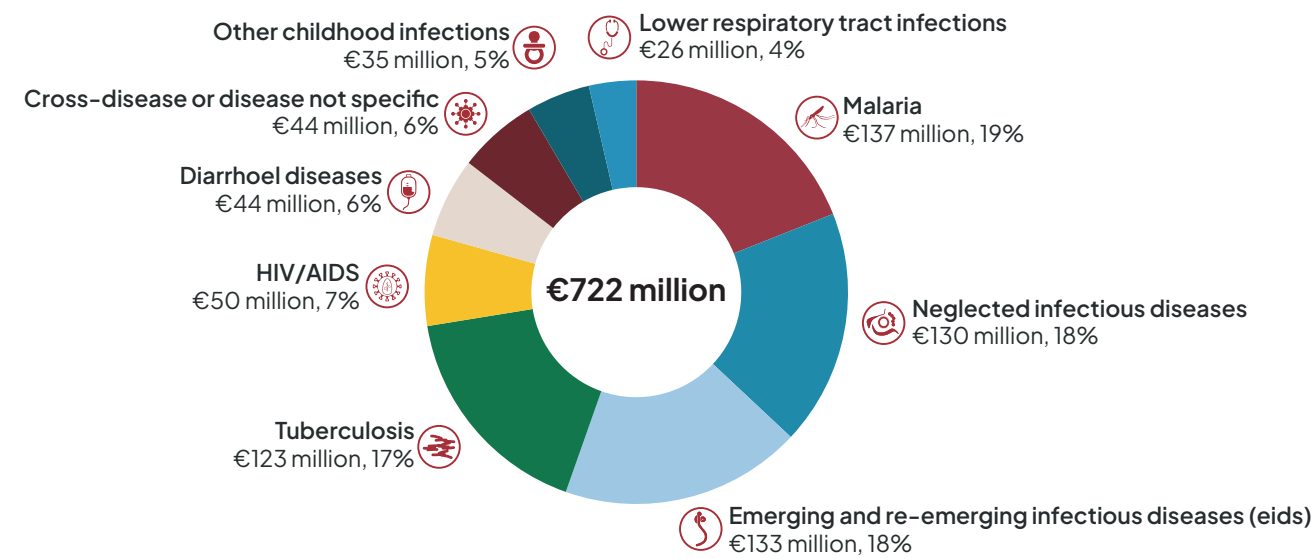
The portfolio also demonstrates the ability of Global Health EDCTP3 to mobilise co-funding from Member States and Contributing Partners to respond rapidly to emerging health threats. Since 2021, the African continent has continued to face major outbreaks, including new mpox outbreak in 2024 and the current Ebola Bundibugyo outbreak. In response, Global Health EDCTP3 mobilised **Emergency Response Actions** to support research addressing these urgent challenges. Today, these projects contribute to outbreak preparedness and response, strengthening the capacity to detect and respond to the ongoing and future threats.

I invite you to explore this rich and diverse portfolio and discover the power and added value of sustained and equitable Africa-Europe health research collaboration.

Michael Makanga
Executive Director, Global Health EDCTP3

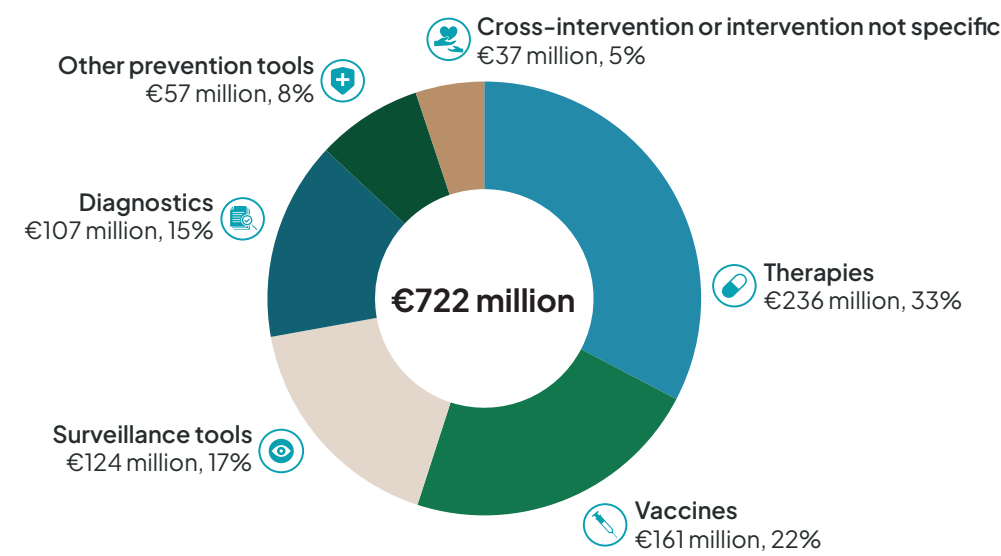
Investment portfolio across disease area 2022-2026

By September 2026, 159 projects were supported by Global Health EDCTP3, with funding amounting to €722 million.



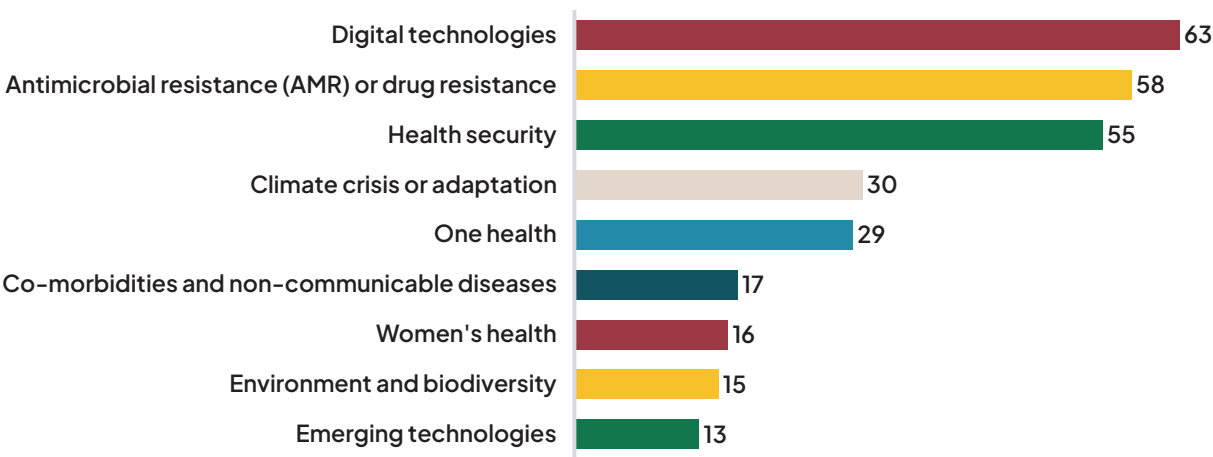
Investment portfolio across intervention type 2022-2026

By September 2026, the 159 projects supported by Global Health EDCTP3 covered six types of interventions.



Contribution to global health challenges

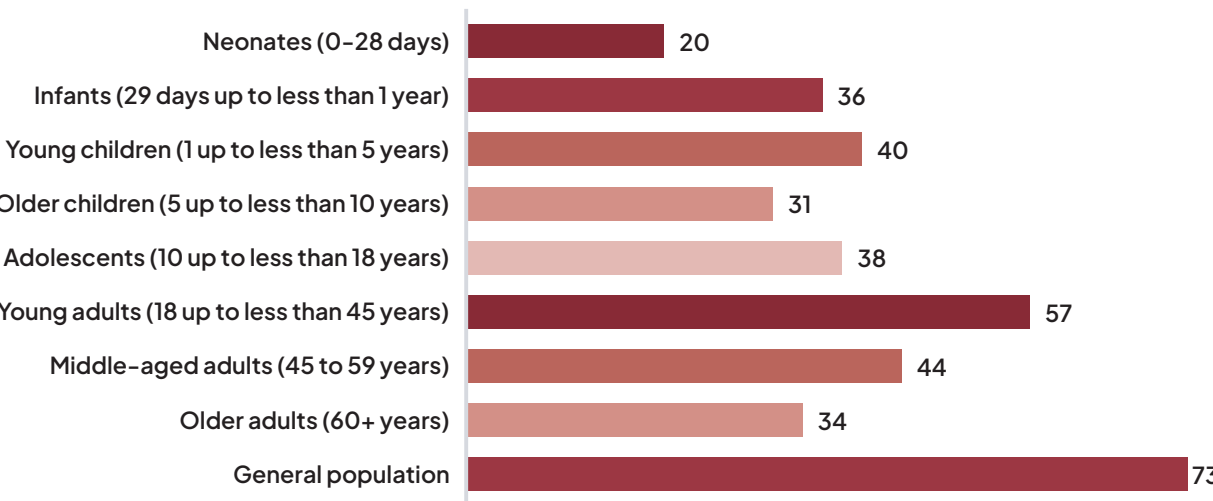
The 159 Global Health EDCTP3 projects contribute to one or more global health challenges.

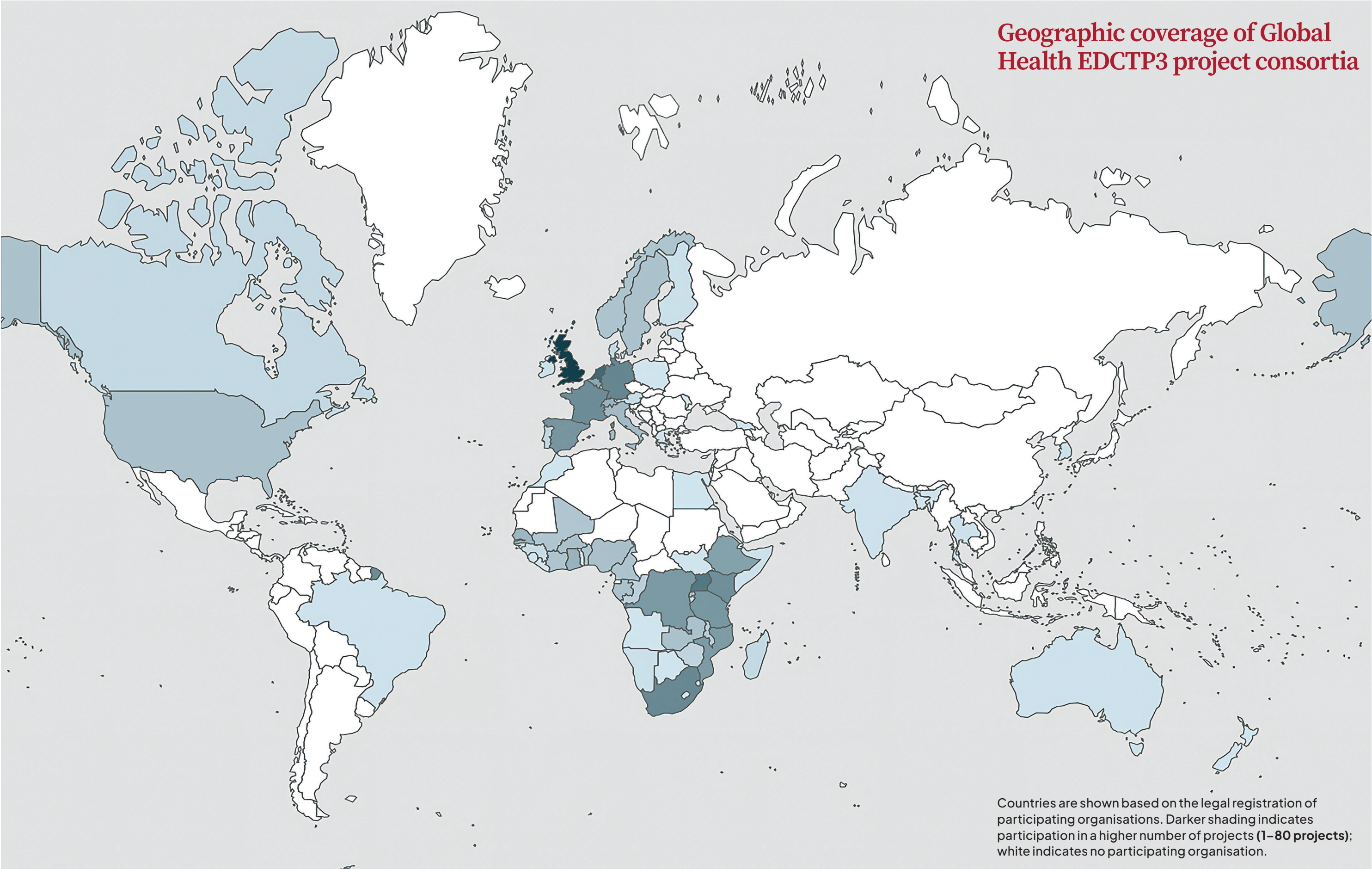


Focus on target populations

The 159 Global Health EDCTP3 projects focus on one or more target populations.

Number of projects per target population:





Guide to the icons

Disease areas

-  HIV/AIDS
-  Tuberculosis
-  Malaria
-  Neglected infectious diseases
-  Diarrhoeal diseases
-  Lower respiratory tract infections
-  Emerging and re-emerging infectious diseases
-  Other childhood infections
-  Cross-disease or disease unspecific

Intervention types

-  Vaccines
-  Therapies
-  Diagnostics
-  Surveillance tools
-  Cross-intervention or intervention unspecific
-  Other prevention tools

Research
and
innovation
actions



HIV/AIDS

DOLPHIN-3

Drug Optimisation in LMICs of Pregnant HIV women and their Infants: temporary switch to CAB/RPV long acting injections

The DOLPHIN-3 project is assessing whether it is feasible to temporarily transfer women living with HIV from oral antiretroviral therapy (ART) to long-acting injectable ART during breastfeeding.

The challenge

Women living with HIV must take daily doses of oral antiretroviral therapy (ART) in order to suppress viral replication. Sticking to this routine can be particularly difficult after childbirth, when mothers also have to contend with the many demands of a new baby. Around half of new mothers with HIV do not adhere to daily ART schedules, which can affect their own health and increase the risk that the virus is transmitted to their baby during breastfeeding.

An additional complication is that women may not have disclosed their HIV status to those around them. Continuing to take ART medication without others knowing may be difficult after birth.

A possible solution could be the use of **long-acting ART**, based on cabotegravir and rilpivirine, as an alternative to daily oral ART. This treatment is administered as an injection every two months, greatly reducing the attention that women have to give to controlling HIV. It could also provide time for mothers to communicate their HIV status if they have yet to do so.

The project

The DOLPHIN-3 project is assessing the impact of a switch from daily oral ART to long-acting injectable ART during breastfeeding. The study, being undertaken in South Africa and Uganda, will determine the feasibility of the switch and its impacts on viral load, adherence and mother-to-child transmission of HIV.

As injectable ART is more expensive than oral ART, long-term use may not be affordable in many sub-Saharan African settings. The trial design, therefore, incorporates a return to oral ART after the period of high vulnerability during breastfeeding. The project will monitor the pharmacokinetics of ART in mothers and babies during the time women spend on long-acting injectable ART and when they transition back to daily oral ART. The feasibility and practicality of returning to daily oral ART will also be investigated.

The project will explore the barriers and enablers of this potential new approach to HIV control through engagement with both mothers and health workers. It will also evaluate a screening tool that has been designed to identify the most vulnerable women – those at highest risk of non-adherence – so that they can be prioritised to receive long-acting injectable ART.

An extensive programme of engagement with communities, policymakers and other stakeholders will be undertaken to raise awareness of long-acting injectable ART and to shape the design of research activities.

The impact

The DOLPHIN-3 project will generate valuable information on one potential use of a highly effective new medical intervention, long-acting injectable oral antiretroviral therapy (ART). It will:

- Reveal whether long-acting injectable ART leads to better viral suppression compared with daily oral ART, in real-world settings.
- Identify key factors associated with the successful implementation of the new care pathway, including the transition back to oral ART.
- Demonstrate whether a screening tool can identify those who would benefit most from long-acting injectable ART.

New mothers are a population that could benefit most from long-acting injectable ART. The DOLPHIN-3 project will identify the potential benefits to mothers and babies and reveal key factors affecting the success of implementation.

Project at a glance	
Project duration	1 Apr 2024 – 31 Mar 2029
Total project cost	€3 205 161,25
Global Health EDCTP3 funding	€3 205 161,25
Disease area	HIV/AIDS
Intervention type	Therapies
Overarching topic	Women's health
Project coordinator	UNIVERSITY OF CAPETOWN
Participating countries	South Africa, Uganda, Netherlands





ELDORADO

Toxicity of dolutegravir and evaluation of doravirine for alternative 1st line antiretroviral treatment in people living with HIV

The ELDORADO trial is testing whether doravirine-based antiretroviral treatment leads to fewer long-term complications while successfully suppressing HIV-1 viral load, than the most commonly used current treatment for HIV.

The challenge

An estimated 25 million people are living with HIV in sub-Saharan Africa and around 20 million are receiving antiretroviral therapy to control their infections. The most commonly used drug combination includes **dolutegravir**. Although very effective at suppressing viral replication, over the longer term, it has been found to lead to weight gain, metabolic conditions such as type 2 diabetes and hypertension, and an increased risk of cardiovascular disease and liver disease, particularly in women. Its use is also associated with sleep disturbance and mental health issues, leading to reduced quality of life.

A new generation of antiretroviral drugs has been developed, including **doravirine**, which could be used instead of dolutegravir in combination therapies. Doravirine appears to be as effective as dolutegravir at suppressing viral replication but is associated with fewer metabolic complications.

Doravirine has been licensed and is in use in multiple high-income countries, but is not available in low- and middle-income countries, including sub-Saharan Africa. It has also not yet been directly compared with dolutegravir in a large-scale clinical trial.

The project

The ELDORADO project aims to generate the evidence that could underpin a switch from dolutegravir- to doravirine-containing antiretroviral therapy in sub-Saharan Africa (and in other countries in a related project).

The project is carrying out a trial comparing the use of dolutegravir- and doravirine-containing treatments in adults newly diagnosed with HIV infections. A total of 610 patients will be recruited at sites in Cameroon, Côte d'Ivoire, and Mozambique, as well as in other countries in a related project.

In addition to tracking the treatments' effects on viral suppression, the trial incorporates a comprehensive assessment of their effects on key metabolic functions and weight gain, as well as cardiovascular and hepatic assessments, for around 22 months of treatment. Questionnaires will be used to collect data on the mental health and quality of life of participants.

Data from this project and previous trials of doravirine will be collated to estimate the cost-effectiveness of the two options.

The impact

The ELDORADO project will close an important gap relating to optimal HIV treatment in sub-Saharan Africa. It will:

- Generate directly comparable data on doravirine- and dolutegravir-containing antiretroviral therapy.
- Provide data on the holistic impacts of treatments, including those relating to quality of life.
- Provide policymakers with a clear indication of the economic implications of the new treatment option.
- Train young researchers and health professionals in order to improve patients' medical care.

WHO has indicated its support for the ELDORADO project, which will generate evidence that will feed directly into global and national policy on HIV treatment regimens.

Project at a glance	
Project duration	1 May 2025 - 30 Apr 2029
Total project cost	€5 164 865,00
Global Health EDCTP3 funding	€5 164 865,00
Disease area	HIV/AIDS
Intervention type	Therapies
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	UNIVERSITE DE BORDEAUX
Scientific project leader	INSTITUT DE RECHERCHES MEDICALES ET D'ETUDES DES PLANTES MEDICINALES
Participating countries	France, Cameroon, United Kingdom, Mozambique, Côte d'Ivoire



CHAPAS-5

CHAPAS-5: An Adaptive Platform Trial for Evaluation of Novel Treatment Regimens in ART-naïve and Treatment-experienced Viraemic Children and Adolescents Living with HIV in Africa

The CHAPAS-5 project is establishing a flexible clinical trial platform that will accelerate the evaluation of antiretroviral treatments for children and adolescents.

The challenge

An estimated 1.4 million children and 1 million adolescents are living with HIV, around 90% of them in sub-Saharan Africa. Every year, 140,000 adolescents become infected with HIV, £two-thirds of them girls.

Children and adolescents experience worse outcomes than adults living with HIV: although they make up 3% of people living with HIV, children account for 13% of HIV-related deaths. Adolescents are significantly less likely to achieve good suppression of viral replication and also experience higher mortality rates than adults.

Initial clinical trials of new treatments typically exclude children and adolescents, and new formulations may need to be developed for adolescents, leading to long delays in access. For a commonly used treatment, **dolutegravir**, there was a seven-year gap between initial licensing and its first use in young children.

This is an increasingly important issue, as the treatments currently used have significant drawbacks. Several new treatment options are becoming available, including **dolutegravir/lamivudine combinations, triple antiretroviral therapy (ART) incorporating** tenofovir alafenamide (TAF), and long-acting injectables (such as cabotegravir and lenacapavir) that do not require daily pill-taking.

The project

The CHAPAS consortium has been working for more than 20 years to enhance young people's access to novel HIV treatments. The CHAPAS-5 project aims to go a step beyond trials that compare new and existing regimens by establishing an innovative **adaptive clinical trial platform**. Encompassing sites in Mozambique, Uganda, and Zimbabwe, the platform will be able to test multiple treatment options simultaneously across a range of patient groups.

The project will recruit two main groups of patients: those about to start their first antiretroviral treatment and those who are already receiving antiretrovirals but have developed resistant infections, and, therefore, need to be switched from first-line to second-line back-up treatment.

For each group, patients will be randomised to either the currently recommended treatment or to possible alternatives already used in adults (provided at least two options exist). As these treatments have already been shown to be effective in adults, the key aim is to rank each option by efficacy and safety.

This approach can also be used to assess efficacy and safety in different subgroups of patients, such as those in particular weight bands, generating more nuanced evidence to guide the choice of treatment. The project will initially focus on the above

combinations, but the platform will also enable the evaluation of other emerging treatment options in young people.

The project also includes **pharmacokinetic studies** to determine whether dosing is appropriate for different age groups. In addition, it will explore whether a range of new technologies, such as **point-of-care testing** for viral load and/or immune cell counts, hepatitis B virus testing, and **local-level genome sequencing** to identify resistance mutations, can also improve patient care and outcomes.

Embedded within the project is a strong **social science** strand that will focus on adherence among adolescents and treatment preferences. This is particularly important, as uncontrolled viral replication in adolescents is more likely to reflect lack of adherence than drug resistance. The project will also explore the feasibility of a new approach to care, **community-based dosing**, which will provide young people with easier access to antiretrovirals through community health workers.

The impact

The CHAPAS-5 project will make a major contribution to the treatment of HIV infections in children and adolescents. It will:

- Provide a highly efficient and cost-effective way to generate data on multiple new first-line and second-line antiretroviral treatments.
- Provide decision-makers with data on multiple possible treatment options and indicate which would be most suitable for particular groups of patients.
- Establish a platform for testing new treatments in young people as they become available.
- Evaluate other innovations that could have a significant impact on retention in care and adherence.
- Explore options to ensure the availability and accessibility of preferred antiretroviral drugs, for example, through local manufacturing.

Project at a glance	
Project duration	1 Nov 2025 - 31 Oct 2029
Total project cost	€6 587 149,00
Global Health EDCTP3 funding	€6 587 149,00
Disease area	HIV/AIDS
Intervention type	Therapies, Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITY COLLEGE LONDON
Scientific project leader	JOINT CLINICAL RESEARCH CENTRE
Participating countries	United Kingdom, Uganda, Zimbabwe, Italy, Netherlands, Mozambique





PREGART

Safety and efficacy of Dolutegravir and EFV400 for pregnant and breastfeeding women – a randomised non-inferiority clinical trial

Global Health EDCTP3 funding will enable the EDCTP2–supported PREGART project to complete a key trial that will provide evidence on the optimal antiretroviral treatment for pregnant women in sub-Saharan Africa.

The challenge

Pregnant women are particularly badly affected by HIV infections. Pregnant women living with HIV have an eightfold higher risk of adverse pregnancy-related outcomes compared with women without HIV infections. In areas where HIV is common, HIV accounts for 12% of maternal deaths during pregnancy and soon after birth.

Because of concerns about the effects of drugs on the developing foetus, pregnant women are typically excluded from pivotal trials of new pharmaceutical interventions. This can delay the use of effective new treatments in such women. In addition, although pregnancy has a profound physiological impact on women, when drugs are recommended for use in pregnant women, it is usually based primarily on data from men and non-pregnant women.

For HIV treatment, WHO recommends **dolutegravir-based regimens** or **low-dose efavirenz-based regimens**. However, there are limited data from pregnant women on the efficacy and safety of low-dose efavirenz, or possible impacts on the health and development of their babies.

The project

Funded through the EDCTP2 programme, the PREGART project has been carrying out a clinical trial comparing treatment outcomes for pregnant women living with HIV given either dolutegravir-based regimens or low-dose efavirenz-based regimens. The trial was due to recruit more than 1000 women at sites in Ethiopia and Uganda.

However, the trial was badly disrupted by the COVID-19 pandemic, by insecurity in areas of Ethiopia where recruitment was taking place, and by an Ebola outbreak in Uganda. Funding from the Global Health EDCTP3 programme will enable the project to complete recruitment and follow-up of participants during pregnancy and for 12 months after birth to assess potential impacts on maternal health and infant development.

The project is comparing key aspects of HIV control, including maternal viral load at delivery, cases of maternal-to-child transmission of HIV, and adverse pregnancy outcomes. The 12-month follow-up will reveal whether either treatment has any significant impact on infant health and development.

The project team is also monitoring bloodstream levels of the drugs to determine whether doses achieve therapeutic levels and to explore associations between drug levels and efficacy and safety signals.

The impact

The PREGART study is providing key evidence on safe and effective HIV treatment for pregnant women. It will:

- Generate high-quality and directly comparable evidence of efficacy and safety for two possible antiretroviral treatments for pregnant women living with HIV in sub-Saharan Africa.
- Provide safety data on both pregnancy outcomes and early infant development.

By ensuring the trial will be completed as originally planned, the new funding will enable the PREGART study to provide both global and national policymakers with critical information to inform the choice of antiretroviral treatment for pregnant women living with HIV in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jan 2026 – 31 Dec 2028
Total project cost	€1800 000,00
Global Health EDCTP3 funding	€1800 000,00
Disease area	HIV/AIDS
Intervention type	Therapies
Overarching topic	Women's health
Project coordinator	KAROLINSKA INSTITUTET
Scientific project leader	HAWASSA UNIVERSITY
Participating countries	Sweden, Ethiopia, Italy, Uganda



ENABLE

Early neutralising antibodies in infants living with HIV to enhance their life

The ENABLE project is assessing whether broadly neutralising antibodies could make the HIV virus undetectable in young infants.

The challenge

An estimated 130,000 babies become infected with HIV every year. Such infants are at very high risk of death – mortality within the first 12 months after diagnosis is around 10%. This largely reflects **poor control of viral replication**: good virological suppression is seen in only 25–35% of infants after a year, and baseline viral load is the biggest risk factor for death.

These figures persist despite the availability of antiretroviral drugs suitable for young infants. Supplementary interventions to provide additional protection to this vulnerable group could therefore have a major impact.

The project

The ENABLE project is evaluating whether **broadly neutralising antibodies (bnAbs)** against HIV could make the virus undetectable in young children living with HIV. In very rare cases, HIV infection generates antibodies that are active against a wide range of different strains of HIV. Methods have been developed to isolate these antibodies and to manufacture them in large quantities so that they can be used to block infection.

The ENABLE project is assessing whether two bnAbs in clinical development (ePGT121v1–LS and VRC07–523–LS), given on diagnosis and after 3, 6 and 9 months, can provide an additional layer of protection against infection in young infants. These antibodies have been engineered so that they persist for longer in the bloodstream, offering protection for up to 3 months.

The project is carrying out a phase II/III trial at eight sites in Cameroon, Mozambique and South Africa, comparing standard antiretroviral treatment with an enhanced approach that also includes bnAb administration. The trial will compare viral suppression at 12 months in the two groups, as well as factors such as overall mortality and safety.

In addition, the project will analyse multiple patient and viral markers to determine whether any are associated with protection. These include various markers of different types of **immune response** as well as **viral mutations** and levels of key biomolecules. Pharmacokinetic studies will track bnAb levels in

a subset of children, to determine whether therapeutic levels are maintained and the levels associated with treatment failure.

Consultations will also be organised to explore the **acceptability of bnAb use in children** and to identify any barriers or facilitators that might affect take up or implementation of a new intervention.

The impact

The ENABLE project will generate key evidence on whether an innovative new intervention can protect newly diagnosed children with HIV. It will:

- Show whether bnAbs can offer additional protection beyond standard antiretroviral therapy.
- Identify biomarkers associated with successful responses or inadequate control, to inform the refinement of treatment strategies.
- Assess the acceptability of the approach among caregivers and identify any factors that could delay implementation.

If bnAbs are shown to improve the virus control, they could protect young infants through a window of vulnerability, and ultimately enable them to survive and thrive into adulthood.

Project at a glance	
Project duration	1 Jan 2026 – 31 Dec 2029
Total project cost	€6 161 157,50
Global Health EDCTP3 funding	€6 161 157,50
Disease area	HIV/AIDS
Intervention type	Therapies
Overarching topic	(Other) emerging technologies
Project coordinator	SERVICIO MADRILENO DE SALUD
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	Spain, South Africa, Italy, France, Mozambique, Kenya, Netherlands, Cameroon





POA

Pragmatic use of long-acting Oral Antiretrovirals in Africa

The POA project is evaluating a radically simplified HIV treatment regimen that could make it much easier for people living with HIV to control viral replication.

The challenge

Antiretroviral treatments have revolutionised HIV care. However, they are not a cure, and people living with HIV must continue to take a daily cocktail of drugs to control their infections. Over time, this daily pill-taking can become difficult to maintain and creates a risk of stigmatisation.

Long-acting injectable treatments overcome the need for daily pill-taking but have drawbacks. They require cold chain infrastructure, must be administered by trained health workers, and disrupt the regular contacts with HIV services that are now integral to HIV care.

A possible alternative approach is offered by a new oral drug combination, **lenacapavir plus islatravir**, which needs to be taken just once a week. In addition, the components of this combination may have fewer side effects than current standard treatments. Although a phase II trial of lenacapavir plus islatravir has been carried out in the USA, there are no data on its use in sub-Saharan Africa, even though the region accounts for 75% of people living with HIV.

The project

The POA project is conducting the first trial of lenacapavir plus islatravir in sub-Saharan Africa to generate critical data to support its introduction in the region.

A **phase III trial** is being carried out, involving more than 500 people living with HIV in Côte d'Ivoire, Kenya, Uganda and Zimbabwe. It will compare how well viral replication is controlled by standard antiretroviral drug treatments and by the weekly use of lenacapavir plus islatravir. The study will also examine patients' preferences and the impact on daily life, as a weekly treatment option could substantially improve quality of life.

Other key aspects of the project include:

- **Pharmacokinetic studies** to check circulating drug levels, as the drugs may be metabolised differently in African populations.
- **Implementation science studies** to identify facilitators and barriers that could influence the speed of introduction into routine care.
- Development and evaluation of a **new assay to measure drug metabolite levels in urine samples**, which could provide a simple-to-use tool for monitoring patients' adherence to treatment.

In addition, although pregnant women will not be recruited into the trial, the study will carefully monitor women who become pregnant during the trial and carry out pharmacokinetic modelling to assess the suitability of the new treatment for this group. Such work would provide a foundation for studies of lenacapavir plus islatravir in pregnant women, potentially accelerating their access to this new treatment.

The impact

Weekly lenacapavir plus islatravir treatment could have a profound positive impact on HIV treatment in sub-Saharan Africa. The project will:

- Generate the first data on weekly oral lenacapavir plus islatravir treatment in sub-Saharan African people living with HIV.
- Provide sufficient data to support licensing approvals of the new combination.
- Provide policymakers with key evidence on cost-effectiveness and potential barriers to implementation.
- Potentially shorten the pathway to approval of lenacapavir plus islatravir for use in pregnant women.

Introduction of weekly oral lenacapavir plus islatravir treatment could have a potentially transformative impact on HIV care in sub-Saharan Africa. By making adherence easier, it would deliver health benefits, reduce demands on health services, and improve the quality of life of people who currently face a demanding schedule of daily drug-taking.

Project at a glance	
Project duration	1 Feb 2026 - 31 Jan 2031
Total project cost	€5 499 083,03
Global Health EDCTP3 funding	€5 499 083,03
Disease area	HIV/AIDS
Intervention type	Therapies, Other prevention tools
Project coordinator	THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS
Scientific project leader	THE INFECTIOUS DISEASES INSTITUTE LIMITED
Participating countries	United Kingdom, Uganda, Zimbabwe, Italy, Côte d'Ivoire, Kenya



MAGFA

Innovative Point of Care for combined screening of Infectious diseases: application to Prevention of Mother to Child Transmission

The MAGFA project is developing a point-of-care test to simultaneously detect HIV, syphilis and hepatitis B virus infections in pregnant women, and to identify those with active hepatitis B infections requiring treatment.

The challenge

Great strides have been made in HIV testing in sub-Saharan Africa, and most people living with HIV are now aware of their HIV status. The same is not true of many other chronic infections, particularly where symptoms may not be obvious but long-term harms can occur. In pregnant women, if undetected, there is a risk that these infections are passed on to their babies during pregnancy.

For example, only about half of women are screened for **syphilis infections** during pregnancy, and less than 1% are tested for the **hepatitis B virus (HepB)**. This leads to around 216,000 cases of congenital syphilis each year, as well as 360,000 new HepB infections. Although HepB vaccination at birth can protect newborns, in most countries in sub-Saharan Africa, HepB vaccine is given too late to prevent mother-to-child transmission.

Several **point-of-care tests** have been developed for HIV and other infections. However, they are separate tests with different procedures and run times, making it difficult to use them in many types of health facilities. Furthermore, testing for active HepB replication, which is associated with an increased risk of transmission, requires specialist facilities and is costly, limiting its use in sub-Saharan African settings.

The project

The MAGFA project is addressing these challenges by adapting an existing point-of-care testing platform to detect HIV, syphilis and HepB infections simultaneously, and to provide a quantitative assessment of HepB virus levels to identify women in need of treatment.

Its MagIA platform detects antibodies to infections, using a cartridge-based system that can simultaneously analyse 10 samples (two cartridges, each with five samples). Its **MagIA Analyser** device carries out automatic sample analysis and delivers simple-to-understand results to users.

The company behind the MagIA platform has already developed a cartridge for the co-detection of HIV, HepB and hepatitis C virus. In the MAGFA project, it will incorporate syphilis detection rather than the hepatitis C virus. The new test will be validated in the laboratory before being field-tested at 22 antenatal care sites in Côte d'Ivoire, the Democratic Republic of the Congo (DRC), and Kenya.

A second strand of work will focus on HepB. A cartridge will be developed based on antibodies against HepB antigens, with quantification of antibody levels to indicate viral replication. Women showing high levels of HepB replication will be eligible for prophylactic antiviral treatment.

The project will determine the impacts on the prevention of mother-to-child transmission of the different infections, and also track women who test positive to assess their retention in care. Cost-effectiveness analyses will also be carried out.

The impact

The MAGFA project could have a major impact on the identification, treatment and prevention of important infections affecting women and children. It will:

- Create a new tool for rapidly detecting HIV, syphilis and hepatitis B infections in pregnant women.
- Help to identify those women who could benefit most from antiviral treatment for HepB infections.
- Show whether the platform is a cost-effective way to prevent mother-to-child transmission of these infections.
- Generate economic returns for device distributors in sub-Saharan Africa.

With an estimated 46 million pregnancies occurring a year, and 6% of women likely to have HepB infections, widespread use of the platform could have a significant impact on the transmission of HepB and other infections to children in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2027
Total project cost	€5 078 875,50
Global Health EDCTP3 funding	€5 078 815,50
Disease area	HIV/AIDS, Other childhood infectious diseases
Intervention type	Diagnostics
Overarching topic	Women's health, Co-morbidities and non-communicable diseases, Climate crisis or climate adaptation
Project coordinator	MAGIA DIAGNOSTICS
Scientific project leader	GARDIENS DE VIES ASBL
Participating countries	France, Democratic Republic of the Congo, Côte d'Ivoire, Kenya, Thailand, Brazil





PROMISE-ZERO

Implementation of an upgraded strategy to reach zero HIV transmission by breastfeeding in rural and urban settings in Zambia – the PROMISE-ZERO study

The PROMISE-ZERO project is assessing the wider roll-out of a strategy for reducing mother-to-child transmission of HIV, with the potential to eliminate transmission during breastfeeding.

The challenge

The babies of mothers living with HIV are at risk of acquiring HIV while in the womb and during breastfeeding. With more pregnant women receiving antiretroviral therapy during pregnancy, leading to effective viral suppression, HIV transmission during breastfeeding is becoming the most common route of mother-to-child transmission. This can happen because HIV is inadequately suppressed, or mothers acquire HIV during pregnancy or breastfeeding.

The EDCTP-funded PROMISE-EPI study assessed whether at-risk infants could be identified when mothers bring their babies for routine vaccination at 6–8 weeks. Point-of-care tests for viral load in mothers and HIV testing of infants were used to identify babies who had acquired HIV or were at risk of infection, so that they could be given antiretrovirals throughout breastfeeding. The study found that use of this approach, tested in Burkina Faso and Zambia, led to almost no cases of HIV transmission during breastfeeding.

The project

The follow-on PROMISE-ZERO project, funded by Global Health EDCTP3, is extending these encouraging findings. The project is exploring whether the same approach can be applied in remote areas of Zambia. It is also extending follow-up to 18 months after birth, by which time more than 80% of mothers will have ceased breastfeeding.

The project is recruiting pregnant women living with HIV and their infants at a 6–8-week vaccination visit at 40 rural and urban sites in two provinces of Zambia. At large maternal and child health centres, point-of-care HIV testing equipment will be installed. Where this is not possible, district-level mobile teams will organise point-of-care testing to assess viral load and infant infection status. Alternatively, blood samples will be collected and transported to health centres for analysis, with results returned to facilities so that antiretroviral therapy can be initiated when necessary.

The project will use a single-drug antiretroviral treatment for at-risk infants (lamivudine), which is affordable and readily available, and a simpler option than the triple-drug therapy currently recommended in Zambia.

As well as infection rates in comparison with usual care, the study will explore the factors affecting the implementation of the new approach in the different settings. A cost-effectiveness analysis will also be carried out.

The impact

The PROMISE-ZERO project will determine whether point-of-care testing of mothers and babies at vaccination visits is an effective strategy for preventing mother-to-child transmission of HIV during breastfeeding. It will:

- Provide global and national policymakers with **evidence on effectiveness and cost-effectiveness** to inform policymaking.
- Show whether a **simplified antiretroviral regimen** is effective at preventing HIV transmission in infants; this could lead to a shift in national policy, reducing the risk of adverse events and saving money.
- Provide insights into the **key factors** to consider to ensure the successful implementation of the new approach.

If the new strategy is found to be effective, its implementation could further reduce mother-to-child transmission of HIV, potentially even helping to achieve complete elimination of transmission during breastfeeding.

Project at a glance	
Project duration	1 Jul 2023 – 30 Jun 2027
Total project cost	€3 995 300,00
Global Health EDCTP3 funding	€3 995 300,00
Disease area	HIV/AIDS
Intervention type	Other prevention tools
Overarching topic	Women's health
Project coordinator	UNIVERSITÉ DE MONTPELLIER
Participating countries	France, Zambia, Uganda, Norway, Belgium



MOBILE MEN

Implementing oral and long acting Pre-exposure prophylaxis in mobile men in sub-Saharan Africa [MOBILE MEN]

The MOBILE MEN project aims to identify the preferred HIV prevention option for men who migrate for work, as well as the key health system factors that affect delivery of these options.

The challenge

In most sub-Saharan African countries, heterosexual men have generally not been considered a high-priority population for HIV prevention. However, there is growing interest in targeting such men, particularly those who migrate for work, such as truck drivers, farm workers and, in countries such as Uganda, fishermen. The prevalence of HIV is typically high in these populations and shows little sign of declining.

Mobile men could benefit from new HIV prevention options, such as long-acting cabotegravir (CAB-LA), an injectable antiretroviral providing protection for two months; or oral on-demand pre-exposure prophylaxis (PrEP), which means using oral antiretrovirals in advance of a sexual encounter. On-demand PrEP gives people control over medication use but requires men to carry a supply of drugs with them. CAB-LA removes this need but requires that men attend health facilities every two months for a CAB injection.

Little is known about the preferences of mobile men for these options, or how feasible it would be to deliver CAB-LA or on-demand PrEP services to them.

The project

The MOBILE MEN project is gathering background information on mobile populations, exploring their mobility patterns, knowledge, attitudes and current HIV prevention practices, and the existing national policies for HIV prevention in this group.

The project will also carry out a trial, in which 400 mobile men from South Africa or Uganda will be provided with either CAB-LA or a choice of daily or on-demand PrEP (at the end of the trial, they will be able to choose which intervention they would like to continue with). The study will assess the success of the two approaches at retention in care during a 9-month follow-up, as well as the number of unprotected sexual encounters covered by PrEP. It will also explore the perceptions of participants and barriers to uptake.

Health system factors affecting access or uptake will also be explored, alongside healthcare worker perceptions and a cost-effectiveness analysis. Materials will be created to support the effective implementation of mobile men-focused HIV prevention services.

The impact

The MOBILE MEN project will provide much-needed evidence on the HIV prevention option preferred by mobile men, and on factors associated with successful implementation and take-up. It will:

- Provide key insights into the preferences and use of different prevention methods, helping to shape national policy and the options made available to mobile men.
- Provide a better understanding of issues affecting implementation and take-up, to inform the planning of service introduction.
- Ensure that HIV prevention programmes reflect mobile men's needs and preferences, and are compatible with healthcare systems, increasing the likelihood that they are successful.

Successful implementation of on-demand PrEP or CAB-LA-based HIV prevention programmes for mobile men would help to reduce the burden of HIV in this currently overlooked population and those with whom they interact.

Project at a glance	
Project duration	1 Jul 2023 – 31 Jan 2027
Total project cost	€4 665 192,50
Global Health EDCTP3 funding	€4 665 192,50
Disease area	HIV/AIDS
Intervention type	Other prevention tools
Project coordinator	DESMOND TUTU HEALTH FOUNDATION NPC
Participating countries	South Africa, France, United Kingdom, Uganda





The 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

With Global Health EDCTP3 funding, the META Trial project will be able to complete its landmark EDCTP2–funded trial of metformin for diabetes prevention in people living with HIV.

The challenge

An estimated 26 million people are living with HIV in sub-Saharan Africa, 20 million of whom are receiving antiretroviral therapy. At the same time, around 25 million people in the region are affected by type 2 diabetes, a number that is projected to increase to 60 million by 2050. Around half a million people in the region already die from diabetes every year.

These are not independent epidemics. People living with HIV are at higher risk of developing type 2 diabetes. In HIV clinical trial participants in Tanzania, for example, 15% were found to have type 2 diabetes, despite never having been diagnosed. This rate is significantly higher than in the general population.

Type 2 diabetes is a progressive condition that is preceded by an asymptomatic stage, **pre-diabetes**, which is associated with impaired glucose control. Pre-diabetes is highly predictive of type 2 diabetes, and early detection provides an opportunity to intervene to reduce the risk of full-blown disease. Although type 2 diabetes can be prevented by the adoption of healthier lifestyles, in practice, lifestyle interventions are ineffective unless accompanied by intensive individual support, which would be impractical in sub-Saharan Africa settings.

The project

The META Trial project has been pursuing an alternative strategy, based on the use of **metformin**, a commonly used and highly effective diabetes drug, which also appears able to slow progression from pre-diabetes.

Funded through the EDCTP2 programme, the META project has been conducting a trial in Tanzania to assess whether metformin prevents pre-diabetes progression in people living with HIV. The trial planned to recruit more than 2,000 patients and follow them for three years.

However, the study was badly affected by the COVID-19 pandemic, which led to delays in regulatory approvals and to the decentralisation of HIV care, which slowed recruitment. Global Health EDCTP3 funding will enable the project to complete recruitment, full follow-up of participants and data analysis, generating the largest body of trial evidence on pre-diabetes prevention in sub-Saharan Africa to date.

The project has proceeded with close engagement with policymakers from Tanzania to ensure that it delivers policy-relevant evidence and has an immediate impact on national policymaking.

The impact

The META Trial project will generate key data on metformin use to prevent type 2 diabetes in people living with HIV. It will:

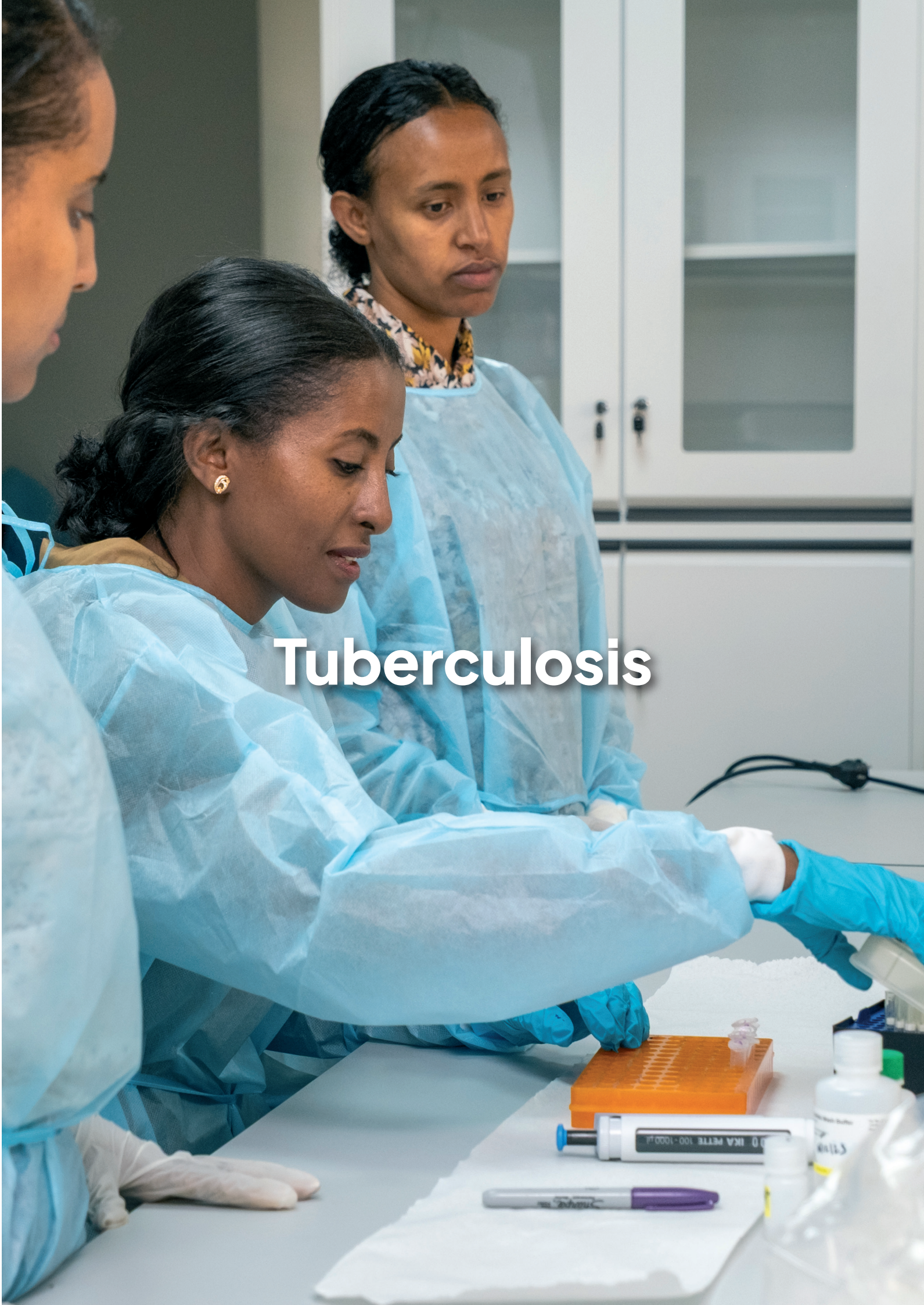
- Provide global and national policymakers with definitive evidence on the efficacy of metformin for diabetes prevention in this critical group.
- Generate clinical, cost-effectiveness and qualitative data to inform national decision-making.
- Provide important insights into how diabetes and other non-communicable disease care can be integrated with HIV management.

The META Trial project received a national UK award, the Times Higher Education award for International Partnership of the Year, for 'creating an equitable partnership that led to a step change in research'. Results from other studies suggest that the risk of diabetes could be cut by more than a third by metformin, delivering a significant reduction in the disease burden associated with HIV infection.

Project at a glance	
Project duration	1 Jan 2025 – 31 Dec 2026
Total project cost	€1 811 067,50
Global Health EDCTP3 funding	€1 811 067,50
Disease area	HIV/AIDS
Intervention type	Other prevention tools
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA
Scientific project leader	NATIONAL INSTITUTE FOR MEDICAL RESEARCH
Participating countries	Spain, Tanzania, Ireland, Sweden, United States, India



Tuberculosis





MTBVAC-AVANTE

Advancing a Vaccine for Adolescent/Adult and Neonatal TB Epidemic

The MTBVAC-AVANTE consortium, led by Biofabri, is advancing one of the world’s most advanced tuberculosis vaccine candidates, MTBVAC, towards licensure and deployment.

The challenge

More than 100 years have passed since the only TB vaccine, Bacille Calmette–Guérin (BCG), was first administered. Although BCG provides important but incomplete protection against severe disease in infants and young children, it has several important limitations: critically, it does not prevent progression to TB disease in adolescents and adults with *Mycobacterium tuberculosis* (Mtb) infections, among whom most transmission and disease occurs.

A new effective TB vaccine could have an **enormous public health impact**. While TB vaccine development is highly complex, years of scientific ingenuity and perseverance have brought multiple promising candidates into late-stage efficacy trials today. At the same time, efforts are advancing to lay the groundwork to ensure their introduction as rapidly as possible, should they be found safe and effective. This includes a range of country- and region-led approaches and work under the WHO TB Vaccine Accelerator Council.

One of the most advanced candidates is MTBVAC. MTBVAC is the only live, attenuated vaccine candidate derived from Mtb currently in development by Biofabri and uses a weakened, harmless form of the pathogen to stimulate an immune response. Genes that trigger disease have been removed from the Mtb genome, while retaining the full range of antigenic targets that are missing from BCG, which may be involved in generating an immune response against TB. Importantly, MTBVAC is being studied to prevent TB disease in both young children (as a superior alternative to BCG) and adolescents and adults (for whom no vaccine is yet licensed).

Several MTBVAC clinical trials are underway. These include a Biofabri-sponsored phase 3 trial in infants (MTBVACN3, partly funded by EDCTP), which is recruiting more than 7,000 newborns in Madagascar, Senegal and South Africa, and an IAVI-sponsored phase 2b trial in adolescents and adults (IMAGINE), which is recruiting more than 5,000 participants at 16 clinical research centres in South Africa, Kenya, and Tanzania. A phase 2a trial sponsored by Fred Hutchinson (HVTN group) is meanwhile underway in adolescents and adults living with and without HIV in South Africa, while a phase 2 trial sponsored by Bharat Biotech has been completed among adolescents and adults in India. A Phase 3 trial is set to begin by the end of 2026 in adolescents and adults in India, also sponsored by Bharat Biotech.

The project

Over the next four years, the MTBVAC-AVANTE, a 12-partner project, will work to **advance the clinical development of MTBVAC** and ensure that the clinical evidence produced is well placed to be **translated into policy**. Under the name Advancing a Vaccine for Adolescent/Adult and Neonatal TB Epidemic (MTBVAC-AVANTE), the project will support the expansion and completion of these two trials, as well as several concurrent and post-trial activities that will lay the ground for more rapid country introductions of MTBVAC, should it be found safe and effective.

- **MTBVACN3**: It will help ensure the successful conclusion of the trial and production of the final clinical summary report, as well as biobanking of samples from participants for future analysis. The project team plans to submit a **licensing application to a**

- **regulatory authority**, likely the European Medicines Agency (EMA), for the use of MTBVAC to prevent TB disease in neonates, followed by an extension to older age groups as more data become available.
- **IMAGINE**: The project will co-fund the expansion of the Phase 2b trial with the inclusion of an additional cohort to assess the safety and immunogenicity of participants who test negative on the IGRA test for Mtb infection. Under an earlier grant from Coefficient Giving, the IGRA negative cohort began enrolment in February 2026. The addition of around 1,200 Mtb-unexposed participants will complement the IMAGINE trial’s initial target of enrolling 4,300 participants with prior Mtb exposure (IGRA-positive) but without TB disease.
- **Innovative exploratory objectives**: The project funding will co-support the collection of sputum samples at three consortium partners (Ifakara Health Institute, Kenya Medical Research Institute, and University of Cape Town Lung Institute PTY LTD) to facilitate the future assessment of the contribution of different immune responses to protection against TB disease to inform future TB vaccine development. Samples will be stored in a biorepository overseen by IAVI and made available to experts for MTBVAC-correlates research, with biobanking supported by other grants.
- **MTBVAC-AVENTE** will also support **regulatory and policymaker engagement**. The project consortium will carry out a wide range of activities with national regulatory authorities and policymakers, as well as global stakeholders and regional procurement bodies. These engagements will lay the groundwork for timely licensing and policy translation to facilitate the introduction of MTBVAC and equitable access to it, should positive findings emerge from trials.

The impact

The MTBVAC-AVANTE project will help accelerate tuberculosis vaccine development and access by:

- Ensuring that key phase 2b and 3 trials of the MTBVAC vaccine candidate can be successfully completed in full.
- Facilitating sample collection, storage and analysis, generating evidence to support TB vaccine development.
- Enabling extensive engagement with regulatory authorities and policymakers to anticipate potential barriers and accelerate assessments by regulators and policymakers in high-burden countries.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2030
Total project cost	€74 817 313,76
Global Health EDCTP3 funding	€18 223 012,83
Disease area	Tuberculosis
Intervention type	Vaccines
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	BIOFABRI SL
Scientific project leader	IAVI SOUTH AFRICA NPC
Participating countries	Spain, South Africa, Kenya, Netherlands, Tanzania, Switzerland



T5-TBVAC

Evaluating a multi-valent aerosol booster TB vaccine for adolescents and young adults in diverse African settings: T5 TBVAC

The T5–TBVAC project is introducing a BCG-based human challenge model in Uganda to accelerate the evaluation of a candidate tuberculosis vaccine and using this model to generate initial efficacy data on a novel multi-antigen TB vaccine.

The challenge

More than 10 million people develop tuberculosis each year, and over a million people die of the disease. The only licensed vaccine, BCG, does not prevent the development of TB disease in adolescents and adults with *Mycobacterium tuberculosis* (Mtb) infection, which is a critical gap in TB control. The TB vaccine pipeline is not well-stocked, particularly at early stages of clinical development, and new candidates are urgently needed.

TB vaccine development is highly challenging. Although various types of immune response are known to be associated with protection, protective immunity remains incompletely understood. In addition, the efficacy of vaccines in animal models is poorly predictive of clinical benefits in humans. More effective ways to assess the performance of candidate vaccines and to prioritise candidates for large-scale field evaluation are therefore critically needed.

The project

The T5–TBVAC project is gathering data on a promising new tuberculosis vaccine candidate while also building capacity to run controlled human BCG-based challenge studies to evaluate TB vaccines in sub-Saharan Africa.

Because animal models are poorly predictive, data are more reliable when obtained directly from humans. **Human challenge studies**, in which volunteers are deliberately infected with pathogens under highly controlled conditions, enable the collection of rich data without the need for lengthy and expensive field trials.

Deliberate infection with virulent strains of Mtb itself is generally considered inappropriate. However, there is an alternative – challenge with **BCG**, an attenuated form of *Mycobacterium bovis* that still replicates and is very closely related to Mtb. (In challenge studies, BCG is not being used as a vaccine but as a ‘weakened’ pathogen).

The T5–TBVAC project team has already successfully established a **BCG-based human challenge model** in the UK. In this model, BCG is administered to the skin, and skin biopsies are used to assess the effect of prior vaccination on BCG replication.

The efficacy of TB vaccination varies markedly across countries, likely reflecting the degree of prior exposure to mycobacterial and other pathogens. Therefore, to provide a reliable indication of likely vaccine performance, studies need to be carried out in high-burden countries where the vaccine will be used. The T5–TBVAC project will address this crucial issue by establishing the BCG challenge model in sub-Saharan Africa.

The T5–TBVAC project team has developed a candidate vaccine based on a well-established **viral vector platform**. While a candidate vaccine containing a single Mtb antigen stimulated

strong immune responses and protected mice, such a vaccine is unlikely to protect diverse populations worldwide. The team has therefore developed a refined vaccine with **five immunogenic Mtb antigens** (Ag85A, PPE15, PE8, ESXJ, ESXI), which should provide protection across a broader proportion of the population.

Furthermore, T5–TBVAC has been designed to be delivered by **aerosol**, stimulating immune responses at the site of Mtb infection in the lungs. Aerosol delivery has another potential advantage: recipients are likely to prefer a nasal spray to an injection, thereby increasing the likelihood of vaccine uptake.

The project first assesses the safety of the multi-antigen candidate in the existing UK human challenge model. The model will then be introduced in Uganda, where studies will compare the impact of both aerosol and intramuscular delivery of T5–TBVAC on BCG replication. In addition, conventional Phase 2a studies in Senegal, West Africa, will provide safety and immunogenicity data on the vaccine in a very different African setting.

A wide range of cellular and antibody-based immune responses will be monitored to assess the vaccine’s immunogenicity across different settings. This may also provide new insights into key **correlates of protection** – immune mechanisms that show a strong association with the vaccine’s protective effects.

The impact

The T5–TBVAC project will provide a major impetus to tuberculosis vaccine development. It will:

- Generate key safety and immunogenicity data on a novel multivalent vaccine.
- Provide initial efficacy data from a human challenge model in both the UK and sub-Saharan Africa.
- Create a platform for further TB vaccine evaluation in human participants in East Africa.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2031
Total project cost	€13 812 427,50
Global Health EDCTP3 funding	€12 687 077,50
Disease area	Tuberculosis
Intervention type	Vaccines
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD
Scientific project leader	UGANDA NATIONAL HEALTH RESEARCH ORGANISATION
Participating countries	United Kingdom, Uganda, Senegal, Netherlands





ACTTIVAC

A Phase 2a Randomised Clinical Trial to Identify the Optimal Dose of the Thermostable ID93+GLA-SE Tuberculosis Vaccine for Further Clinical Evaluation and Local Manufacture in Africa

The ACTTIVAC project is advancing a novel single-vial thermostable multi-antigen tuberculosis vaccine, ID93+GLA-SE, which is now available as a convenient, freeze-dried formulation designed to improve delivery in resource-limited settings.

The challenge

Tuberculosis (TB) remains one of the world's biggest public health challenges, with an estimated 10 million new cases a year. Transmission of TB is mostly due to **infections in adolescents and adults**, who are therefore a critical target group for new vaccine development.

TB vaccine development has proven highly challenging. The exact nature of protective immunity remains unclear: T-cell responses (particularly Th1-type responses) appear to be critical but are not by themselves a guarantee of protection. Relatively few vaccine candidates are in the pipeline, and there is a high risk of failure, so there is a continuing need to advance potential new options. The ACTTIVAC project is focusing on a **highly promising TB vaccine candidate, ID93+GLA-SE**, developed by the Access to Advanced Health Institute (AAHI). ID93+GLA-SE is a protein subunit vaccine that incorporates four TB antigens associated with virulence or disease, as well as an adjuvant (GLA-SE) designed to enhance immune responses against vaccine antigens.

The project

A key innovation in the ACTTIVAC project is the transition to a **single-vial lyophilised (freeze-dried) formulation** of the ID93+GLA-SE vaccine. Unlike the earlier two-vial liquid version, the single-vial presentation simplifies preparation and administration, reduces the risk of dosing errors, and streamlines supply chain logistics. These are **critical advantages** for large-scale immunisation programmes. Critically, the thermostable formulation remains stable at higher ambient temperatures, eliminating or greatly reducing dependence on a cold chain/refrigeration storage. This **enables reliable delivery to remote, hard-to-reach, or hot-climate settings** across sub-Saharan Africa and other resource-limited regions, where maintaining refrigeration is often challenging and costly. Together, these improvements significantly enhance the vaccine's practicality, accessibility, and potential for rapid rollout in TB-endemic countries.

AAHI's agreement to the **technology transfer** of ID93+GLA-SE adjuvant manufacturing to African partners such as Afrigen Biologics represents a strategic step toward greater health sovereignty on the continent. By enabling local production of this critical vaccine, often one of the most complex and expensive elements, the initiative reduces reliance on distant global supply chains, mitigates risks of shortages or delays, and can lower long-term costs.

Beyond ID93+GLA-SE, this capacity-building effort strengthens Africa's overall vaccine manufacturing ecosystem, fosters skills development and technology ownership, and positions the continent to **better respond to future health threats** with home-grown solutions rather than depending on imports. This collaborative approach not only accelerates access to the current TB vaccine candidate but also lays a foundation for sustainable, regionally controlled vaccine production.

This same principle extends to the trial's data: BioInformatiCo will manage the study's clinical data to regulatory standards, keeping regulatory-grade research data and the capacity to produce it on the continent.

The ACTTIVAC project, coordinated by Stichting Tuberculosis Vaccine Initiative, is a **phase 2a clinical trial** of this new formulation, with the main goal of **selecting a suitable dose and administration regimen** for a future phase 2b efficacy trial. Safety and immunogenicity of four different doses will be evaluated at two ethnically and geographically diverse sites in South Africa, led by the South African Tuberculosis Vaccine Initiative of the University of Cape Town and the Aurum Institute, focusing on BCG-vaccinated, TB-exposed adolescents and adults.

In addition to antibody and T-cell responses, the study will assess a wide range of other immune responses that might be associated with long-term protection against TB disease. The thermostability properties of the new formulation will also be evaluated in field conditions by Obafemi Awolowo University at sites in Nigeria.

The impact

The ACTTIVAC project will advance a much-needed new vaccine for tuberculosis by:

- Generating safety and immunogenicity data for the new thermostable, lyophilised formulation of ID93+GLA-SE in TB-endemic populations in sub-Saharan Africa.
- Identifying the optimal dose of ID93+GLA-SE for a subsequent field efficacy trial.
- Establishing the foundation for local manufacturing of the GLA-SE adjuvant in Africa, strengthening regional production capabilities.
- Advancing AAHI's shark-free squalene, which is a plant-based Solanesol rather than shark liver oil, supporting ethical sourcing, scalable manufacturing and a more resilient supply chain in Africa.

Project at a glance	
Project duration	1 Aug 2026 - 31 Jul 2030
Total project cost	€14 361 817,00
Global Health EDCTP3 funding	€11 943 468,75
Disease area	Tuberculosis
Intervention type	Vaccines
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	STICHTING TUBERCULOSIS VACCINE INITIATIVE
Scientific project leader	UNIVERSITY OF CAPE TOWN
Participating countries	Netherlands, South Africa, United Kingdom, Nigeria, Switzerland



SPOTLIGHT

Establishing safety, potent immunity and optimal tuberculosis vaccine dose of H107e/CAF10b including in younger age groups in high-burden trial sites

The SPOTLIGHT project is advancing a multi-antigen TB vaccine designed to boost protective immune responses in the lung.

The challenge

Mycobacterium tuberculosis (Mtb) causes more deaths than any other single pathogen. Globally, more than a million people die of tuberculosis each year. Controlling TB will require an effective vaccine, but the only licensed vaccine, BCG, is only partially effective and does not prevent disease in **adolescents and adults**, who are the primary drivers of TB transmission.

Other vaccines are in development, but the most advanced offer only around 50% protection – high enough to deliver major public health benefits but leaving room for improvement. One promising candidate at an earlier stage of development is **H107eV/CAF10b** – a subunit vaccine based on eight distinct Mtb antigens, each of which is individually protective in animal models.

Key features of the vaccine include the breadth of protective responses stimulated due to the diversity of antigens presented. Furthermore, due to the properties of the adjuvant used in the vaccine (CAF®10b), it is **highly effective at stimulating T-cell responses** thought to be critical to protection against TB – **Th17 responses**, which direct immune cells to the lung, where Mtb infections are first established, and promote local immune responses.

A further advantage is that the CAF®10b adjuvant is relatively straightforward to make. As adjuvants can be subject to supply shortages and are often the most expensive component of a vaccine, this has major benefits for availability and cost.

The project

In a phase Ia trial testing the earlier construct H107e with CAF10b, it has been found to be immunogenic and to have a reasonable safety profile. The SPOTLIGHT project is now moving the vaccine to the next stage in development – **evaluation of immunogenicity and safety in high-burden endemic settings** using the newer H107eV construct with the same adjuvant. The project is focusing on **adolescents and adults**. A complementary NIH-funded trial is evaluating H107eV/CAF10b in people living with HIV.

The SPOTLIGHT trial, being conducted in South Africa and Tanzania, includes a **dose-finding component**. In addition to the doses of antigen and adjuvant used in the earlier trial, lower doses of both will be evaluated in a two-by-two factorial design (full or low antigen dose combined with full or low adjuvant dose). A lower dose that retains good immunogenicity may cause fewer injection-site reactions and reduce costs.

The trial will focus on **adolescents and adults**: people with a positive IGRA test (used to detect likely Mtb infections) are at the highest risk of TB disease and would benefit most from vaccination. However, it would not be feasible to test for IGRA status during vaccine rollout, so it is also important to collect data on IGRA-negative individuals. The SPOTLIGHT trial will recruit equal numbers of IGRA-negative and IGRA-positive participants in this age group.

The project is also exploring a new way to assess the **vaccine's immunogenicity**. Immune responses in the lung are likely to be critical to protection, but these require an invasive procedure (bronchoalveolar lavage (BAL)) to obtain samples. Conventionally, **blood samples** are analysed to assess immune responses, but these may not be a good indication of what is happening in the lung. The SPOTLIGHT team is investigating **nasal immune responses** in easily collectable nasal fluid and tissue samples. The results will be compared with bloodstream immune response data and BAL data from another planned parallel trial. The key aim is to establish correlations between datasets so as to identify bloodstream markers that track protective lung responses and can be used to assess candidate vaccines.

The impact

The SPOTLIGHT project will advance a highly promising TB vaccine. It will:

- Provide critical data on the safety and immunogenicity of H107eV/CAF10b, to inform progression to a pivotal phase III trial.
- Identify the optimal dose of both the antigen and adjuvant to be taken forward.
- Capture key information on mucosal immune responses and potentially identify bloodstream markers associated with protective immune responses in the lung.
- Facilitate scalable adjuvant GMP manufacturing for phase II and beyond.

H107eV/CAF10b has the potential to be an affordable and accessible TB vaccine. If shown to be efficacious, it could have a major impact on disease prevention, delivering substantial health and economic benefits to some of the poorest communities and countries in sub-Saharan Africa.

Project at a glance	
Project duration	1 Sep 2026 - 31 Aug 2030
Total project cost	€28.266.054,75
Global Health EDCTP3 funding	€15.138,800
Disease area	Tuberculosis
Intervention type	Vaccines
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	STICHTING TUBERCULOSIS VACCINE INITIATIVE
Scientific project leader	AURUM INSTITUTE
Participating countries	Netherlands, South Africa, Denmark, Tanzania, Guinea-Bissau



PROTID

Randomised Controlled Trial of Preventive Treatment of Latent Tuberculosis Infection in Patients with Diabetes Mellitus

The EDCTP2–funded PROTID project has received additional Global Health EDCTP3 funding, enabling it to complete its trial of preventive TB treatment in people with type 2 diabetes.

The challenge

Type 2 diabetes is responsible for more than one in ten adult deaths globally. Furthermore, its prevalence is predicted to increase, particularly in sub-Saharan Africa, as Western lifestyles become more common.

Type 2 diabetes also has implications for infectious diseases, particularly tuberculosis (TB). It increases the risk of TB disease threefold and doubles the risk of death from TB. Risks are reciprocal, with TB infections exacerbating the impact of diabetes, for example, leading to more cardiovascular complications.

TB infections are extremely common and often undiagnosed, so household and social contacts are at risk of acquiring infection. New TB cases could be reduced by the use of highly effective **preventive antibiotic treatments** in high risk groups, which could include people with type 2 diabetes.

The project

Funded through the EDCTP2 programme, a key aim of the PROTID project was to assess the impact of TB preventive treatment in people living with type 2 diabetes. Project activities were severely hampered by the COVID-19 pandemic, which disrupted recruitment and supply of medicines, and led to project personnel being redeployed to pandemic-related duties. The project has therefore been awarded supplementary Global Health EDCTP3 funding to enable it to complete its trial and data analysis, as well as related project activities.

The project is founded on the world’s largest diabetes and TB cohorts in Uganda and Tanzania. Despite COVID-19 disruptions, the project had already screened 3,000 people, finding that more than half had latent TB (infected, but no symptoms) and 6.1% also had HIV infections. Those with latent TB infection were enrolled in a placebo–controlled trial of antibiotic treatment to prevent progression to active TB disease. The project team is also following those without latent TB infection to confirm that they would not have benefited from TB treatment.

The new funding will enable the project team to complete recruitment and data analysis. In addition, the project team has been assessing the care provided to people living with type 2 diabetes. It has systematically reviewed care guidelines

in the region, identifying more than 300 recommendations. A consultation is being organised to generate a consensus on the optimal care for such patients at different stages along the care pathway. Additionally, the project is tracking the care provided to patients in the study cohorts to assess the quality of care and identify gaps in care provision.

The impact

The PROTID project will generate key data on a potential application of preventive tuberculosis (TB) treatment, which is currently not being fully used in TB control. It will:

- Reveal whether preventive treatment reduces the burden of TB disease in people living with type 2 diabetes.
- Provide policymakers with data on the population impacts of preventive TB treatment in this group of patients and its cost–effectiveness.
- Identify the optimal care pathway for type 2 diabetes in African settings and key gaps in care in East Africa.

The project’s findings will feed into global and national policymaking on both TB control and diabetes management, potentially reducing the burden of TB disease and protecting the health of the increasing number of people with type 2 diabetes.

Project at a glance	
Project duration	1 Jul 2024 - 31 Dec 2026
Total project cost	€2 337 586,25
Global Health EDCTP3 funding	€2 337 586,25
Disease area	Tuberculosis
Intervention type	Therapies, Other prevention tools
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM
Scientific project leader	NATIONAL INSTITUTE FOR MEDICAL RESEARCH
Participating countries	Netherlands, Tanzania, Uganda, New Zealand



INTENSE-TBM-2

Intensified tuberculosis treatment to reduce the high mortality of tuberculous meningitis in HIV–infected and uninfected patients

With Global Health EDCTP3 funding, the EDCTP2–funded INTENSE-TBM project is completing a trial that could radically improve the treatment of tuberculosis (TB) infections affecting the brain.

The challenge

Although tuberculosis (TB) is primarily a disease of the lungs, it can also affect other body tissues, including the membranes lining the brain, the meninges. **Tuberculous meningitis (TBM)** is the most deadly form of TB. In sub-Saharan Africa, the TBM death rate is around 40%, but rises to 70% for patients who also have HIV infections. As well as deaths, TBM can also trigger damage to blood vessels, leading to localised brain damage and a wide range of neurological symptoms.

TBM is currently treated with the same multidrug regimens used for pulmonary TB. These are only partially effective, in part because the drugs do not reach high levels at the sites where TB bacteria are present in the brain. However, there is growing evidence that higher concentrations of key TB drugs such as **rifampicin** can be safely used and may be more effective in TBM.

The project

Funded through the EDCTP2 programme, the INTENSE-TBM project has been running a clinical trial evaluating a novel treatment regimen for TBM. The new approach has two key innovations:

- Use of **high-dose rifampicin** alongside **linezolid**, which is used to treat drug-resistant TB and shows good penetration into the brain.
- Inclusion of **low-dose aspirin** to reduce the risk of neurological damage due to leakage from blood vessels in the brain.

The trial, launched in Côte d’Ivoire, Madagascar, South Africa and Uganda, was badly affected by the COVID-19 pandemic, with recruitment significantly slower than anticipated. Global Health EDCTP3 funding will enable the INTENSE-TBM-2 project, the largest currently underway on TBM treatment, to complete recruitment up to its target of more than 750 patients, to follow up patients and to analyse trial data.

The project is also exploring the nature and implications of the neurological damage linked to TBM, including impacts on daily life, to provide a picture of the full impact of TBM infections.

In addition, in patients with HIV infections, the project is tracking possible interactions between anti-TB drugs and antiretrovirals, particularly dolutegravir, and monitoring for cases of TB–IRIS (immune reconstitution inflammatory syndrome), when antiretroviral treatment leads to a rebound in immune function that drives harmful reactions to TB.

The impact

The INTENSE-TBM-2 project is generating key evidence on the safety and efficacy of a potentially transformational treatment for Tuberculous meningitis (TBM). It will:

- Show whether the intensified treatment with high-dose rifampicin and linezolid reduces the alarmingly high TBM mortality rate.
- Demonstrate whether low-dose aspirin has similarly beneficial effects by reducing the likelihood of neurological impacts.
- Provide high-quality data to inform national and global policymaking.
- Generate evidence on the interactions between anti-TB and antiretroviral treatments for HIV, to guide care of this important group of patients.

The INTENSE-TBM-2 project is a crucial trial that will shape the future of TBM care, with each intervention anticipated to lower TBM mortality by 30% and reduce the risk of neurological harms that can severely affect day-to-day life.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2026
Total project cost	€2 497 565,00
Global Health EDCTP3 funding	€2 497 565,00
Disease area	Tuberculosis
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITÉ DE BORDEAUX
Scientific project leader	ASSOCIATION PAC-CI
Participating countries	France, Côte d’Ivoire, Madagascar, South Africa, Spain, Switzerland





TASP

Tuberculosis Antimicrobial Stewardship Programme (TASP): tackling Bedaquiline-resistant tuberculosis

The TASP project is evaluating new approaches to extend the lifespan of the critical tuberculosis drug, bedaquiline, by improving detection of drug-resistant TB infections, tailoring treatments to drug-resistance profiles, and intensifying treatment for drug-resistant infections.

The challenge

When new antibiotics are introduced, selection pressures favour the survival of microbes that can tolerate their presence. Over time, drugs lose their effectiveness as a higher proportion of microbes become resistant.

Although it has been used for only a few years, there is accumulating evidence that this is the fate of bedaquiline, a novel TB antibiotic that has become the mainstay of treatment for drug-resistant TB infections. The use of bedaquiline has enabled these treatment programmes to be significantly shortened, from 18 months to 6–9 months.

The development of resistance can be delayed by careful use of antibiotics, restricting their use to cases where they are most likely to eliminate TB infections. However, it is currently challenging to determine when TB cases might have reduced sensitivity to bedaquiline, and alternative treatments are preferred.

The project

The TASP project is evaluating a combination of innovative approaches to improve the use of bedaquiline in sub-Saharan Africa to preserve its long-term potency.

The first innovation is to use an **intensified TB treatment regimen** for patients known to have drug-resistant TB infection or at risk of such infection. During this critical time, patients will be given a combination of six drugs, using high-dose options where possible.

In addition, a novel method (thin-layer agar) will be used to rapidly assess the susceptibility of infections to **different TB drugs**. While conventional tests can take many weeks to provide such information, this new method should provide results within 2–8 weeks.

The third innovation is to develop and apply an **AI decision-support tool** that will analyse patient data and infection resistance profiles and recommend the most appropriate treatment option. Extensive expert consultations will be organised to agree on which of the four possible treatment regimens is best suited to patients with different patterns of resistance.

A trial of this strategy will then be organised in Mozambique, Nigeria and South Africa, recruiting patients with an identified bedaquiline- or rifampicin-resistant infection, or who have not responded to rifampicin-based treatment. The trial will focus on treatment success rates, with 60% or higher considered a positive result.

In parallel, the project will work with local stakeholders to co-develop **portable air cleaners** using local materials. In addition to capturing airborne pathogens, filters could be analysed to monitor the environment for drug-resistant bacterial strains. This approach was successfully applied during the COVID-19 pandemic, and products built with readily available materials appear to be as effective as commercially produced filters.

The impact

The TASP project will generate key evidence on a possible new bedaquiline stewardship strategy. It will:

- Reveal whether initial intensified treatment of suspected drug-resistant tuberculosis infections leads to better clinical outcomes.
- Demonstrate whether drug-susceptibility data generated using the thin-layer agar method can improve patient management and support more rational antibiotic use.
- Show whether an AI-based clinical decision-support tool enhances bedaquiline stewardship.

More judicious use of bedaquiline through this new approach could improve short-term clinical outcomes and extend its lifespan, thereby maintaining its effectiveness for multidrug-resistant tuberculosis infections.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2030
Total project cost	€6 299 756,05
Global Health EDCTP3 funding	€5 999 990,75
Disease area	Tuberculosis
Intervention type	Therapies, Diagnostics, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies
Project coordinator	INSTITUUT VOOR TROPISCHE GENEESKUNDE
Scientific project leader	CENTRE NATIONAL HOSPITALIER DE PNEUMO-PHTISIOLOGIE
Participating countries	Belgium, Benin, Netherlands, Nigeria, South Africa, Sweden, Canada, Mozambique, Rwanda



EX-DR TB

EX-DR TB: Elimination of Extensive Drug Resistance Through better Regimens for TB

The EX-DR TB project is aiming to preserve the potency of a key TB drug, bedaquiline, and advance the development of potential successors.

The challenge

Tuberculosis is difficult to treat, requiring several months' treatment with a cocktail of antibiotics. When patients acquire infections resistant to components of standard drug regimens, even more intensive treatments are required, which have traditionally lasted at least 18 months.

The development of **bedaquiline** was a major advance in TB therapeutics. Of particular note, it has been incorporated into shortened and simplified regimens for **multidrug-resistant TB (MDR-TB)**, including all-oral 6–9-month treatment programmes.

Unfortunately, there are growing signs that TB bacteria are developing **resistance to bedaquiline**. The situation is particularly severe in Mozambique, where 14% of multidrug-resistant TB isolates were resistant to bedaquiline in 2021, up from 3% in 2016. Resistance has also been detected in other countries in sub-Saharan Africa.

The project

Part of a major global initiative, the EX-DR TB project has twin aims: to promote improved stewardship of bedaquiline to reduce drivers of resistance, and to advance the development of **new treatment options** to supplement or replace bedaquiline.

Although molecular diagnostics can detect resistance to some components of TB drug treatments (such as rifampicin), these are not routinely used, particularly for bedaquiline. As a result, a drug-resistant infection is often only detected when patients fail to respond to treatment, which may be several months after treatment has begun.

It is becoming clear that patients primarily acquire bedaquiline-resistant infections from others; infections do not typically become resistant during treatment. Hence, if patients were tested for bedaquiline resistance as soon as the disease was detected, they could be initiated on a more effective regimen immediately.

Recently, a new strategy for detecting bedaquiline resistance has been developed. Mechanistically, resistance most often develops because of mutations that boost the activity of pumps that eject bedaquiline out of TB bacteria. Mutations can be detected by a combination of PCR, which specifically amplifies DNA copies of the gene coding for the efflux pump, followed by sequencing of this amplified DNA. Importantly, this approach can be applied directly to clinical samples, yielding rapid results.

This technology is being widely introduced in sub-Saharan Africa thanks to a Gates Foundation project. Through the EX-DR TB project, this infrastructure to detect bedaquiline resistance will be explored. In addition, the technology will be used to detect a mutation associated

with isoniazid resistance that is not picked up by existing molecular tests and is frequently found alongside bedaquiline resistance.

Alongside this work, consultations will be held to agree a **standard treatment regimen** for bedaquiline-resistant TB to ensure that use of the drug is optimised.

This will help to slow the development of drug resistance, but alternative treatments will still be needed. As part of a wider global programme, the EX-DR TB project will assess the efficacy and safety of two novel drug combinations. One will include a relative of bedaquiline showing significantly higher efficacy. The other will focus on drugs from different chemical classes, which should not be affected by bedaquiline resistance. The project is linked to multiple drug development networks, enabling them to select the most promising options.

The impact

The EX-DR TB project is addressing one of sub-Saharan Africa's most pressing health problems, multidrug-resistant tuberculosis. It will:

- Validate an approach for detecting bedaquiline-resistant TB bacteria.
- Ensure more consistent and targeted use of bedaquiline-containing regimens and improve treatment of bedaquiline-resistant infections.
- Advance the development of new TB drug treatments.

Collectively, project activities will help to preserve the potency of a critical drug central to the treatment of multidrug-resistant TB and also ensure the availability of additional drug treatments.

Project at a glance	
Project duration	1 Oct 2025 – 30 Sep 2031
Total project cost	€7 098 992,01
Global Health EDCTP3 funding	€7 098 991,26
Disease area	Tuberculosis
Intervention type	Therapies, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN
Scientific project leader	UNIVERSITY OF CAPE TOWN
Participating countries	Germany, South Africa, Eswatini, Moldova, Sweden, Mozambique, Netherlands, United Kingdom, Italy, Spain





RECENT-TB

Recurrent TB Screening and Prevention Study

The RECENT-TB project is exploring whether a course of preventive antibiotics after TB treatment can prevent disease recurrence and how to target those who would benefit most.

The challenge

Every year, around 1.5–2 million people in sub-Saharan Africa are treated for tuberculosis. Of those successfully treated, around one in ten suffer a relapse or reinfection (collectively termed **TB recurrence**) within two years. Although they represent around 5–30% of the global TB burden, such patients receive relatively little attention.

TB recurrence is associated with a range of risk factors, linked to patient characteristics, exposure risks, and microbiological factors such as residual bacterial load. Although a simplified **preventive antibiotic regimen** is used in certain high risk groups to reduce the risk of TB recurrence (secondary preventive treatment), the lack of evidence of its effectiveness for other patient populations means that it is only recommended for people living with HIV.

Potentially, secondary preventive treatment could be used more widely. Modelling suggests that it could reduce the incidence of TB by 40% over 10 years and save costs. In addition, as an alternative to blanket use, **risk stratification** might enable secondary prevention to be directed at those who would benefit most.

The project

To close this knowledge gap, the RECENT-TB project is conducting a large-scale trial of secondary preventive treatment for tuberculosis in two high-burden settings, South Africa and Uganda, while also evaluating the implementation context and the potential of various simple tests to identify patients at the highest risk of recurrence.

The project's main trial is recruiting 1,800 patients following treatment for pulmonary TB, with half receiving secondary preventive treatment (12 weekly doses of isoniazid plus rifapentine, known as 3HP). Participants will be followed for two years to determine their impact on recurrence. The trial's hybrid implementation design will allow gathering information on the feasibility and acceptability of secondary preventive treatment to inform future policy and practice.

Embedded within this trial will be a cohort study evaluating four potential risk markers for recurrence:

- **C-reactive protein (CRP):** A simple point-of-care test for inflammation based on a finger-prick blood sample.
- **Haemoglobin:** Another simple point-of-care blood finger-prick test, which detects anaemia, a risk factor for TB.
- **CXR+CAD4TB:** Computer-aided interpretation of chest X-ray images which detects lung abnormalities related to TB. This will detect patients with structural abnormalities at the end of TB treatment, which may increase the risk for TB recurrence.
- **TB-Microbial Load Assay (TB-MBLA):** A molecular assay that detects RNA from TB bacteria, so it provides a highly sensitive test for live bacteria.

The project will collect data on these markers to determine if they are predictive of recurrence. A **personalised risk score** will be developed based on the best combination of markers, which will then be integrated alongside other patient data into a **risk-stratification algorithm** – providing a simple 'high/medium/low' TB recurrence risk assessment that could be used to select patients for secondary preventive treatment.

In addition, the project will include a study to evaluate the potential use of TB-MBLA for **diagnosing recurrence**. A case-control approach will be used, with TB-MBLA data on participants with recurrence compared with data from participants in the same cohort who remained healthy. The diagnostic performance of TB-MBLA will be compared with gold-standard culture methods and a widely used molecular diagnostic (Xpert Ultra).

The impact

The RECENT-TB project could provide a new option for a relatively neglected group, those recovering from tuberculosis disease. It will:

- Demonstrate whether the 3HP regimen reduces the risk of recurrence after TB treatment.
- Provide data on implementation considerations for scale-up of secondary preventive treatment in policy and practice.
- Reveal whether simple tests can distinguish patients at the highest risk of recurrence, so 3HP use could be targeted at those most in need.
- Provide an estimate of the likely cost-effectiveness of different approaches to secondary prevention with 3HP.

If shown to be effective, wider use of 3HP for secondary prevention of tuberculosis could improve the survival and quality of life of TB patients after treatment, reduce community transmission of TB, and lower the overall cost of treating TB (thanks to a reduced number of patients with recurrences requiring treatment).

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2030
Total project cost	€2 435 813,75
Global Health EDCTP3 funding	€2 394 773,75
Disease area	Tuberculosis
Intervention type	Therapies, Diagnostics, Other prevention tools
Project coordinator	STICHTING AMSTERDAM UMC
Scientific project leader	THE INFECTIOUS DISEASES INSTITUTE LIMITED
Participating countries	Netherlands, Uganda, United Kingdom, South Africa



Decide-TB

Validation of treatment decision algorithms for childhood tuberculosis at low levels of healthcare in high burden countries – effectiveness, implementation, and integration into policy and practices

The Decide-TB project is evaluating tools that could help clinicians diagnose TB more reliably in children.

The challenge

Missed cases are a well-known challenge in tuberculosis, particularly so for childhood TB. More than a million children and adolescents develop TB each year. Of these, an estimated 250,000 die, 95% of them without a diagnosis. When TB is diagnosed and treated, nearly all children survive.

Tuberculosis diagnosis is particularly difficult in children. Symptoms are non-specific, bacterial load is typically low, and sputum samples may be hard to collect. Diagnosis is therefore generally based on assessment of signs and symptoms and whatever test results are available. WHO has developed two **treatment decision algorithms** to guide clinician decision-making (one with and one without chest X-ray results), but there is very little data to support their use.

The project

The Decide-TB project is integrating a wide range of data sources to generate two refined treatment decision algorithms, backed up by practical tools to support clinical decision-making.

These tools will include additional refinements, including modules specifically designed for TB diagnosis in children living with HIV and for children with severe acute malnutrition, where different criteria need to be applied. In addition, while the standard course of treatment for TB is six months of antibiotics, four months' treatment has been shown to be effective in children with non-severe TB. The new tools will therefore point clinicians towards this option when appropriate.

To evaluate these tools, the project is organising a cluster randomised trial in Mozambique and Zambia. As well as assessing the effectiveness of the approach at TB case detection, this study incorporates an implementation research aspect, and will also collect evidence on the feasibility and practicalities of introduction. National TB Control Programmes in Mozambique and Zambia are project partners, so the results of the study will feed directly into policymaking.

Existing health data platforms (DHIS2) will be adapted to support data collection, facilitating data use for action by national disease control programmes. The project will also collate individual patient-level data to provide a comprehensive evidence synthesis of the diagnostic accuracy of new treatment decision algorithms.

The impact

The Decide-TB project will provide critical evidence on the effectiveness and feasibility of new tools to detect TB in children. It will:

- **Reveal how effective** the treatment decision algorithms and clinical decision support systems are for detecting TB in children.
- **Generate a package of evidence** for the WHO, to inform global guidance and development of materials to support implementation.
- Directly **facilitate implementation** in countries participating in the project.

If shown to be effective, the new tools would deliver multiple benefits, reducing the number of missed cases of TB in children, enhancing detection in vulnerable children such as those living with HIV or affected by severe acute malnutrition, and leading to greater use of shortened treatment regimens for those with less severe disease. This would ensure that more children receive TB treatment and reduce the number of children dying unnecessarily from the disease.

Project at a glance	
Project duration	1 Apr 2023 – 31 Mar 2027
Total project cost	€5 299 965,00
Global Health EDCTP3 funding	€5 299 965,00
Disease area	Tuberculosis
Intervention type	Diagnostics, Other prevention tools
Overarching topic	Digital technologies
Project coordinator	UNIVERSITÉ DE BORDEAUX
Participating countries	France, Germany, Zambia, United Kingdom, Mozambique, South Africa, Switzerland





EPiTB

EPiTB: Addressing an unmet need: same day diagnosis of extra-pulmonary TB in a high burden setting

The EPiTB project is assessing the clinical impact of a new diagnostic device that is better able to detect TB infections outside the lung.

The challenge

Tuberculosis is generally thought of as a respiratory disease, but *Mycobacterium tuberculosis* can also infect other body compartments, including membranes around the heart (pericardial TB), lungs (pleural TB), or abdominal cavity (peritoneal TB). It can also lodge in the brain, causing TB meningitis. This so-called **extra-pulmonary TB** accounts for around 15% of cases, but more than a third of cases occur in areas with a high burden of HIV.

Traditional diagnostic tools are not necessarily effective at detecting some or all categories of extra-pulmonary TB. Researchers in South Africa have recently shown that the detection of interferon-gamma in tissue samples is a more accurate way to detect extra-pulmonary TB infections. The test differs from conventional interferon-gamma testing (the IGRA test), requiring no stimulation of blood cells.

This new test, known as IRISA-TB, has been developed by a local biotech company into a diagnostic product, which has been approved by the South African national medicines regulatory authority and endorsed by the Global Fund.

Although small-scale trials have demonstrated good diagnostic performance for extra-pulmonary TB, a large-scale trial would provide strong evidence to national decision-makers on its performance in programmatic settings and its potential impact.

The project

The EPiTB project is conducting a large-scale trial of IRISA-TB at centres in South Africa, Zambia and Zimbabwe. It is recruiting more than 2,000 patients with different types of suspected extra-pulmonary TB (pericardial, pleural or peritoneal, or TB meningitis).

Because of the likely use of empiric TB treatment, a randomised controlled trial of IRISA-TB is not feasible. Instead, the study will examine how the phased release of test data, from IRISA-TB and other diagnostic tools, affects clinical decision-making on treatment. This will provide real-world evidence on how IRISA-TB is actually used and its clinical impact.

Although a point-of-care version of the test would be of less clinical utility than in other diagnostic contexts, a prototype lateral flow assay has been developed. The project will explore whether new detection technology used in other diagnostics can improve the performance of this test and ultimately provide an additional diagnostic option.

The impact

The EPiTB project will provide further data on an innovative diagnostic that has been developed and manufactured in sub-Saharan Africa and could have a significant impact on patient care. It will:

- **Provide data on diagnostic performance** from a large-scale trial in a programmatic trial, delivering evidence highly relevant to policymakers.
- **Show more clearly** how clinical practice could be changed using IRISA-TB and provide insight into its likely cost-effectiveness.
- **Help to grow an innovative biotech company** based in sub-Saharan Africa.

Implementation of IRISA-TB could potentially reduce empirical use of TB antibiotics in people suspected of having extra-pulmonary TB, ensuring that treatment is directed at those in need and initiated quicker – a key advance given that many patients begin treatment after significant delays or are never treated appropriately.

Project at a glance	
Project duration	1 May 2023 - 30 Apr 2027
Total project cost	€3 989 909,25
Global Health EDCTP3 funding	€3 989 909,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	(Other) emerging technologies
Project coordinator	UNIVERSITY OF CAPE TOWN LUNG INSTITUTE PTY LTD*
Participating countries	South Africa, Netherlands, Zambia, Zimbabwe, United Kingdom



GenPath Africa

Genomic surveillance to control pathogen infections in Africa

The GenPath Africa project is expanding existing genomic surveillance infrastructure to capture information on drug-resistant strains of tuberculosis (TB) and HIV, as well as to detect a pathogen with epidemic potential: Rift Valley fever virus.

The challenge

Pathogens rapidly evolve. Genetic variants may have different properties, affecting a pathogen's ability to spread, its susceptibility to drugs and vaccines, and the severity of disease. Understanding which variants are in circulation is therefore critical to controlling diseases.

The COVID-19 pandemic emphasised the importance of tracking variants. During the pandemic, South Africa established a highly effective collaborative approach across institutions, known as the Network for Genomic Surveillance, to monitor SARS-CoV-2 variants and provide policymakers with up-to-date data to inform control efforts.

Although the pandemic led to an expansion of genomic surveillance in sub-Saharan Africa, the potential of this new technology has yet to be fully exploited across the region.

The project

The GenPath project is leveraging the genomics capabilities established at two centres of excellence in sub-Saharan Africa: the Centre for Epidemic Response and Innovation (CERI) at Stellenbosch University in South Africa, and the International Livestock Research Institute (ILRI) in Kenya. Genomics surveillance platforms will be strengthened for HIV and TB in South Africa and for Rift Valley fever in Kenya. Additionally, the project will collaborate with authorities in Mozambique to enhance capacity for monitoring HIV and tuberculosis.

For HIV, the focus will be on patients experiencing treatment failure. More portable technologies, such as Nanopore sequencing, will be piloted at central South African sites before being introduced more widely in other South African centres and Mozambique. The possible use at peripheral facilities will also be explored.

For TB, rifampicin-resistant isolates will be sequenced to generate information on resistance-associated variants, to inform treatment, to provide policymakers with data on the prevalence of drug-resistant strains and to alert them to highly resistant isolates. Factors associated with resistance will also be explored.

In Kenya, the focus is on Rift Valley fever, a zoonotic infection. A One Health approach is being adopted, with surveillance activities spanning the medical and veterinary sectors. Veterinarians will collect samples from stillbirths and low-birth-weight animals at rural sites to complement hospital-based surveillance.

In addition, a One Health approach will be introduced in two South African cities to investigate the transmission of different mycobacteria from domestic animals and wildlife to humans, as well as to explore factors associated with the transmission to humans. In both Kenya and South Africa, the project will extend wastewater surveillance systems to identify pathogens and genes associated with antimicrobial resistance (AMR).

The work will be underpinned by the development of integrated data platforms that collate genetic, clinical, and epidemiological data. The project will engage with policymakers to develop dashboards to support decision-making, and an extensive training programme will be organised across the three countries.

The impact

The GenPath Africa project will have an immediate and long-term impact. It will:

- Generate data on the drug resistance profiles of individual infections, guiding clinicians' choice of treatment.
- Create an enhanced surveillance infrastructure, providing policymakers with information on geographical and temporal trends in drug resistance to support targeted control efforts.
- Integrate technologies and processes into national systems, building their capacity to apply genomics routinely in surveillance.
- Provide an early warning of Rift Valley fever outbreaks.

Ultimately, the project will ensure that patients with drug-resistant infections receive appropriate treatment rapidly, while also providing national policymakers with key insights to inform disease control activities.

Project at a glance	
Project duration	1 May 2023 - 30 Apr 2027
Total project cost	€4 999 170,25
Global Health EDCTP3 funding	€4 999 170,25
Disease area	Tuberculosis, HIV/AIDS, Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Health security, Digital technologies
Project coordinator	STELLENBOSCH UNIVERSITY
Participating countries	South Africa, Kenya, Belgium, Mozambique, Germany





OPTIC-TB

Optimising the implementation and scale-up of the WHO TB treatment decision algorithms for children with pulmonary tuberculosis in sub-Saharan Africa

The OPTIC-TB project is assessing whether the use of WHO-recommended clinician guidance (treatment-decision algorithms, TDAs) can improve the detection of tuberculosis in children.

The challenge

Every year, more than a million children under 15 years of age are diagnosed with tuberculosis, and at least 200,000 children die of the disease. Sub-Saharan Africa accounts for around 20% of the global burden of TB in children.

This figure is almost certainly an underestimate, as many cases of TB in children go undiagnosed due to a combination of challenges, including diagnostic uncertainty, weak health systems, and inadequate clinical and laboratory infrastructure. Only about a third of children under 5 years of age with TB are diagnosed and treated each year, and more than 96% of deaths occur because children are not receiving adequate treatment.

Diagnosis of TB in children is difficult because symptoms are non-specific. WHO now recommends the use of two **treatment decision algorithms (TDAs)**, which integrate various symptoms and test results to guide physicians' decision-making. The two TDAs are the same, except one includes X-ray results (which may not be available in all settings). However, the WHO's recommendations were based on limited evidence.

The project

The OPTIC-TB project aims to generate additional evidence on the value of the WHO-recommended TDAs for the diagnosis of TB in children under 10 years of age. It is also gathering information on the practicalities of their implementation at primary healthcare facilities.

A cluster randomised controlled trial is being conducted in the Democratic Republic of the Congo (DRC), Tanzania and Uganda, comparing the use of the WHO's TDAs with existing diagnostic practice. A total of 40 facilities in each country will be randomised to each arm, with 60,000 children screened across all sites.

The trial will assess whether the use of the WHO TDAs increases the proportion of TB cases detected and the number of children who start treatment, and whether it improves treatment outcomes. It will also estimate the population-level impact of TDA use on TB disease burden, as well as its costs and cost-effectiveness.

In addition, the project will examine the factors associated with the successful implementation of the TDAs. It will also generate data on diagnostic performance in different health system contexts across different population groups, such as malnourished children or those living with HIV.

The impact

The OPTIC-TB project will provide key evidence on the impact of treatment decision algorithms (TDAs) to detect cases of tuberculosis in children in real-world settings. It will:

- Reveal whether the WHO-recommended TDAs improve the detection of missed cases of TB in children and reduce the burden of TB disease.
- Identify key factors associated with successful implementation to guide introductions into routine practice.
- Show whether, in real-world contexts, the TDAs are cost-effective.

A demonstration of the superiority of the TDAs compared with usual practice could greatly increase the number of children with TB who are diagnosed and receive treatment each year, reducing mortality and the community burden of TB disease.

Project at a glance	
Project duration	1 Apr 2024 - 31 Mar 2028
Total project cost	€3 999 998,25
Global Health EDCTP3 funding	€3 999 998,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITETET I BERGEN
Scientific project leader	NATIONAL INSTITUTE FOR MEDICAL RESEARCH
Participating countries	Norway, Tanzania, Uganda, Democratic Republic of the Congo, United Kingdom



4-CAGE-TB

Fortifying the automated smartphone-based Cough Audio classification for rapid triaGE testing for tuberculosis project

The 4-CAGE-TB project has received Global Health EDCTP3 support to complete its EDCTP2-funded study of cough analysis to identify possible TB cases for follow-up.

The challenge

In sub-Saharan Africa, an estimated 2.5 million new cases of tuberculosis occur each year, of which about 1 million are undiagnosed. This means that many patients do not receive timely treatment, and there are more opportunities for the disease to spread.

Case finding is therefore an important aspect of TB control, but presents multiple challenges. Identification of TB cases is not straightforward, as symptoms are non-specific and traditional culture methods are very time-consuming. Screening large numbers of people for TB is therefore very difficult to implement. Molecular platforms have simplified case detection; however, their use in routine population screening would be prohibitively expensive and overwhelm health systems.

A possible solution could be **triage**, whereby a simple and inexpensive test is used to distinguish those most likely to have TB, who could then be followed up using more sensitive molecular testing.

The project

The 4-CAGE-TB project has been exploring an innovative approach based on an analysis of **cough vocalisations**. Coughs are a sensitive way to detect tuberculosis disease (most patients with TB have a cough), but they are not very specific (patients may have a cough for a wide variety of other reasons).

To address this issue, the project has been using machine learning technology to identify the features of a 'TB cough' that would differentiate it from coughs of other causes. The coughs of a cohort of possible TB patients have been recorded, and their clinical history is then tracked, including the results of gold-standard TB diagnostic tests. Using this data, a **'cough classifier'** has been trained to identify the acoustic features of coughs associated with a positive TB test.

The cough classifier thus developed will be integrated into a simple-to-use mobile phone app, which analyses a patient's cough and assesses its similarity to a TB cough. A health worker is presented with a simple binary readout - that TB is likely or unlikely. If TB is likely, a patient can be referred for further testing. This approach would be quick and simple, making it possible to introduce into primary care settings.

The project was disrupted by the COVID-19 pandemic, which affected recruitment and led multiple project team members to be diverted to COVID-19-related work. The additional funding will enable the project to complete its work, including consultations with health workers on the design of the app and integration into practice, and on the acceptability of the approach.

The project aims to identify key factors that would affect implementation and generate an initial indication of cost implications. The outcome of the project will be a prototype device and supportive evidence to justify its testing in a formal clinical trial.

The impact

The 4-CAGE-TB project could have a major impact on tuberculosis case detection in sub-Saharan Africa. It will:

- Demonstrate whether a cough classifier has the potential to distinguish between TB and other coughs, meeting the sensitivity and specificity criteria for triage set out by WHO.
- Produce a practical prototype for clinical evaluation.
- Provide an indication of its likely impact on TB case detection and costs of use; modelling suggests that a simple triage test could reduce costs by 40% compared with molecular testing of all presumptive cases.

Ultimately, the project could deliver a simple, widely applicable health tool able to identify possible TB cases for follow-up, helping to reduce the huge number of new cases that are still being missed every year.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2026
Total project cost	€981 469,25
Global Health EDCTP3 funding	€981 469,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	Digital technologies, Climate crisis or climate adaptation
Project coordinator	STELLENBOSCH UNIVERSITY
Participating countries	South Africa, Netherlands, Germany, Uganda, United Kingdom, Switzerland





STOOL4TB

Evaluating a new stool based qPCR for diagnosis of tuberculosis in children and people living with HIV

The STOOL4TB project has been awarded Global Health EDCTP3 funding to complete its EDCTP2-funded study of TB detection in children and people living with HIV using stool samples.

The challenge

Many cases of tuberculosis go undetected, so patients do not receive treatment, and the disease has more opportunity to spread. This issue is particularly acute for groups such as **children** and **people living with HIV**, where it can be difficult to obtain a sputum sample for analysis, and diagnostics may not pick up the relatively small numbers of bacteria in many infections.

In children, TB treatment is generally empirical, without firm diagnosis. This means that many children with TB are missed, and some children receive powerful drugs unnecessarily when they do not have TB infections. It is estimated that more than 96% of pediatric TB deaths occur in children who are not treated for TB.

Great strides have been made in developing easier-to-use tests for TB, including molecular platforms such as Xpert. However, obtaining a sputum sample for analysis using such tools can still be a major barrier in groups such as children and people living with HIV.

The project

Funded by the EDCTP2 programme, the STOOL4TB project has been exploring an alternative approach based on detecting TB bacteria in stool samples. When people with TB disease cough, some bacteria end up being swallowed and pass through the intestinal tract. Stool samples are relatively easy to collect from all patients and can be shipped to laboratories for high-throughput molecular (PCR) analysis.

Initial small-scale studies showed that this approach could increase confirmed case detection (by 12% in Eswatini adults and 19% in Tanzanian children). Stool samples could be collected from at least 87% of patients. The WHO recommends the use of stool samples for detecting TB in children.

The STOOL4TB project is conducting a larger-scale study to confirm these encouraging findings, focusing on around 1,500 children less than 8 years old and 650 adults living with HIV (15 years and older) in high-burden settings in Eswatini, Mozambique and Uganda. The project was hit by delays in regulatory approvals and recruitment difficulties during the COVID-19 pandemic, and additional Global Health EDCTP3 funding will enable it to complete its important work.

As well as demonstrating whether the stool-based approach identifies more cases than alternative detection methods, the project is also investigating the feasibility and acceptability of this approach through consultations with patients, caregivers, health workers, and health system officials.

It is also exploring whether the approach could be used to monitor responses to treatment, which could help to identify drug-resistant infections and the need to change treatments if patients are not responding.

The impact

The STOOL4TB project could have a major impact on the diagnosis of tuberculosis in children and people living with HIV. It will:

- Provide high-quality evidence on the potential of stool-based approaches to detect TB cases.
- Potentially facilitate task shifting in primary care, as stool collection can be carried out by a broader range of health workers.
- Support the development of a point-of-care test based on stool samples (manufacturers of the Xpert platform have expressed interest in developing a stool-specific test).
- Potentially provide a tool for monitoring responses to treatment.
- Create a platform for additional studies – more than 10 further studies are drawing on the study's data and sample biorepository.

If the advantages of the stool-based approach are confirmed, this could have a major impact on TB case detection in two critical groups, children and people living with HIV, where many avoidable deaths are currently occurring because of the failure to identify TB.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2025
Total project cost	€348 247,50
Global Health EDCTP3 funding	€348 247,50
Disease area	Tuberculosis, HIV/AIDS
Intervention type	Diagnostics
Project coordinator	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA
Scientific project leader	FUNDACAO MANHICA
Participating countries	Spain, Mozambique, Eswatini, Netherlands, Uganda, Germany



CAD LUS4TB

Computer assisted diagnosis with lung ultrasound for community based pulmonary tuberculosis triage in Benin, Mali and South-Africa

The CAD LUS4TB project is assessing whether point-of-care ultrasound can be used in tuberculosis triage, ensuring that patients with the highest likelihood of TB are prioritised for further testing.

The challenge

Tuberculosis is one of the world's most common infectious diseases, infecting an estimated one in four of the world's population. Only a proportion of those infected develop active TB disease, which can be fatal if not treated. However, it is challenging to identify these patients because the symptoms of TB are non-specific, and diagnostic tests require specialist equipment (such as chest X-rays) or expensive molecular tests that are not available at many primary care facilities.

As a result, many patients with TB are not identified, so they do not get the right treatment, leaving the disease with more opportunities to spread. To enhance detection rates, there is interest in **TB triage** (rapid, easy-to-use assessments of the likelihood of TB disease), enabling diagnostic follow-up to focus on those most likely to have active TB.

Point-of-care lung ultrasound has emerged as a promising approach for TB triage. Point-of-care ultrasound is beginning to be used in primary care centres in sub-Saharan Africa, and a study in Benin has shown that the technology can discriminate between TB and other lung infections. However, while health workers were comfortable using the technology and acquiring images, they were less confident in interpreting them.

The project

Building on these promising findings, the CAD LUS4TB project is refining a digital tool for automatically categorising lung ultrasound images and assessing its suitability for TB triage.

Around 50,000 expert-labelled images from 500 patients from Benin will be analysed to fine-tune the diagnostic algorithm. At seven sites in Benin, Mali, and South Africa, the use of this algorithm will be assessed in a stepped-wedge clinical trial, in which introduction is phased over time and sites scheduled for later-stage introduction act as controls.

The diagnostic performance of the lung ultrasound algorithm will be compared with gold-standard methods, such as culture and molecular diagnostic tests. The project will also compare lung ultrasound's performance with a WHO-recommended diagnostic strategy that incorporates chest X-rays.

The project will also investigate ways to simplify image collection and analysis for non-expert use. In addition, it will use the trial to investigate whether lung ultrasound images can help identify the likely causes of respiratory symptoms not caused by TB.

To support routine implementation, the project will develop a **mobile phone-based app** and conduct consultations to assess issues such as health worker perceptions, workflow integration, and patient acceptability.

The project builds on the work of another Global Health EDCTP3-funded project, **IMCI-Plus**, which is evaluating the use of point-of-care ultrasound to determine the need for antibiotic use in children with respiratory tract infections.

The impact

The CAD LUS4TB project will assess the potential of an emerging new technology for triaging potential TB cases. It will:

- Generate high-quality evidence on the ability of automated lung ultrasound image analysis to rule out TB infection.
- Provide a way for expensive molecular testing to be focused on those most likely to have TB.
- Generate insights into the factors that might affect the implementation of the new approach in routine practice.

If the value of lung ultrasound for TB triage is confirmed, it could be rapidly adopted to refine the TB diagnosis pathway, reducing the very large number of patients who currently do not receive a diagnosis and appropriate treatment.

Project at a glance	
Project duration	1 Sep 2025 - 31 Aug 2030
Total project cost	€7 072 368,25
Global Health EDCTP3 funding	€6 809 786,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	Digital technologies
Project coordinator	STELLENBOSCH UNIVERSITY
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	South Africa, Benin, Mali, Belgium, United Kingdom





AddiCAD

Field testing of AddiCAD: An innovative diagnostic test for tuberculosis that adds to CAD

The AddiCAD project is advancing a new digital tool that combines AI analysis of chest X-rays with protein biomarker data to improve TB diagnosis.

The challenge

An estimated 10 million people develop tuberculosis disease each year, yet around a quarter are never formally diagnosed. This means they do not receive the appropriate treatment and can act as a source of additional household and community infections.

This gap reflects difficulties in **TB diagnosis**. Respiratory symptoms are non-specific, culture methods take weeks to perform, and molecular platforms are expensive and not available in all settings. As a result, new approaches to TB detection are highly prioritised, such as **triage strategies** to identify those most likely to have TB disease for intensive assessment, and **confirmatory testing** methods that are more accessible, quicker, and easier to use.

Progress is being made in the search for alternative approaches. For example, **computer-aided diagnosis (CAD) using chest X-rays** can improve diagnosis rates. There is also great interest in using **blood biomarkers** as the basis of tests to identify patients with active TB.

The project

The AddiCAD project is based on an innovative approach that combines chest X-ray CAD and blood biomarker technologies to identify tuberculosis cases.

The project team has developed a **blood test** that detects three protein markers associated with TB disease: SAA-1, CRP, and IP-10. A lateral flow test has been developed, known as **3P-TB**, based on these markers. In addition, the team has assessed the additional value of combining 3P-TB with an existing chest X-ray CAD product, **CAD4TB** (developed by Delft Imaging).

In an initial study of 600 people with possible TB disease, the combined approach (**AddiCAD**) showed very good performance. When tuned for **triage**, AddiCAD achieved a significant increase in **specificity** without loss of sensitivity (fewer patients would be sent for confirmatory testing, with no increased risk of cases being missed). When tuned for **diagnosis**, AddiCAB achieved the best performance yet seen for non-sputum-based tools, nearly meeting WHO benchmarks.

In the AddiCAD project, the team is building on these promising results and advancing the tool towards implementation in routine practice. In a first step, the 3P-TB test is being transferred into a new technology platform, based on **'aptamers'** – specially designed nucleic acids that bind specifically to the three targeted biomarkers. This will enable the markers to be detected at lower concentrations, using smaller volumes of blood (so fingerprick samples can be used) and with results available sooner (almost immediately). Importantly, the improved detection technology will not be more expensive.

The team will also develop a simple-to-use **app to integrate CAD and 3P-TB results**. The new tool will then be evaluated in a clinical study in The Gambia, Namibia and South Africa. Around 1,000 patients with signs of possible TB will be recruited, and the results obtained with AddiCAD will be compared with those from culture and molecular testing technologies. The study will examine the use of AddiCAD for both triage and confirmatory testing.

The project will assess performance in key patient subgroups, including those with a low microbial load and people living with HIV. The device will also be 'stress tested' to ensure it is robust enough for use in challenging primary care settings in the region.

The project team will also engage with key stakeholders to map out pathways for intellectual property management, regulatory approval and commercial sustainability.

The impact

The AddiCAD project could have a major impact on tuberculosis detection. If successful, it will:

- Show whether the promising performance data seen to date are confirmed in a larger study.
- Significantly enhance triage, reducing the number of patients referred for confirmatory testing, thereby saving costs.
- Provide an on-the-spot test for TB disease, allowing treatment to begin immediately.
- Create commercial opportunities for African-based product developers.

If shown to perform as expected, AddiCAD could significantly reduce the number of missed cases of TB, ensuring patients start treatment more rapidly and reducing opportunities for community spread of TB.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2029
Total project cost	€2 508 155,25
Global Health EDCTP3 funding	€2 176 905,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	(Other) emerging technologies
Project coordinator	STELLENBOSCH UNIVERSITY
Participating countries	South Africa, United Kingdom, Netherlands, Namibia, Germany, Switzerland



SWAB -IMPACT

SWAB-IMPACT: Swab-Based Molecular Testing for Impact on TB Diagnosis and Treatment

The SWAB-IMPACT project is assessing whether a novel technology platform could offer a more practical and affordable way to detect TB cases.

The challenge

Diagnosis of tuberculosis disease remains an enduring challenge. Of the 10 million people who develop TB each year globally, only around one in four receive a diagnosis. The 'missing millions' are not treated effectively and continue to transmit TB in the community.

Detection of cases has improved following the widespread introduction of molecular testing platforms, such as Gene Xpert. However, these are expensive and are typically based in centralised facilities, leading to delays in testing and lost contact with patients. Furthermore, testing typically relies on **sputum samples**. These can be difficult to obtain, particularly from young children and people living with HIV.

Rapid point-of-care tests for TB could therefore have an enormous impact by ensuring that newly diagnosed patients begin treatment promptly.

The project

The SWAB-IMPACT project is evaluating a possible solution to this challenge: a newly developed rapid point-of-care diagnostic platform, PlusLife MTB, which has the potential to be used on non-sputum samples (simple tongue swabs).

The PlusLife device has been shown to be **highly usable**, **relatively affordable**, and capable of delivering **good performance** – similar to Xpert Ultra on sputum samples, with only slightly lower performance on tongue swabs. The SWAB-IMPACT project is collecting the first evidence on its use in the field in high-burden settings.

The project is evaluating the PlusLife test in a **cluster randomised trial in South Africa and Zambia**. In clusters, tuberculosis programmes will either use standard methods to assess potential TB patients (referral to a regional lab for molecular testing) or an adapted pathway including the use of a PlusLife test. Both sputum-based and tongue-swabbing approaches will be assessed. The key outcome will be the number and proportion of patients who complete testing, have confirmed TB, and begin treatment within seven days.

During the trial, the project will also assess the feasibility and acceptability of implementing PlusLife testing by engaging key stakeholders, including patients, healthcare workers, and programme managers. Potential financial implications and cost-effectiveness will also be explored.

The impact

The SWAB-IMPACT project could have a radical impact on the detection of tuberculosis cases. It will:

- Provide high-quality evidence on the clinical utility of the PlusLife platform for detecting TB cases.
- Identify potential barriers and enablers of implementation and generate an implementation toolkit to aid wider introduction.
- Provide an indication of the potential cost implications of routine PlusLife MTB use.

More efficient detection of cases could have a profound impact on TB control, ensuring more patients begin treatment, reducing transmission and lowering the colossal TB disease burden, which disproportionately affects the poorest countries and communities.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2029
Total project cost	€2 352 076,25
Global Health EDCTP3 funding	€2 352 076,25
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	(Other) emerging technologies
Project coordinator	THE AURUM INSTITUTENPC
Scientific project leader	THE AURUM INSTITUTENPC
Participating countries	South Africa, Germany, Zambia, Ethiopia, United States, Benin





PRECISE-TBM

Prospective evaluation and refinement of novel biomarker-based point-of-care tests for the diagnosis of tuberculous meningitis in children

The PRECISE-TBM project aims to accelerate the detection of tuberculous meningitis, the deadliest form of TB that is a particular threat to children.

The challenge

Although tuberculosis is mostly a disease of the lungs, the bacterium that causes TB (*Mycobacterium tuberculosis*, Mtb) can also infect brain tissues. This can lead to a potentially deadly form of meningitis, tuberculous meningitis (TBM). The condition particularly affects children, leading to either death or long-term neurological conditions in around half of those who are successfully diagnosed and put on TB treatment. If the brain is infected with Mtb and the patient is not treated, it will certainly result in death.

One of the biggest challenges in TBM care is diagnosis. Symptoms are shared with multiple other conditions and there is no simple diagnostic test for TBM. It may take up to six visits to health facilities before a diagnosis is made, leading to significant delays in treatment initiation.

The project

The PRECISE-TBM project is building on previous EDCTP-funded research to develop a **rapid diagnostic test** for TBM suitable for use in sub-Saharan African settings.

In a previous EDCTP project, members of the PRECISE-TBM team discovered that the presence of three proteins (known as VEGF, MPO, and IFN- γ) in cerebrospinal fluid (CSF) samples was highly indicative of TBM. This led to the development of a prototype **lateral flow test** that could provide diagnostic information within 15 minutes.

The team has subsequently worked with a South African biotech company to transfer the test onto a new, more sensitive **biosensor platform**. In addition, it has identified a five-protein signature characteristic of TBM in **blood samples**, which could eliminate the need to collect CSF samples.

The PRECISE-TBM project is progressing both the CSF and blood-based biomarker technologies. The new biosensor version of the CSF-based test will be evaluated in a clinical study in South Africa, Zambia and Zimbabwe. The study will recruit more than 500 children with presumed meningitis and compare the performance of the CSF-based test with the gold-standard diagnostic assessment. In parallel, the blood-based biomarker test is being refined, and its performance is being evaluated using stored samples. It will then be transferred onto the biosensor platform and evaluated alongside the CSF-based tests.

The project is also conducting studies to assess a potential issue with the three-protein signature. IFN- γ is an important component of the host immune response to Mtb. However, the ability to generate IFN- γ responses varies within a population, and some people are at risk of Mtb infections because they are less able to produce IFN- γ . This could potentially lead to a false-negative TBM test result.

The project is therefore collecting data on IFN- γ responses in blood and CSF samples during the trial, to determine whether participants have antibodies against IFN- γ (which block its action) or carry genetic variants leading to low IFN- γ responses. It will then assess the implications of these findings for the reliability of test results.

The impact

The PRECISE-TBM project could have a major impact on the care of patients with TBM. It will:

- Generate clinical data on the performance of the three-protein CSF-based test.
- Create a potentially more accessible blood-based test and compare its performance with the CSF tests.
- Determine whether variation in IFN- γ responses might affect the reliability of test results.

A rapid point-of-care test for TBM could transform the diagnostic journey for TBM patients, most of them children, who currently face multiple visits to health facilities before receiving a diagnosis and being started on treatment.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2030
Total project cost	€2158 288,75
Global Health EDCTP3 funding	€2158 288,75
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	(Other) emerging technologies
Project coordinator	STELLENBOSCH UNIVERSITY
Participating countries	South Africa, Zimbabwe, Zambia, France, Germany



R2D2-xDRTB

Rapid Research in Next-Generation Diagnostics Development for Drug-Resistant Tuberculosis

The R2D2-xDRTB project is creating a platform to simultaneously evaluate multiple tools for detecting resistance to commonly used TB drugs.

The challenge

Every year, around 400,000 people develop tuberculosis infections resistant to commonly used drugs. These **multidrug-resistant infections** require longer and more intensive treatments, although new drugs have significantly shortened treatment duration and reduced toxicity.

However, less than half of patients with drug-resistant TB infections receive the appropriate treatment. Only around 50% are tested for the most common type of resistance, to **rifampicin**, and a much smaller number are tested for resistance to other key TB drugs, even though resistance levels are showing a worrying increase.

The main bottleneck is the availability of tests to assess **drug susceptibility**. Low-complexity molecular testing platforms exist but are primarily used to test for rifampicin resistance. Genome sequencing can provide information on multiple resistance genes, but requires complex infrastructure and is costly. Culture methods can provide comprehensive information on the drug susceptibility of infections but take weeks to complete.

To overcome this barrier, rapid, affordable and accessible drug susceptibility tests are needed. Multiple such tests are in development, but they must be clinically evaluated and validated.

The project

The R2D2-xDRTB project is building on an existing international platform for tuberculosis diagnostic evaluation to accelerate the assessment of new TB drug susceptibility tests.

The NIH-funded **R2D2 TB Network** has established an adaptive international platform for testing a variety of TB tests (for example, for diagnosis across different groups, for screening or drug susceptibility testing). It has established standard protocols across a network of sites in six countries, generating comparable data on more than 40 products, helping to advance products beyond the proof-of-principle stage.

In the R2D2-xDRTB project, the team is expanding on this approach by creating a platform specifically designed to evaluate the performance and validate **drug-susceptibility tests** for TB. It will focus on one specific use case - further testing of patients who have received a positive rifampicin resistance test. A total of 500 such adults and adolescents, as well as 100 patients with rifampicin-sensitive infections, will be enrolled in two high-burden countries (Georgia and South Africa). Results from the candidate tests will be compared with those from gold-standard drug-susceptibility testing to assess the accuracy of each test.

In addition to technical performance, the project will provide a platform for assessing the usability, acceptability, and feasibility of each product. This will be based on systematic consultation with end-users and an analysis of how well new tools would integrate into existing clinical pathways.

To provide policymakers with additional valuable evidence, the project will also develop models to estimate the potential epidemiological, health, and health-economic impacts of different implementation scenarios. These will provide insights into the likely cost-effectiveness of tools and the budgetary implications of their introduction.

The impact

The R2D2-xDRTB project will ensure that emerging tuberculosis drug-susceptibility testing tools receive a comprehensive and consistent evaluation. It will:

- Provide a rigorous assessment of the technical performance of TB drug-susceptibility testing tools.
- Assess their usability and compatibility with existing health system TB care pathways.
- Deliver a standardised analysis of their likely cost-effectiveness.
- Create a platform that can add new devices for evaluation as soon as they reach the appropriate point of development.

The R2D2-xDRTB project will accelerate the introduction of new TB drug-susceptibility testing tools, ensuring that patients more rapidly receive the most appropriate treatment, improving health outcomes and reducing disease transmission and wasteful use of health service resources on ineffective treatments.

Project at a glance	
Project duration	1 Jun 2026 - 31 May 2029
Total project cost	€2 258 415,50
Global Health EDCTP3 funding	€2 099 625,50
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITÄTSKLINIKUM HEIDELBERG
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	Germany, South Africa, Switzerland, Georgia, United States





ACT4KIDS-TB

Actiphage-supported Clinical Tools for Knowledge-driven Innovations in Diagnostic Solutions for TB in young children

The ACT4KIDS-TB project is assessing whether combining different data sources can enable a clinic-decision-making app that supports health care providers in better diagnosing TB in children in high tuberculosis-burden settings with limited numbers of specialists.

The challenge

Underdiagnosis of tuberculosis in children is a major global challenge. An estimated 1.25 million children develop TB each year, but less than half get diagnosed and treated. Globally, 96% of children who die from TB did not receive treatment; 80% of them are less than 5 years old.

TB diagnosis in children is highly challenging. Symptoms are shared with multiple other conditions. In addition, sputum samples can be difficult to obtain from young children, and TB disease typically involves a relatively small number of bacteria, making them difficult to detect. Chest X-rays can provide useful diagnostic information, but accurate interpretation and experienced readers are limited in many sub-Saharan African countries.

To guide decision-making, WHO has developed treatment decision algorithms for TB diagnosis, with separate versions depending on the availability of chest X-ray results. Computer-assisted diagnosis (CAD) tools have also been developed to automate analysis of chest X-ray results, but are not yet WHO-approved for children. Consequently, there remains considerable scope to improve TB diagnosis in children, particularly at lower levels of care, which may have fewer specialists but see the bulk of patients.

The project

The ACT4KIDS-TB project is developing an app based on WHO treatment decision algorithms but incorporating additional sources of information to provide a new tool to support the diagnosis of tuberculosis in children.

One advance is to integrate the results of Actiphage analyses of patients' blood samples into the decision-making tool. Actiphage is a relatively simple laboratory technique in which phages (viruses that infect bacteria) are used to break open Mycobacterium tuberculosis (Mtb, the bacterium that causes tuberculosis), increasing the amount of Mtb DNA that can be detected and, consequently, diagnostic sensitivity, particularly in paucibacillary disease, where conventional methods frequently fail to detect infection. This approach provides results within hours, requires only simple laboratory equipment, and is specific for viable Mtb cells, so it detects only active infections.

In addition, ways to improve Actiphage analysis are being explored, such as using finger-prick blood samples and collection devices that begin processing blood samples even before they arrive at a laboratory, to speed up the delivery of results. The Actiphage approach has shown promising results in TB detection studies involving adults. ACT4KIDS-TB will be the first to explore its use in children, for whom there is a dire need for sensitive, non-sputum-based point-of-care TB diagnostic tests.

A second potential source of information to be incorporated is CAD interpretation of chest X-ray images. The project will validate the application of this technology for children at the bedside.

A co-creation approach will be used to develop the app, which is designed to accept multiple inputs, calculate the probability of a TB diagnosis, and generate a 'treat/do not treat' recommendation. The app will initially be trained on a wide range of data sources from patients with well-characterised TB, with Actiphage and CAD data added when they become available. A large-scale consensus-building exercise will be used to establish a probability threshold above which TB treatment would be recommended.

To evaluate the new app, the project will organise a clinical study in Benin and South Africa, two high-burden countries with differing socioeconomic statuses. Recruiting around 200 children with presumed TB, the study will determine whether use of the app increases the number of children who are correctly diagnosed compared with standard methods of assessment.

The app will also provide guidance on household contact tracing when TB is likely, and also provide health workers with information on nutritional status, based on patient information provided, including recommendations for action for children with malnutrition. The project will additionally explore issues that might affect the implementation and use of the new app within health systems in sub-Saharan Africa.

The impact

The ACT4KIDS-TB project could help to address a major challenge in tuberculosis control and diagnosis of TB disease in children. It will:

- Create a simple-to-use tool to advise on clinical decision-making, suitable for use at lower levels of care in resource-limited settings.
- Demonstrate whether Actiphage technology is feasible to introduce and increase the likelihood of TB diagnosis.
- Show whether CAD systems for chest X-rays can improve childhood TB diagnosis at the bedside.

Project at a glance	
Project duration	1 Aug 2026 - 31 Jul 2030
Total project cost	€2 478 225,75
Global Health EDCTP3 funding	€2 059 163,75
Disease area	Tuberculosis
Intervention type	Diagnostics
Overarching topic	Digital technologies
Project coordinator	INSTITUUT VOORTROPISCHE GENEESKUNDE
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	Belgium, South Africa, Kenya, Benin



PANGenS

Pan-Africa network for genomic surveillance of poverty related diseases and emerging pathogens

The PANGenS project will introduce standardised approaches for identifying malaria and TB genetic variants associated with drug resistance across 12 sub-Saharan African countries.

The challenge

Drug resistance is an increasing challenge for both tuberculosis (TB) and malaria. Using antibiotics for TB and antimalarials such as artemisinin combination therapy (ACT) creates selection pressures that favour the spread of drug-resistant pathogens. A reduced response to drugs leads to poorer clinical outcomes for individuals and provides more opportunities for pathogens to spread through populations.

Genomic surveillance provides an opportunity to detect pathogens carrying genetic variants associated with drug resistance. This can provide policymakers with key information to shape disease control policies and treatment guidelines based on local patterns of drug resistance.

However, genomic surveillance capabilities are currently limited in sub-Saharan Africa. In addition to applying sequencing technologies, countries need to manage and analyse the huge volumes of data generated and develop tools to communicate findings to policymakers to inform actions. Many countries face similar challenges, so coordinated development of genomic surveillance capabilities will deliver significant efficiency gains.

The project

The PANGenS project is bringing together policymakers and representatives from national public health institute from 12 African countries (Ghana, Nigeria, South Africa, Togo, Benin, Sierra Leone, The Gambia, Liberia, Tanzania, Namibia, Mozambique and Gabon), the Africa Centre for Disease Control and Prevention (Africa CDC), and genomics researchers from Europe to develop a common platform for detecting and tracking resistance to anti-TB drugs and antimalarials.

The project will apply a shared technological approach, adapting newly developed technologies to characterise drug-resistant strains of TB bacteria and malaria parasites. A comprehensive training programme will cover key areas such as the use of sequencing technologies, bioinformatics analysis, and data management. Infrastructure upgrades will enable countries to apply the latest sequencing technology. PANGenS will also develop integrated data platforms that collate genetic data with the associated epidemiological and clinical data.

For TB, the project will have a particular focus on the emergence and spread of resistance to newer drugs, bedaquiline and clofazimine. Surveillance will also help to identify new mutations associated with drug resistance.

To maximise impact, national public health institutes, disease control programmes and the African Pathogen Genomics Initiative will be at the heart of project activities. An extensive programme of training activities will be undertaken, covering genomics, bioinformatics and data management, with hands-on workshops and the creation of a web portal for virtual bioinformatics training.

The impact

The PANGenS project will enhance the ability of a large group of countries in sub-Saharan Africa to track the spread of resistance to anti-tuberculosis and antimalarial drugs. It will:

- Provide a deeper understanding of drug-resistant TB and malaria in the African region.
- Help to identify hotspots where drug resistance is a particular challenge, so control efforts can be targeted more effectively.
- Feed into improved diagnostic tools able to identify a wider range of isolates carrying drug-resistance genes.
- Support research into the mechanisms of drug resistance.

These new insights will enable countries to adapt treatment policies as needed, better control the spread of resistance, and reduce the burden of disease associated with hard-to-treat, drug-resistant infections.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2027
Total project cost	€4 998 433,75
Global Health EDCTP3 funding	€4 998 433,25
Disease area	Tuberculosis, Malaria, Cross-disease or disease unspecific
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies, Health security
Project coordinator	FORSCHUNGSZENTRUM BORSTEL LEIBNIZ LUNGENZENTRUM
Participating countries	Germany, Ghana, South Africa, Netherlands, Benin, Nigeria, Tanzania, Mozambique, United Kingdom, Gabon, Namibia, Madagascar, Switzerland





TEST4TPT

AI assisted innovative low-cost skin testing model to accelerate person-centered TB prevention services in Tanzania, Mozambique and Uganda

The TEST4TPT project seeks to facilitate uptake of TB preventive treatment by enhancing early detection of exposure to TB bacteria.

The challenge

Approximately one in four people globally have been infected with the bacteria causing tuberculosis (TB), *Mycobacterium tuberculosis* (Mtb). However, only a proportion of those exposed to Mtb will progress to active TB disease, and the risk can be significantly reduced through a short course of anti-TB medications, known as TB preventive treatment (TPT).

Although TPT is recommended by the World Health Organization, its implementation in routine practice remains challenging. The main barrier is identifying people who have been exposed to Mtb but do not have TB disease. The tuberculin skin test (TST) requires repeated visits to healthcare facilities and assessment by healthcare workers; it also gives false-positive results in those who have been vaccinated with BCG. An IGRA test is more reliable but also more expensive; it requires laboratory infrastructure and is not easily deployable at scale.

A possible alternative is the Cy-TB skin test, which detects allergic responses to Mtb antigens. A preparation containing Mtb proteins is applied to the skin, generating a localised swelling that is significantly larger in people exposed to Mtb. This is as reliable as the IGRA test, is not affected by BCG vaccination or HIV status, and an affordable product is available (SIILTIBCY).

The project

The TEST4TPT project is assessing whether routine SIILTIBCY testing, potentially augmented with new AI-based tools to automatically assess skin reactions, can increase the number of people exposed to Mtb who receive and complete preventive treatment.

One drawback of the SIILTIBCY test is that it still requires a return trip to health facilities for an assessment after 2–3 days. However, assessment of skin reactions could potentially be carried out in the community by **community health workers**, reducing loss to follow-up.

A **community-based approach** could be facilitated by two new innovations: a specially designed QR-coded skin patch to guide test administration (**SmartPatch**), and an AI-driven **assessment app** that provides a test result and links results to a patient record (using the QR code on the patch). Supported by facility-based TB focal points, community health workers could then ensure that people who test positive start preventive treatment.

The TEST4TPT project is carrying out **field-based studies** to assess a new SIILTIBCY-based testing pathway. In a first step, reliability and inter-user consistency are being assessed at sites in Mozambique, Tanzania and Uganda. Results from the AI-based app generated by community health workers will be compared with the interpretations made by healthcare workers based on visual assessment, focusing on a mix of age ranges (adults, older children and young children).

Depending on the results obtained in this study, a combined **effectiveness/implementation study** will then be organised, comparing standard assessment procedures with the use of the SmartPatch and app by community health workers. Participants will be the household and other close contacts of patients newly diagnosed with TB, who are at increased risk of Mtb infection. If they are already showing signs of TB disease, they will be started on TB treatment and excluded from the study. The key outcome measures will be the numbers and proportions of participants who start and complete TPT.

In parallel, the team will carry out **acceptability and feasibility studies** to identify factors that could accelerate or hinder programmatic use of the new tools. A cost-effectiveness analysis will also be carried out for a range of implementation strategies.

The impact

The TEST4TPT project could lead to accelerated change in tuberculosis care and prevention. It will:

- Demonstrate whether detection of exposure to Mtb by SmartPatch/app use in the community can increase use of TB preventive treatment.
- Identify potential practical barriers to the new approach and its financial implications for TB care and prevention programmes.
- As an additional benefit, provide information on transmission in the community and the annual risk of infection in different age groups.

Tuberculosis preventive treatment (TPT) is an underexploited tool in TB care and prevention. More efficient detection of exposure to Mtb among contacts of new people with TB could facilitate greater TPT use, thereby reducing the number of people progressing to TB disease, limiting further transmission of Mtb, and reducing financial impacts on both households and health systems.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2029
Total project cost	€2 248 980,50
Global Health EDCTP3 funding	€2 248 980,50
Disease area	Tuberculosis
Intervention type	Other prevention tools, Diagnostics
Overarching topic	Digital technologies
Project coordinator	KONINKLIJKE NEDERLANDSE CENTRALE VERENIGING TOT BESTRIJDING DER TUBERCULOSE (KNCV)
Scientific project leader	MAKERERE UNIVERSITY LUNG INSTITUTE
Participating countries	Netherlands, Uganda, Tanzania, Mozambique, Spain, United Kingdom



Malaria



SMV delivery

Determining optimal approach to deliver malaria vaccine in seasonal transmission areas through Phase 4 implementation research

The SMV delivery project is exploring when and how to provide booster doses of malaria vaccine to children in areas with seasonal transmission to maximise their impact.

The challenge

The development of **malaria vaccines** was a major step forward in the battle against malaria. However, they do not completely eliminate the risk of malaria, and they are recommended to be used alongside other control measures, such as insecticide-impregnated bed nets and seasonal malaria chemoprevention (SMC). In addition, the malaria vaccine schedule is complex, requiring at least 4 doses in the first 2 years of life.

Malaria vaccination generally follows an age-based schedule, with a primary series of three doses given at monthly intervals starting at around 5 months of age. However, protection declines over time after vaccination, so at least one booster dose of vaccine is subsequently given to help maintain protection. This is generally also given according to an **age-based schedule** (~1 year after the priming doses). However, in areas where malaria cases typically occur only during certain months of the year, such as the Sahel, it has been suggested that a **seasonal schedule**, i.e. giving a booster dose just before the malaria season (regardless of the precise interval since their priming doses) would better protect young children during these crucial months, but this remains to be proven. Moreover, vaccine coverage is generally lower for later doses.

Discussions with policymakers suggest that the primary series of three doses is best delivered through countries' standard childhood immunisation programme, but there is less consensus on how booster doses should be delivered: through these same national childhood **vaccination clinics**, or through dedicated **community mass campaigns**.

The project

The SMV delivery project aims to compare the impact of three different malaria vaccine booster delivery strategies, following a standard initial three-dose primary series:

- Strategy 1: **Age-based delivery** of a booster dose through national childhood immunisation programme clinics.
- Strategy 2: **Seasonal delivery** of a booster dose through **national childhood immunisation** programme clinics.
- Strategy 3: **Seasonal delivery** of a booster dose through a **dedicated community mass campaign**.

To compare these approaches, two trials are underway, one in Guinea and one in Mali. Two matched areas have been identified in each country, and each will adopt a different strategy:

- **Guinea:** Age-based booster (strategy 1) versus seasonal booster (strategy 2).
- **Mali:** (Seasonal) booster delivered through childhood immunisation programme clinics (strategy 2) versus (seasonal) booster delivered through a community mass campaign (strategy 3).

The trials assess the effects of the two strategies on booster-dose coverage and the number of malaria cases. In addition, aspects such as cost-effectiveness, barriers to implementation, and caregiver and health worker attitudes toward different strategies are investigated, as is the impact of different booster-dose delivery strategies on vaccine-induced immune responses.

The impact

The SMV delivery project will generate evidence directly relevant to health policymakers. It will:

- Provide comparative evidence on the vaccine booster coverage and malaria control achieved by the different delivery strategies.
- Generate insights into barriers and facilitators that could affect the implementation of each strategy.
- Provide an indication of the cost implications of the different strategies.

The SMV delivery project is designed to provide policymakers with the evidence they need to introduce the optimal strategy to minimise malaria cases among young children, thereby further reducing deaths from this disease.

Project at a glance	
Project duration	1 Oct 2024 - 31 Mar 2028
Total project cost	€4 352 355,00
Global Health EDCTP3 funding	€4 352 355,00
Disease area	Malaria
Intervention type	Vaccines
Project coordinator	STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM
Scientific project leader	UNIVERSITE DES SCIENCES DES TECHNIQUES ET DES TECHNOLOGIES DE BAMAKO
Participating countries	Netherlands, Mali, Guinea, Spain, Australia



IMVACS

Building multidisciplinary evidence to support Integrating Malaria VACcine with Seasonal malaria chemoprevention in West Africa

The IMVACS project is assessing whether delivering malaria vaccines as part of seasonal malaria chemoprevention campaigns will strengthen protection against malaria.

The challenge

Although preventive measures have had a major impact, in malaria-endemic countries, the disease is so common that it continues to be a huge public health challenge, as more than 250 million cases occur each year in sub-Saharan Africa.

In areas where malaria is seasonal (most cases occurring during a particular period of the year), the WHO recommends seasonal malaria chemoprevention (SMC) – multiple rounds of pre-emptive antimalarial drug use – to protect young children against infection. More recently, two **malaria vaccines** – RTS,S/AS01 and R21/Matrix-M – have been shown to offer good levels of protection and are recommended for use alongside other control measures, such as insecticide-impregnated bed nets.

However, the malaria vaccine schedule is complex, involving a three-dose primary schedule in the first year of life and a fourth dose in year 2. As with most vaccines, it is recommended that doses be given at specific ages to optimise protection. Where malaria is highly seasonal, however, the age-based approach may be less effective than one in which a fourth booster dose is given directly before the malaria season, so that children are maximally protected when the risk of malaria is highest. Modelling suggests that seasonal vaccination would likely prevent more infections.

In addition, there is generally a **high take-up** of seasonal malaria chemoprevention. Integrating malaria vaccination with SMC campaigns might therefore improve vaccine coverage, which tends to be lower for later doses. While combining the two programmes would require careful operational coordination, it also offers an opportunity to build on existing delivery systems and strengthen real-world impact.

The project

The IMVACS project is testing the hypothesis that **integrating malaria vaccination with seasonal malaria chemoprevention (SMC)** might provide better overall protection, and is exploring the acceptability, feasibility, and cost-effectiveness of the integrated approach.

The project is **conducting a trial** in Burkina Faso and Mali, in areas where malaria transmission is highly seasonal and represents a major public health concern. The trial will compare the community-level malaria burden under two different vaccine delivery strategies:

- **Age-based delivery** for both the three-dose primary series and the booster dose, all provided through the national immunisation programme.
- Delivery of the primary vaccine series **during successive SMC rounds**, with the booster dose administered during the following year's SMC campaign.

The project team is working with a broad range of stakeholders to optimise the integrated delivery strategy in both countries. It is collecting data on malaria cases treated in health facilities, surveying communities at the end of the malaria season to assess infection rates, and tracking vaccine coverage achieved. Consultations with caregivers and health workers will provide insights into the acceptability and feasibility of the integrated approach. A cost-effectiveness analysis will also be carried out.

The impact

The IMVACS project will provide health managers with **highly policy-relevant evidence on malaria prevention**. It will:

- Show whether integration of malaria vaccination with seasonal malaria chemoprevention (SMC) leads to higher vaccine coverage and reduces the community burden of malaria.
- Reveal whether an integrated approach is practical to implement and acceptable to caregivers.
- Demonstrate whether the benefits justify any additional costs.

With malaria still requiring a multifaceted approach to prevention, the IMVACS project will show whether integration of SMC and vaccination further reduces the burden of malaria, thereby preventing even more childhood deaths and cases of serious disease.

Project at a glance	
Project duration	1 Dec 2024 - 30 Nov 2028
Total project cost	€5 736 729,64
Global Health EDCTP3 funding	€5 736 729,64
Disease area	Malaria
Intervention type	Vaccines
Overarching topic	Climate crisis or climate adaptation
Project coordinator	R-EVOLUTION WORLDWIDE SRL - IMPRESA SOCIALE
Scientific project leader	CENTRE NATIONAL DE RECHERCHE SCIENTIFIQUE ET TECHNOLOGIQUE INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTÉ
Participating countries	Italy, Burkina Faso, Mali, France, Switzerland, United States





OPT-MVAC

Optimising the delivery and uptake of malaria vaccines in countries with areas of highly seasonal transmission in West and Central Africa

The OPT-MVAC project is exploring whether strengthening national malaria vaccine programmes can serve as a springboard for improved coverage of other childhood vaccines.

The challenge

Malaria vaccination is being introduced across multiple countries in sub-Saharan Africa. Although it promises to save the lives of thousands of young children, delivering malaria vaccines poses significant practical challenges. In particular, four doses of vaccine have to be administered – more than for any other vaccine. Although some doses can be administered during clinic visits for other vaccines, additional visits must be scheduled at unfamiliar times, including during the second year of life. Additional efforts may therefore be needed to ensure that infants complete the schedule.

Given the major impact of malaria in affected countries, malaria vaccination has generally been welcomed by most populations. Efforts to increase coverage could be used to enhance uptake of other childhood vaccines, particularly those administered in the second year of life, such as the second dose of measles vaccine (MCV2).

The project

The OPT-MVAC project team previously worked on a project to increase the uptake of **seasonal malaria chemoprevention (SMC)** in areas where preventive malaria treatment is provided during months when malaria transmission peaks. Its approach was to use **implementation research** methodologies to identify and address practical barriers to the delivery and take-up of SMC.

In the OPT-MVAC project, the team is using a similar approach to optimise the delivery of malaria vaccination and to leverage these efforts to improve the coverage of other vaccines. It is focusing on countries in West and Central Africa where malaria is highly seasonal. Here, there is interest in **intensifying malaria vaccination efforts** ahead of the malaria season to maximise the number of children protected. These efforts also provide an opportunity to check children’s vaccination records and to provide catch-up vaccination when necessary.

The project will carry out an initial investigation to understand why caregivers have not had their children vaccinated against malaria. These insights will be used to design interventions to address key barriers and increase uptake, with a focus on intensification before the malaria season. The project will also draw on learnings from SMC programmes, which typically reach a very high proportion of households.

A household survey will be conducted at baseline to measure vaccine coverage and repeated after the intervention to assess its impact. In each country, activities will be coordinated by a

locally led **country steering committee**. The project uses an innovative approach: providing **small grants and technical assistance** to national immunisation programmes to enable them to study their local contexts and introduce tailored interventions.

These activities will initially focus on year 1 of vaccination, before being repeated in year 2 of the vaccination schedule. In a subset of countries, the work will provide a foundation for measuring malaria vaccine effectiveness, while a detailed costing and cost-effectiveness analysis will be carried out in a further four countries.

The impact

The OPT-MVAC project will help strengthen vaccine delivery across a wide area of sub-Saharan Africa, which accounts for a significant proportion of the malaria disease burden. It will:

- Identify barriers and potential enablers of malaria vaccination.
- Place country teams central to activities so that solutions are tailored to local contexts.
- Strengthen implementation research capacity within national immunisation programmes, expertise that can be applied to other immunisation challenges.
- Strengthen connections within and between countries to promote the sharing of learnings.

With malaria still one of the biggest causes of child mortality in sub-Saharan Africa, and malaria vaccines known to reduce mortality by more than 10%, the project could save tens of thousands of lives a year by increasing vaccine coverage.

Project at a glance	
Project duration	1 Jan 2025 – 30 Jun 2029
Total project cost	€5 297 181,25
Global Health EDCTP3 funding	€5 297 181,25
Disease area	Malaria
Intervention type	Vaccines, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Environment and biodiversity, Climate crisis or climate adaptation
Project coordinator	LUXEMBOURG INSTITUTE OF HEALTH
Scientific project leader	UNIVERSITÉ IBADERTHIAM DE THIES
Participating countries	Luxembourg, Senegal, Germany, Switzerland, United Kingdom



PfVIMT

A Multi-stage Malaria Vaccine for Control and Elimination

The PfVIMT project will move an innovative transmission-blocking malaria vaccine a major step towards authorisation.

The challenge

Malaria vaccines are one of the most significant public health advances of the past decade and are being rolled out across multiple countries in sub-Saharan Africa. The two licensed malaria vaccines, **RTS,S** and **R21**, have the potential to save hundreds of thousands of children’s lives every year.

However, these vaccines are of moderate efficacy, and work continues on next-generation products. Malaria parasites have a complex life cycle, and vaccines could potentially target different stages of parasite development. RTS,S and R21, for example, both interfere with parasite invasion of **liver cells**, which provide a safe haven for the initiation of parasite multiplication.

But there is also interest in targeting a later stage – the **gametocytes** that are taken up by mosquitoes and develop into the form that can reinfect people. This strategy – known as **transmission blocking** – does not directly prevent infection or illness in vaccinated individuals but reduces parasite circulation and the total malaria burden in a community.

The project

The PfVIMT project team has been working on a highly promising transmission-blocking malaria vaccine, **Pfs230D1**. Field studies supported by EDCTP2 and U.S. NIH have shown that it is highly effective at reducing parasite transmission in school-age children and adults – groups that typically experience less severe disease but are an important reservoir of parasites that sustain transmission within communities.

In the Global Health EDCTP3-funded PfVIMT project, the team is combining Pfs230D1 with the existing vaccine R21 to develop a product with both **disease-prevention and transmission-blocking** activity.

Initially, a phase II study is planned in Mali, in which various formulations and doses of Pfs230D1 combined with R21 and will be tested in school children and adults. This study will assess the transmission-blocking effects of the vaccine using a ‘**direct skin feeding assay**’, through which laboratory-bred mosquitoes are allowed to feed on naturally infected participants and are then dissected to determine whether they contain malaria parasites (and how many). Prior vaccination with a Pfs230D1-containing vaccine should reduce both the number of mosquitoes that take up parasites and the parasite load in infected mosquitoes. Once the new combination has been shown to be safe, studies will begin enrolling younger children, down to 5 years of age.

The phase II study of the combination vaccine will establish the **efficacy to block mosquito transmission**. The safety and efficacy will then be confirmed in a multi-country phase III trial involving participants of all ages 5 years and older, again using the direct skin feeding assay to assess its impact on transmission. Based on the observed effects on mosquitoes, the team will use modelling to estimate the likely impact on the malaria disease burden when entire communities receive the vaccine.

The key advantage of the direct skin feeding assay is that results are available very quickly, supporting regulatory submissions through accelerated approval mechanisms. Actual impacts on disease incidence and malaria burden can be determined in post-licensing phase IV studies.

The impact

The PfVIMT project will advance the development of a combination malaria vaccine that could provide additional public health benefits. It will:

- Establish the safety and efficacy of a Pfs230D1+ R21 combination vaccine.
- Generate the evidence needed to support an application for regulatory approval.

If the promise of Pfs230D1+R21 is confirmed, a combination vaccine could be used across a much wider age group than is currently vaccinated, significantly reducing both symptomatic and asymptomatic infections and further reducing the burden of this critical disease.

Project at a glance	
Project duration	1 Mar 2025 – 28 Feb 2030
Total project cost	€15 028 272,50
Global Health EDCTP3 funding	€14 996 172,50
Disease area	Malaria
Intervention type	Vaccines
Project coordinator	INSTITUT DE RECHERCHE POUR LE DÉVELOPPEMENT
Scientific project leader	UNIVERSITE DES SCIENCES DES TECHNIQUES ET DES TECHNOLOGIES DE BAMAKO
Participating countries	France, Mali, Ghana, Burkina Faso, United Kingdom, Tanzania, Benin, Kenya, United States, Nigeria, Guinea, Belgium, Liberia





MVC-2G

Optimising a Deployable High Efficacy Multi-Stage Vaccine for Plasmodium falciparum Malaria: 2nd Generation Malaria Vaccine Consortium

The MVC-2G project is advancing a second-generation malaria vaccine targeting an additional stage in the malaria parasite life cycle.

The challenge

The development of effective malaria vaccines was a major step forward in malaria control. They are now being used in more than 20 countries in sub-Saharan Africa to protect young children, alongside other control measures such as insecticide-impregnated bed nets.

However, the two currently licensed vaccines, RTS,S/AS01 and R21/Matrix-M, have moderate efficacy and only target the pre-erythrocytic (liver) stage of the parasite life cycle. There remains scope to improve their impact by also intervening at the blood stage, when parasites invade and multiply within red blood cells.

The project

Members of the MVC-2G project have focused on target antigens central to red blood cell invasion, and the potential to combine these antigens with R21/Matrix-M in a second-generation vaccine product. Since R21-induced immunity appears to be independent of natural blood-stage immunity, targeting both pathways in a single product should provide an additional layer of protection.

The **RH5 protein** is essential for red blood cell invasion and is highly conserved across *Plasmodium falciparum* malaria parasite strains. Studies in UK adults have shown that immunisation with RH5 reduces parasite growth rates. Safety and tolerability of RH5-based vaccines have been confirmed in Tanzania, while a Phase 2b study in Burkina Faso demonstrated significant efficacy against clinical malaria in young children.

In addition, structural analysis of the multi-protein complex critical to red blood cell invasion revealed another highly conserved structure that could be included in a vaccine. An antigen derived from this structure, known as **R78C**, strengthens the immune response induced by RH5.

Building on these promising findings, the MVC-2G project is extending clinical evaluation of blood-stage and multi-stage vaccine approaches in young children in Burkina Faso, including longer-term follow-up to further assess safety, immunogenicity and durability of protection, as well as additional evaluation of R78C and proof-of-concept combinations with R21 in a seasonal transmission setting. In parallel, the project is advancing clinical development through Phase 2b trials in children aged 5 to 17 months, comparing the safety and efficacy of a second-generation multi-stage vaccine candidate incorporating R21, RH5.1 and R78C with R21 alone, and optimising its delivery strategy for use in endemic settings.

In addition, the project is exploring whether a simplified vaccination schedule could be adopted. Four doses of the R21/Matrix-M vaccine are currently administered at different ages during the first two years of life. This requires caregivers to make special visits to health facilities, outside the routine childhood immunisation schedule. The MVC-2G project is therefore conducting a study in Uganda to optimise dosing schedules, including alternative four-

dose schedules better aligned with routine immunisation visits, to assess their safety and ability to elicit strong immune responses.

A Phase 2b trial of an optimised schedule will then be run in Sierra Leone and Burkina Faso, representing different transmission settings, both perennial and seasonal.

Ultimately, elimination of malaria will require vaccination of older children and adults, who typically acquire natural immunity and do not experience significant disease but are an important reservoir of malaria parasites. The MVC-2G project is thus also generating data to support the use of the vaccine in older age groups for elimination. A Phase 1b trial in Tanzania will first be conducted to optimise the vaccination schedule and downselect the most promising regimen. This selected regimen will then be evaluated in subsequent studies, including controlled human malaria infection (CHMI) studies in Kenya to assess safety and efficacy in adults, and an age-de-escalation study in Nigeria to assess safety and immunogenicity in older children.

The impact

The MVC-2G project will generate critical data on a second-generation multi-stage malaria vaccine, building on the R21/Matrix-M vaccine. It will:

- Demonstrate whether the combination vaccine is more effective at preventing malaria in young children than R21/Matrix-M alone.
- Reveal whether more practical vaccination schedules in young children could offer good protection, which in turn could provide programmatic benefits.
- Generate data on multi-stage vaccines in older children, who are less susceptible to malaria disease but are a key reservoir of parasites driving transmission.
- Build capacity for malaria vaccine trials, including in Nigeria, which has not hosted such major trials before, despite having a very high malaria burden.

Project at a glance	
Project duration	8 Sep 2025 – 7 Sep 2030
Total project cost	€14 999 800,00
Global Health EDCTP3 funding	€14 999 800,00
Disease area	Malaria
Intervention type	Vaccines
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Women's health
Project coordinator	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD
Scientific project leader	CENTRE NATIONAL DE RECHERCHE SCIENTIFIQUE ET TECHNOLOGIQUE, INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTÉ
Participating countries	United Kingdom, Burkina Faso, Nigeria, Denmark, Tanzania, Senegal, Germany, Sierra Leone



R21-PD

R21/M-Malaria vaccine to extend the protection of Post-Discharge Malaria Chemoprevention in children recovering from severe anaemia: a randomised-controlled trial in Malawi, Kenya and Uganda

The R21-PD project is exploring whether malaria vaccination benefits children discharged from hospital after treatment for severe anaemia, who remain at high risk of death.

The challenge

Anaemia is common among children in sub-Saharan Africa, due to malnutrition, malaria and other infections. Severe anaemia is treatable, but successfully treated children remain highly vulnerable after discharge from hospital, and at elevated risk of readmission and death.

In malaria-endemic areas, **malaria** is a major cause of readmission. High mortality after treatment of anaemia has been partially addressed through **post-discharge malaria chemoprevention** – provision of antimalarial drugs to children over the first few months after they leave hospital. This has been shown to reduce the risk of death by 77% and the risk of readmission by 55%. The WHO recommends this strategy and has been introduced in several African countries.

Despite its success, post-discharge malaria chemoprevention offers protection for only 3–4 months, while the elevated risk of death extends out to 12 months. Longer periods of preventive treatment could be considered, but this would be expensive, and adherence becomes a major challenge with long courses of drugs.

The project

Having pioneered the use of post-discharge malaria chemoprevention, the R21-PD project team is exploring whether an **R21/Matrix-M malaria vaccine booster** could provide longer-term protection after hospital discharge.

With malaria vaccination being rolled out widely in sub-Saharan Africa, many hospitalised children are now likely to have been vaccinated. A booster dose could generate an additional immune response during the post-discharge period of vulnerability. It takes 2–4 weeks for immune responses to peak after vaccination, during which time children would be protected by conventional malaria chemoprevention.

To test this theory, the project is carrying out a clinical trial in moderate- to high-transmission areas of Kenya, Malawi, and Uganda. More than 600 children treated for severe anaemia will be randomised to either standard post-discharge malaria chemoprevention or 'enhanced' protection with the addition of

an R21/Matrix-M vaccine boost. The trial will evaluate whether this approach further reduces mortality and the risk of readmission during the following year.

The project will also explore the acceptability of the new approach to key groups, such as caregivers and health workers, and estimate its likely cost-effectiveness and budget impact.

The impact

The R21-PD project could help to protect a highly vulnerable group of children. It will:

- Determine whether R21/Matrix-M vaccination further reduces post-discharge mortality after treatment for severe anaemia.
- Show whether the strategy is feasible, acceptable and offers good value for money.

With more than half of all children in sub-Saharan Africa being affected by anaemia, enhancing protection against malaria during the critical first year after hospital recovery could not only significantly reduce mortality but also reduce pressures on health systems by preventing readmission.

Project at a glance	
Project duration	1 Nov 2025 – 31 Oct 2030
Total project cost	€5 325 102,49
Global Health EDCTP3 funding	€5 325 102,49
Disease area	Malaria
Intervention type	Vaccines, Therapies
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	LIVERPOOL SCHOOL OF TROPICAL MEDICINE
Scientific project leader	TRAINING & RESEARCH UNIT OF EXCELLENCE LIMITED
Participating countries	United Kingdom, Malawi, Uganda, Norway, Kenya, United States





IMPRIMA

Implementing Primaquine Single Low Dose in Africa

The IMPRIMA project is working with national stakeholders and communities to ensure the successful introduction of new primaquine formulations explicitly targeted to young children.

The challenge

As countries progress towards malaria elimination, additional strategies will be needed to identify and treat malaria infections and prevent transmission of the malaria parasite. One tool that is not yet fully used is single low-dose primaquine. Unlike most other antimalarials, primaquine acts on gametocyte stages of the parasite's life cycle, the form taken up by mosquitoes and transmitted to a new host.

Although the antimalarial activity of primaquine is well-established, its use has been held back because of its effects on people with glucose-6-phosphate dehydrogenase (G6PD) deficiency, which is common in sub-Saharan Africa. G6PD is important to red blood cell function, and people with G6PD deficiency are at increased risk of anaemia when given standard primaquine doses.

However, a single low dose of primaquine is still effective against gametocytes and can safely be given to children with G6PD deficiency. The WHO recommends using single low-dose primaquine alongside conventional malaria treatments like artemisinin combination therapies (ACT). Nevertheless, residual fears about impacts on children with G6PD deficiency have led to limited use of single low-dose primaquine.

A further obstacle has been the formulation of primaquine. Standard tablets are large and bitter-tasting, making them difficult to administer to young children.

The project

Through a previous EDCTP2-funded project, the Developing Pediatric Primaquine, the team has been working on a child-friendly version of primaquine suitable for single low-dose use in children. It has developed smaller tablets, shown that they have the same biological properties as existing products, and worked with children and caregivers on preferred flavourings to mask the bitter taste of primaquine.

The Global Health EDCTP3-funded IMPRIMA project will work with national malaria control programmes in Burkina Faso, Burundi and Madagascar to understand and address barriers to the introduction of this new child-friendly version of primaquine, providing a model for introduction in other countries. Burkina Faso and Burundi have signalled an interest in introducing single low-dose primaquine for children, while Madagascar has introduced it for adults but not yet for children.

In particular, the project will address residual concerns about the effects of primaquine on children with G6PD. It will carry out a trial comparing standard ACT treatment of malaria in children with enhanced treatment including single low-dose primaquine, paying particular attention to the risk of anaemia. The trial will be undertaken in Burkina Faso, Burundi and Madagascar, countries with different geographies and intensities of malaria transmission.

The project team will also carry out extensive community engagement to understand and address community concerns and to pave the way for successful implementation.

The impact

The IMPRIMA project will generate key evidence on the efficacy and safety of single low-dose primaquine. It will:

- Provide national decision-makers in Burkina Faso, Burundi and Madagascar with key evidence on the safety of single low-dose primaquine, the likely main barrier to introduction.
- Demonstrate to other countries the feasibility of introducing primaquine into their malaria control programmes.

Although not directly benefiting individuals with malaria infections, routine use of single low-dose primaquine would help to disrupt malaria transmission, delivering population-level benefits and accelerating malaria elimination.

Project at a glance	
Project duration	1 Apr 2023 - 31 Mar 2027
Total project cost	€3 969 906,25
Global Health EDCTP3 funding	€3 967 406,25
Disease area	Malaria
Intervention type	Therapies, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITÉ DE STRASBOURG
Participating countries	France, Netherlands, Burkina Faso, Madagascar, United Kingdom, Burundi



SEMA ReACT

SEvere MAlaria treatment with Rectal artesunate and Artemisinin-based Combination Therapy [in remote settings]

The SEMA ReACT study will determine whether children with severe malaria can be treated entirely in the community, when transportation to health facilities is difficult or impossible.

The challenge

Children living in remote rural locations who develop severe malaria are at high risk of dying before they get to health facilities for treatment. As they may be unable to take oral medicines, rectal artesunate suppositories have been developed, which can be administered by community health workers to keep children alive while they are transported to a health facility.

In trials, rectal artesunate suppositories have been shown to be highly effective at reducing parasite numbers, and dramatically cut death rates in remote settings. However, a programmatic evaluation following introduction of rectal artesunate in the Democratic Republic of the Congo (DRC), Nigeria and Uganda found that, after introduction, survival rates actually fell. This led WHO to suspend its recommendation of rectal artesunate use where it wasn't introduced.

The programmatic evaluation was a 'before and after' comparison rather than a controlled trial, complicating interpretation of the data. Other factors may have affected survival rates after introduction of rectal artesunate use, including delays in transporting children to facilities to complete their antimalarial treatment, for example because of geographic challenges or financial barriers such as transport costs.

The project

The SEMA ReACT project is carrying out a study to evaluate a revised treatment strategy for severe malaria, incorporating rectal artesunate, in settings where access to health facilities is challenging.

In many rural settings, non-severe malaria is already treated by community health workers, who use rapid diagnostic tests to identify cases of malaria and then administer oral artemisinin combination therapy (ACT). However, they are not able to administer injectable artesunate. For severe malaria, the recommended approach has been to immediately administer rectal artesunate then refer children to health facilities, for the administration of injectable artesunate followed by three days of oral ACT.

Focused on remote rural areas of DRC and Zambia, the SEMA ReACT project will compare this approach to one based solely on treatment in the community. After initial administration of rectal artesunate, community health workers will provide children with oral ACT in the community.

The project will compare the efficacy of each approach and survival rates. It will also assess whether the two approaches lead to any differences in drug resistance, as there are concerns that use of artesunate as a monotherapy could promote the development of resistance. The feasibility and acceptability of the two approaches will also be investigated.

The impact

The SEMA ReACT project will generate critical data on a community-based strategy for treatment of severe malaria in remote rural settings where transport to a health facility is challenging. It will:

- Demonstrate whether the community-based approach delivers outcomes similar to those achieved when children are transported to health facilities to complete their treatment.
- Generate evidence to inform WHO policymaking and recommendations on strategies to optimise the use of rectal artesunate for severe malaria.

If the study shows that severe malaria can be effectively treated by community health workers, this would provide an important new option for remote rural settings, with the potential to reduce deaths of some of the most vulnerable children in Africa.

Project at a glance	
Project duration	1 Apr 2023 - 31 Mar 2027
Total project cost	€3 984 316,25
Global Health EDCTP3 funding	€3 984 316,25
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITEIT ANTWERPEN
Participating countries	Belgium, Democratic Republic of the Congo, Tanzania, Zambia





PDMC Saves Lives

Post-discharge malaria chemoprevention in children with severe anaemia in Benin, Kenya, Malawi and Uganda: Formative and implementation research for policy decision-making and implementation

The PDMC Saves Lives project is helping countries identify the best way to introduce a life-saving new approach to prevent deaths from malaria in children with severe anaemia discharged from hospital.

The challenge

Children leaving hospital after being treated for severe anaemia are at greatly increased risk of readmission and death over the following months. Often, this is due to malaria infection, to which they remain highly vulnerable.

Several studies have shown that this increased risk of death can be dramatically cut by providing children with a course of antimalarial drugs to prevent malaria infections – an approach known as post-discharge malaria chemoprevention (PDMC).

Some countries, including Malawi and Uganda, have made a policy decision to begin PDMC. However, there is little evidence, and therefore no formal guidance, on exactly how PDMC should be introduced. Hence, while PDMC has been recommended by WHO, no practical guidance on implementation has yet been produced. Key issues include choice of antimalarial, optimal delivery method, and integration with other malaria control strategies, such as seasonal malaria chemoprevention.

The project

The PDMC Saves Lives project aims to close this knowledge gap by generating additional evidence on the practicalities of PDMC implementation. It includes collaborations with policymakers in Malawi and Uganda, as well as in Benin and Kenya, four malaria-endemic countries that have not yet developed a PDMC policy.

The project team will undertake extensive consultation with stakeholders at different levels – national policymakers, district-level health staff, frontline health workers and community representatives – to explore the issues that could influence the success of a PDMC programme. Approaches that could be used include self-administration of antimalarial drugs prompted by mobile phone calls or texts, or distribution of drugs to households by community health workers.

Initial research will inform the design of implementation trials in Benin and Kenya, which will be co-designed with national ministries of health. A multifactorial design will be used so that multiple different variants of implementation strategies can be assessed in a single study. Running the trial in two countries

will provide evidence relating to two different health systems and populations. The trial's key outcome measure will be the adherence of children to the recommended course of antimalarial treatment.

Based on the trial results, the project team will engage with policymakers to develop or update guidance. A health economic analysis will also be undertaken to inform decision-making.

The impact

The PDMC Saves Lives project will provide important evidence on the practicalities of PDMC delivery within health systems. The project's findings will:

- Facilitate the development of PDMC policy in different malaria-endemic countries in East and West Africa.
- Identify key factors affecting the implementation of PDMC, helping to shape countries' implementation plans.
- Generate guidance for policymakers and a practical toolbox to support national implementation of PDMC.
- Generate evidence to inform WHO implementation guidance.

Ultimately, the findings of the project will enable more malaria-endemic countries to introduce a strategy that, as well as preventing the deaths of young children, is also likely to deliver cost savings to health systems.

Project at a glance	
Project duration	1 Jul 2023 – 31 Dec 2026
Total project cost	€4 531 137,01
Global Health EDCTP3 funding	€4 531 137,00
Disease area	Malaria
Intervention type	Therapies, Other prevention tools
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	INSTITUT DERECHERCHE POUR LE DEVELOPPEMENT
Participating countries	France, United Kingdom, Malawi, Uganda, Benin, Kenya



ASAAP-plus

Clinical evaluation of AntimalarialS tri-therapy with AtovAquone-Proguanil for treatment of uncomplicated malaria in African children

The EDCTP2-funded ASAAP study has received additional Global Health EDCTP3 funding to complete its evaluation of a novel 'triple therapy' for malaria.

The challenge

Malaria continues to pose a threat across a large swathe of sub-Saharan Africa. An estimated 250 million cases occur each year, leading to more than 600,000 deaths.

Although effective antimalarial treatments exist, particularly **artemisinin combination therapies (ACTs)**, there are concerning signs that their effectiveness is being compromised by the emergence and spread of drug-resistant parasites in sub-Saharan Africa. Although drugs remain effective, in some cases they are taking longer to kill parasites.

If ACT resistance takes hold, this would seriously undermine efforts to control malaria in sub-Saharan Africa. Delays in the introduction of ACTs after a previous generation of drugs were compromised led to the deaths of thousands of people, mostly children. It is therefore essential to act now so that steps can be taken immediately should ACT resistance become a major problem.

The project

Funded through the EDCTP2 programme, the ASAAP project focused on one possible strategy: developing 'triple ACTs' by adding an additional drug to existing antimalarial combinations. The idea is that the third drug protects the ACT, since parasites would need to develop resistance to each component of the combination to survive treatment. If the different components of the treatment have different mechanisms of action and different targets, a parasite would need to simultaneously acquire mutations in multiple genes, which is highly unlikely.

The ASAAP-plus project has focused on a commonly used ACT, artemether-lumefantrine (AL), combined with atovaquone-proguanil (AP). AP is known to be an effective antimalarial, but until recently, its use in sub-Saharan Africa was limited by its high cost. However, a cheaper generic form is now available.

AP has an additional advantage: it targets more than one stage of the malaria life cycle. Unlike AL, AP also has activity on blood-stage parasites, so it could have an additional benefit by reducing transmission of parasites to new hosts via mosquitoes.

Although AL and AP are both highly effective antimalarials, a clinical trial is still needed to demonstrate that the triple combination treatment is equally effective and safe. The ASAAP-plus trial is comparing the AL-AP combination with AL alone in a trial involving more than 1,600 young children in Benin, Gabon, Ghana, and Mali, at sites with differing malaria transmission intensities.

The project team is also carrying out pharmacokinetic studies to determine whether administering the drugs together has any effect on their levels in different tissues, which might require modification of dosing. The project is investigating transmission-blocking effects by testing whether mosquitoes that feed on treated patients become infected with malaria parasites.

The study was severely affected by the COVID-19 pandemic, leading to delays in regulatory approvals and the supply of trial materials. The new funding will enable the ASAAP-plus project to complete the main trial, conduct the pharmacokinetic studies, investigate transmission-blocking activity, and explore whether the triple therapy has any impact on the presence of genetic markers of drug resistance.

The impact

The ASAAP-plus project will provide key data on a possible new approach to malaria treatment. It will:

- Demonstrate whether, as expected, the triple therapy is as effective as its individual components.
- Reveal whether the triple therapy has additional public health benefits by blocking transmission.

Should its safety and efficacy be confirmed, the triple therapy could be rapidly deployed should ACT resistance begin to spread within sub-Saharan Africa, ensuring that children can still benefit from a highly effective antimalarial treatment.

Project at a glance	
Project duration	1 Jan 2024 – 31 Dec 2026
Total project cost	€1 499 996,25
Global Health EDCTP3 funding	€1 499 996,25
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	BERNHARD-NOCHT-INSTITUT FUER TROPENMEDIZIN
Scientific project leader	KWAME NKUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY KUMASI
Participating countries	Germany, Ghana, Mali, Benin, Burkina Faso, France, Gabon, South Korea, United States





PYRAPREG-extended

Efficacy and Safety of a newly registered Artemisinin-Based Combination (Pyronaridine–Artesunate –PYRAMAX®) for the treatment of uncomplicated malaria in African pregnant women – Extended

Additional Global Health EDCTP3 funding is completing the evaluation of a new antimalarial treatment for pregnant women.

The challenge

Because of hormonal and immunological changes, pregnant women are particularly vulnerable to malaria infections. As well as affecting maternal health, such infections can cause a range of adverse birth outcomes, including stillbirths and premature delivery. Around 30 million pregnant women are exposed to malaria infections in sub-Saharan Africa each year, leading to an estimated 10,000 maternal deaths and up to 200,000 infant deaths.

Several highly effective artemisinin-based combination therapies (ACT) have been developed to treat malaria. However, for safety reasons, pregnant women are typically excluded from key clinical trials, so there are limited data to support the use of some key ACTs in pregnancy. There is a need to increase the therapeutic options to treat malaria during the 2nd and 3rd trimester of pregnancy with one combination treatment, such as **pyronaridine–artesunate (PA)**, also known as Pyramax®, which has been developed by the Medicines for Malaria Venture (MMV) and Shin Poong Pharm and is active against both *Plasmodium falciparum* and *P. vivax* malaria.

PA has an excellent safety profile, and pre-clinical studies suggest that it is unlikely to harm developing babies. However, robust clinical data on safety and efficacy are required before the treatment can be recommended for pregnant women.

The project

Funded through the EDCTP2 programme, the PYRAPREG project has organised a clinical trial comparing the treatment success and safety of PA and two other widely used ACTs, artemether–lumefantrine (AL) and dihydroartemisinin piperazine (DP). The project aimed to recruit nearly 2,000 pregnant women diagnosed with malaria, who were randomly allocated to one of the three treatments. The trial is being conducted in Burkina Faso, the Democratic Republic of the Congo (DRC), the Gambia, Mali, and Mozambique, at sites with varying intensities of malaria transmission.

Recruitment into the trial was disrupted by the COVID-19 pandemic. The additional funding from Global Health EDCTP3 will enable the project team to complete a one-year follow-up of newborns to confirm safety and to finalise trial data analysis.

In addition, the project is carrying out pharmacokinetic (PK) studies to determine how pyronaridine is metabolised and distributed through various body tissues. By providing information on drug concentrations in different tissues, PK studies are important for establishing optimal dosing – achieving

concentrations sufficient to kill parasites without raising safety concerns. Due to their differing physiology, pregnant women may require different dosages. Since malaria infection also affects drug metabolism, drug levels in pregnant women are being compared with those in non-pregnant women who are also being treated for malaria.

The impact

The PYRAPREG project will generate key data on the safety and efficacy of pyronaridine–artesunate (PA) in pregnant women. It will:

- Provide high-quality evidence on PA to inform national and global decision-making.
- Identify whether existing dose levels are appropriate for pregnant women.
- Potentially expand the range of treatment options available for malaria treatment in pregnant women.
- Enable ACTs to be used more selectively, for example, allowing some treatment options to be reserved for intermittent preventive treatment in pregnancy (IPTp).

As pregnant women are typically excluded from pivotal clinical trials, they are generally among the last to benefit from new medical interventions. The PYRAPREG-extended project will ensure that they gain access to a highly effective new malaria treatment, which will help to reduce the impact of the disease on both them and their babies.

Project at a glance	
Project duration	1 May 2024 – 30 Apr 2025
Total project cost	€1 539 644,56
Global Health EDCTP3 funding	€1 539 644,56
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Women's health
Project coordinator	STICHTING AMSTERDAM UMC
Scientific project leader	UNIVERSITE DES SCIENCES DES TECHNIQUES ET DES TECHNOLOGIES DE BAMAKO
Participating countries	Netherlands, Mali, Democratic Republic of the Congo, Mozambique, Spain, Sweden, Burkina Faso, Switzerland



SAFIRE

Safety of antimalarials in the first trimester: An adaptive platform trial

The SAFIRE project is establishing an innovative adaptive clinical trial platform to evaluate antimalarial treatments for women in the first trimester of pregnancy.

The challenge

Women are particularly vulnerable to malaria during pregnancy. Malaria infections can affect both their health and that of their foetus, increasing the risk of stillbirth and other adverse pregnancy outcomes.

Early pregnancy is a particularly vulnerable time. More than seven million women are exposed to malaria during the first trimester every year, leading to half a million infections. Preventive antimalarial treatments cannot be used at this time because of concerns about their impact on the developing foetus. Generally, insecticide-impregnated bed nets are provided at a second antenatal visit, during the second trimester.

As pregnant women are typically excluded from clinical trials, data on the safety and efficacy of antimalarial treatments are often lacking, leading to long delays before women begin to benefit from new drugs. Although artemisinin combination therapies (ACTs) have long been known to be effective treatments for malaria, they were first recommended by the WHO for use in pregnancy only in 2022, as data from observational studies confirmed their safety.

Even now, due to a lack of data, only one ACT is recommended for use in the first trimester of pregnancy (**artemether–lumefantrine, AL**), even though the WHO recommends using a range of treatments to limit the risk of drug resistance.

The project

Pregnant women could potentially benefit from multiple ACTs, including treatments that are of greater efficacy and longer acting, providing better protection against reinfection. Relying on pregnancy registries to collect safety data would lead to long delays in access. Data could be generated more rapidly through a clinical trial.

The SAFIRE project has been designed to deliver high-quality safety and efficacy data on newer ACTs in women in the first trimester of pregnancy. It has adopted an innovative **adaptive platform design**, which will allow multiple treatments to be compared with AL. Initial work will focus on a comparison with **pyronaridine–artesunate** (PA, Pyramax), which appears to provide longer-lasting protection and is increasingly being introduced in Africa. Additional studies will be integrated when funding is available. For example, the Medicines for Malaria Venture (MMV) has expressed an interest in assessing dihydroartemisinin–piperazine (DHP) in this population.

The project is adopting a highly **participatory approach**, engaging with global and national stakeholders on trial design, to ensure that the evidence generated is sufficient to inform decision-making. It is also engaging with communities and pregnant women to discuss the potentially sensitive issue of research in early pregnancy, ensuring support for the trial and informing its design.

The impact

The SAFIRE project will provide key evidence on the safety, efficacy and acceptability of pyronaridine–artesunate (PA, Pyramax) and potentially other ACTs in women in early pregnancy. It will:

- Establish whether such women can benefit from new, highly effective ACTs.
- Provide countries with more options for the treatment of malaria in this group.
- Generate communication materials to support the introduction of new treatments.
- Create a platform for the evaluation of additional treatments in pregnant women.
- Build capacity in adaptive trial designs and clinical trials in early pregnancy.

Ultimately, the project will ensure that women in early pregnancy benefit more rapidly from newly developed antimalarials, reducing the number of women and babies harmed by malaria infections during pregnancy.

Project at a glance	
Project duration	1 Jun 2024 – 30 Nov 2028
Total project cost	€5 191 431,44
Global Health EDCTP3 funding	€5 191 431,44
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Women's health, Antimicrobial resistance (AMR) or drug resistance
Project coordinator	STICHTING AMSTERDAM UMC
Scientific project leader	KENYA MEDICAL RESEARCH INSTITUTE
Participating countries	Netherlands, Kenya, Democratic Republic of the Congo, Mali, Uganda, Burkina Faso





CUREMAL

Innovative Transformative CURE for MALARia: Rapid-Action Combinations to Replace Artemisinins

The CUREMAL project is advancing a new antimalarial drug that could provide a much-needed alternative to artemisinin-based agents, to which malaria parasites are becoming increasingly less sensitive.

The challenge

Malaria remains one of the most serious health threats across much of sub-Saharan Africa. Globally, more than 250 million cases occur each year, leading to an estimated 600,000 deaths annually, mostly in Africa.

Uncomplicated malaria is typically treated with **artemisinin combination therapies (ACTs)**, pairs of drugs that include derivatives of artemisinin. However, there are growing concerns that malaria parasites are becoming less sensitive to artemisinin derivatives. New drugs are thus urgently needed in case resistance to artemisinin-based compounds becomes more widespread and severe.

The project

The CUREMAL project is advancing a highly promising new antimalarial, **GSK3772701**, developed by GlaxoSmithKline (GSK). Like artemisinin derivatives, GSK3772701 is a potent, fast-acting *P. falciparum* whole-cell inhibitor with a novel mode of action and is active against both sensitive and multidrug-resistant parasites. Encouraging safety findings have been observed in phase I studies, and no parasites exhibiting reduced sensitivity to the compound have yet been detected.

The CUREMAL project is organising **two sequential phase II trials** in sub-Saharan Africa. The first will be a **safety and pharmacokinetic study** of GSK3772701 in Gabon and Uganda, using different doses and treatment durations in adults with uncomplicated malaria.

A **follow-on trial** will then assess the **efficacy** of the most promising treatment schedules when GSK3772701 is **combined with pyronaridine**. This study will involve children, adolescents and adults with malaria in Gabon, Tanzania and Uganda. This trial will begin in adults and then recruit younger age groups once safety and efficacy have been confirmed.

In addition, the project will **genetically analyse malaria parasites** from infections that are not cleared, screening for known resistance genes and sequencing parasite genomes to detect new variants associated with reduced drug susceptibility. Susceptibility testing studies will also be carried out to provide insights into the mechanisms of action of any resistance genes detected.

The impact

The CUREMAL project will provide initial efficacy data on a highly promising new antimalarial. It will:

- Confirm the safety of GSK3772701 in African populations and provide the first efficacy data.
- Demonstrate whether treatment duration can be reduced from three days to two days.
- Provide critical data on the presence of antimalarial resistance genes, enhancing monitoring of the spread of resistance.

If early promising findings are confirmed, data from the CUREMAL project would support the development of a definitive phase III trial, which would generate the data needed for licensing and introduction of this much-needed new class of antimalarial drug.

Project at a glance	
Project duration	1 Jun 2026 – 30 Nov 2030
Total project cost	€22 888 140,53
Global Health EDCTP3 funding	€8 417 294,00
Disease area	Malaria
Intervention type	Therapies, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation
Project coordinator	GLAXOSMITHKLINE INVESTIGACION Y DESARROLLO SL
Scientific project leader	Centre de Recherches Medicales de Lambaréné
Participating countries	Spain, Gabon, Mozambique, Tanzania, Switzerland, Uganda, Germany, South Africa



ASAQ-PAC

Advancing child-friendly artesunate-amodiaquine taste mask coated micro pellets to combat the threat of artemisinin resistant malaria in Africa

The ASAQ-PAC project is developing a child-friendly version of a key antimalarial combination to enable malaria control programmes to use a mix of treatments to reduce the pressures driving drug resistance.

The challenge

For many years, **artemisinin combination therapies (ACTs)** have been the mainstay of antimalarial drug treatments. Recently, however, genetic mutations have been detected in malaria parasites that reduce their sensitivity to the artemisinin-derived component of such treatments; this is referred to as artemisinin partial resistance. While ACTs remain effective, the spread of less-sensitive strains could be devastating if parasites also develop resistance to the second component of an ACT. Six different ACTs are available to treat malaria. Most countries currently use **artemether-lumefantrine (AL)** as their first-line ACT. However, to reduce drug pressure that drives resistance, the WHO now recommends that countries adopt a **mix of ACTs**, known as multiple first-line treatments. Modelling suggests that the concurrent use of multiple therapies better protects drugs against resistance than periodic switching between drugs. **Artesunate-amodiaquine (ASAQ)** is another effective ACT but is less commonly used. One key barrier is the lack of an age-appropriate, fixed-dose combination of ASAQ suitable for young children. Currently, tablets have to be broken up and dissolved in water, which can lead to inaccurate dosing and poor adherence because AQ has a very bitter taste.

The project

The ASAQ-PAC project is evaluating a new ASAQ formulation that overcomes these challenges, paving the way for its **wider use among young children in Africa**. Formulating AS and AQ together has been a challenge: they need to be kept separate because AS is unstable and prone to degradation when in direct contact with AQ. Existing fixed-dose combination tablets compress the drugs in separate layers. However, the ASAQ-PAC project team has developed an alternative approach in which the individual drugs are encapsulated in **micropellets**, coated with a material that prevents the two compounds from coming into contact.

In addition, the innovative ‘MicroCoat’ technology masks the bitter taste of AQ and prevents the micropellets from clumping together during manufacturing. The micropellets can be made separately for AS and AQ, then combined in a ‘stick pack’ – a disposable pouch that allows the micropellets to be placed directly on a child’s tongue or dispersed in water. This process is compatible with standard manufacturing processes and is easy to scale up at a relatively low cost. It is a technology that could be readily transferred to manufacturing sites in low- and middle-income countries, including those in sub-Saharan Africa. In addition, all the other materials used in manufacture have already been shown to be safe for children, and ASAQ micropellets have been shown to be palatable in studies with adults in the UK. The ASAQ-PAC project is now conducting studies in sub-Saharan Africa to generate the evidence needed to support its adoption by African countries.

The main clinical evaluation will be a trial in Malawi comparing 28-day cure rates in children with uncomplicated malaria given either standard ASAQ tablets or the new micropellets. Although ASAQ is known to have good antimalarial activity, a key challenge is to demonstrate that the new formulation delivers sufficient levels of the drugs in the blood to be effective. This requires detailed

pharmacokinetic studies, whereby multiple blood samples are taken and blood concentrations measured. Repeated blood draws are not feasible for young children. Therefore, as an alternative, the project will assess day 7 levels of desethylAQ, the main active AQ metabolite, which provides a good proxy for drug exposure. We will compare the day 7 desethylAQ concentrations between standard ASAQ tablets and the micropellets in the two clinical studies of the project.

In addition, the project is taking advantage of this trial to generate additional data on a **child-friendly version of primaquine**, developed by the EDCTP-funded Developing Pediatric Primaquine (DPP) project that has developed tropical fruit-flavoured tablet formulations to mask the bitter taste of primaquine. The WHO recommends that single low-dose primaquine be used alongside ACTs, as it has activity against late-stage, sexual malaria parasites, called gametocytes, which are taken up by mosquitoes and seed new infections. Blocking transmission, therefore, reduces the community disease burden. This second study will compare the effect of adding primaquine to the micropellet formulation of ASAQ on transmission-blocking. The transmission-blocking activity will be assessed using a **membrane-feeding assay**, in which laboratory-grown mosquitoes feed through an artificial membrane on blood samples from trial participants. The number of mosquitoes that become infected with malaria parasites following feeding provides an indication of transmission-blocking activity.

The impact

The ASAQ-PAC project could have a significant impact on malaria treatment in Africa. It will:

- Demonstrate whether a child-friendly formulation of artesunate-amodiaquine (ASAQ) is as potent as standard ASAQ.
- Enable ASAQ to be used more widely among children as part of multi-therapy strategies to delay the development of resistance to artemisinin combination therapies (ACTs).
- Generate additional data on the potential of a child-friendly version of primaquine to reduce the community burden of malaria.
- Create commercial opportunities to manufacture the micropellet formulation of ASAQ in Africa.

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2029
Total project cost	€2 099 745,75
Global Health EDCTP3 funding	€2 099 745,75
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD
Scientific project leader	KAMUZU UNIVERSITY OF HEALTH SCIENCES
Participating countries	United Kingdom, Malawi, France, Germany





WANECA M 3

Single dose cure of falciparum malaria using next generation combinations

The WANECA M 3 project is advancing novel non-artemisinin drug combinations as potential innovative single-dose treatments for malaria.

The challenge

Artemisinin-based combination therapies (ACTs) have been the mainstay of malaria treatment for decades. However, strains of the malaria parasite less susceptible to the artemisinin component of ACTs have been detected in various sub-Saharan African countries, raising fears that such treatments could be rendered ineffective and highlighting the need for new drugs with different mechanisms of action.

In addition, the current standard of care for malaria uses **three-day treatment regimens**. It is estimated that up to half of patients do not complete the recommended course, increasing the risk of resistance.

The project

Building on an existing EDCTP-funded clinical trial network in West Africa, the WANECA M 3 project is utilising a clinical trial platform established by Novartis to test new antimalarial compounds. The project brings together African and European researchers, Novartis, and the Medicines for Malaria Venture (MMV), a public-private partnership focused on new antimalarial development.

The key aim of the new WANECA M 3 project is to develop a new antimalarial combination that does not include artemisinin-related components and is sufficient to cure infections when given as a single dose.

The project focuses on three investigational compounds that show highly promising action against malaria parasites and have raised no safety flags in clinical studies to date:

- **Cipargamin (KAE609)**: A potent and fast-acting antimalarial which is active against multiple species of *Plasmodium*, has a novel mechanism of action, and also shows activity against gametocytes – the stage in the *Plasmodium* life cycle that is taken up by mosquitoes, suggesting it will also have transmission-blocking activity.
- **INE963**: A highly active and long-lasting antimalarial with an unknown mechanism of action and a high barrier to resistance.
- **MMV533**: A fast-killing and long-lasting antimalarial, also with an unknown mechanism of action.

Notably, in studies to date, there has been no evidence that malaria parasites develop resistance to these compounds when used in combination.

To advance a new treatment, the phase II PLATINUM platform will be used to test the efficacy and safety of a combination of cipargamin and INE963 against uncomplicated malaria in children aged 2–12 years. In an additional study arm, the efficacy of different doses of MMV monotherapy will be assessed in adults.

Depending on the results of the phase II study arms, a large phase III trial will then be run comparing the chosen dual or triple combination antimalarial when given as a single-dose treatment to a 3-day regimen of standard of care. The clinical program will generate sufficient robust data to support a marketing authorisation application. The clinical studies will include WANECA M 3 partners in Burkina Faso, Gabon, Kenya, Mali and Uganda, with a site in Ethiopia also intended to join phase III following capacity building.

In addition, the project is generating data on gametocyte clearance to reduce onward malaria transmission and on drug resistance by screening all participants for known resistance genes.

The impact

The WANECA M 3 project could lead to a radical shift in the treatment of malaria. It will:

- Reveal whether promising antimalarial compounds can be as effective and safe as 3-day artemisinin-based combination therapies (ACTs) when given as a single-dose malaria treatment.
- Generate the data required to support marketing authorisation applications.
- Demonstrate whether the new combination could also reduce community disease burdens through transmission-blocking effects.
- Generate extensive new data on patterns of drug resistance at multiple sites across sub-Saharan Africa.

A single-dose treatment for malaria would be easier for health systems to deliver and for patients to take, ensuring rapid cure while reducing the risk that treatment effectiveness is undermined by poor compliance and adherence.

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2031
Total project cost	€27 982 115,45
Global Health EDCTP3 funding	€10 296 177,50
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	STICHTING AMSTERDAM UMC
Scientific project leader	UNIVERSITE DES SCIENCES DES TECHNIQUES ET DES TECHNOLOGIES DE BAMAKO
Participating countries	Netherlands, Mali, Kenya, Ethiopia, Burkina Faso, Switzerland, Uganda, United Kingdom, Germany, Gabon



FACT

Antibiotic-based combination therapy fosmidomycin-artesunate-clindamycin for the concurrent treatment of severe malaria and bacterial blood stream infections in African children

The FACT project is developing an innovative treatment that targets both severe malaria and bacterial bloodstream infections in children.

The challenge

Malaria remains a major public health challenge, particularly in the Global South, causing around 600,000 deaths each year. Most deaths occur in children in sub-Saharan countries.

Severe malaria is a medical emergency requiring immediate treatment. However, the fever of malaria overlaps with symptoms of other serious conditions, including invasive bacterial infections. About one-third of patients treated for severe malaria are **misdiagnosed**, and invasive bacterial (co-)infections are the most common missed underlying cause. Even a positive rapid diagnostic test result for malaria may not be conclusive. Malaria is highly prevalent among healthy individuals in endemic regions, and even when *Plasmodium parasites* are present, they may not be the primary cause of illness.

For these reasons, the WHO recommends that children with suspected severe malaria are treated with the injectable antimalarial artesunate, accompanied by **broad-spectrum antibiotics**. In practice, many children do not receive both treatments. Also, artesunate alone increases the risk of parasites escaping treatment, with particular concern for mutations associated with partial resistance to artemisinins. Many African countries also face a growing challenge from antibiotic resistance, highlighting the use of antibiotics with different modes of action.

The project

The FACT project is evaluating a **new treatment approach** that simultaneously covers severe malaria and common bacterial pathogens affecting children in sub-Saharan Africa. It reduces the risk of antimalarial resistance and shortens treatment duration.

The treatment is a novel **antibiotic-based combination therapy** that combines two licensed drugs and one in late-stage development:

- **Artesunate**: standard antimalarial for severe malaria.
- **Fosmidomycin**: a drug in late-stage development with activity against *Plasmodium* parasites and Gram-positive bacteria.
- **Clindamycin**: a licensed drug with activity against *Plasmodium* parasites and Gram-negative bacteria.

This triple combination enhances the spectrum of antimalarial activity and introduces antimicrobial properties. All drugs are individually safe and effective and work in oral combination in adults and children. Importantly, the three drugs have different mechanisms of action while maintaining compatible pharmacokinetic properties, including short half-lives. This combination protects individual partners from developing drug resistance. The full treatment regimen will be delivered by injection in the hospital, further reducing the risk of resistance by ensuring full treatment courses are completed. The combination will also **shorten in-hospital treatment** from up to 6 to 4 days.

The FACT consortium is conducting a **randomised controlled phase II trial** in **Gabon** to determine an optimal dosing for parenteral treatment. At the outset of the development program,

different treatment regimens will be evaluated in children with uncomplicated malaria, using an age-step-down algorithm.

Once the optimal dose of fosmidomycin has been determined, a **randomised controlled multi-country phase III trial** will be conducted in the **Republic of Congo, Ethiopia, Gabon and Ghana**. Children with severe malaria will be randomised to receive either the triple combination or the usual standard of care.

The project team is also conducting susceptibility testing to determine the sensitivity patterns of *Plasmodium* parasites to antimalarial drugs. It will also genotype isolates for genes known to be associated with partial artemisinin resistance. Parasites causing breakthrough infections will be fully sequenced to identify potentially new resistance genes. Similarly, any bacterial pathogens identified will undergo antibiotic susceptibility testing.

Additional studies will examine the **cost-effectiveness** of the new approach, and its **acceptability** to key stakeholders, including community members, will be explored.

The impact

The FACT project will advance a new treatment strategy for severe malaria with several potential advantages. It will:

- Assess if FACT novel triple therapy is as effective as current monotherapy with artesunate for severe malaria.
- Provide an efficacious artemisinin-based treatment option for severe malaria in line with WHO recommendations.
- Reveal whether triple therapy leads to improved outcomes due to additional effects on bacterial bloodstream infections.
- Help to protect individual drugs from selection for parasite resistance.
- Reduce the time spent in hospital by up to two days, financially benefiting both households and health systems.

Project at a glance	
Project duration	1 Sep 2026 – 31 Aug 2031
Total project cost	€12 383 785,94
Global Health EDCTP3 funding	€10 139 216,25
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	BERNHARD-NOCHT-INSTITUT FUER TROPENMEDIZIN
Scientific project leader	CENTRE DE RECHERCHES MEDICALES DE LAMBARÉNÉ
Participating countries	Germany, Gabon, Ethiopia, Austria, Ghana, Congo





RAMP

Ravidasvir to combat the emergence and spread of artemisinin resistance in Africa: a phase 2 and 3 clinical trial to assess its efficacy

The RAMP project is advancing the development of a novel antimalarial drug with the potential to both treat the disease and block the transmission of malaria parasites.

The challenge

Artemisinin combination therapies (ACTs) have proven highly effective in treating **malaria**, saving millions of lives. However, there are growing concerns that parasites in Africa are becoming less susceptible to artemisinin derivatives, particularly in East Africa. While this has not yet had a major impact on clinical outcomes, if parasites also develop resistance to an ACT partner drug, this could seriously undermine the effectiveness of ACTs.

Various strategies are being advanced to address this challenge. One is the use of ‘**triple ACTs**’, which contain a third antimalarial drug. A malaria parasite would need to develop resistance to three distinct drugs with different modes of action to survive such treatments. In addition, WHO recommends using drugs with **transmission-blocking activity**, such as primaquine, alongside ACTs. These drugs target a late stage in parasite development, so they do not prevent disease directly but reduce the risk that parasites will be transmitted to others, delivering community-wide benefits.

The project

The RAMP project is advancing development of an existing antiviral drug, **ravidasvir**, which is not only an effective antimalarial but also has transmission-blocking activity. It has the potential to be added to an existing ACT – not only protecting the ACT against the development of resistance but also reducing community transmission of malaria parasites.

Ravidasvir, developed as a treatment for hepatitis C virus (HCV) by DNDi and Pharco Pharmaceuticals, has completed phase III trials with minimal safety concerns and is now approved in Malaysia for HCV treatment in combination with sofosbuvir. In a screen of a chemical library, it was found to have activity against malaria parasites: it reduces the flexibility of parasite-infected red blood cells, causing them to be removed by the spleen. It can be taken orally and is relatively inexpensive. It has not been tested in children, but other drugs with the same biochemical target have been found to be safe for use in children.

Given this promising backdrop, the RAMP project is assessing the safety, efficacy and transmission-blocking activity of ravidasvir in combination with an existing ACT, dihydroartemisinin–piperaquine (DP). DP has no effect on parasite transmission, so any transmission-blocking activity observed following treatment with the new combination will be due to ravidasvir.

First, a study in Gabon (CERMEL) will assess the ability of ravidasvir to clear asymptomatic infections in adult carriers. Increasing doses of ravidasvir will be assessed to identify the optimal dose for future studies.

Next, a trial in Mali (USTTB) will assess efficacy and transmission-blocking activity in adults with malaria. This study will compare the effects of DP alone, DP plus ravidasvir, and DP plus primaquine, so the transmission-blocking activity of ravidasvir can be compared with

that of primaquine. This activity will be assessed using a **membrane feeding assay**, in which laboratory-grown mosquitoes are given the opportunity to feed on participants’ blood samples through an artificial membrane; the number of mosquitoes that become infected provides a measure of transmission-blocking activity.

Finally, a multi-centre trial will be run in Gabon, Ghana (KNUST/ KCCR), Mali and Uganda (EPICENTRE), comparing the efficacy of the new triple therapy with an existing ACT. The trial will start with older children, enrolling earlier age groups once the combination has been shown to be safe.

The project is also conducting consultations with caregivers about their perceptions of malaria and the use of transmission-blocking drugs to assess their likely acceptability and any potential barriers to their use.

In addition, it assesses the activity of the drug combination on parasites carrying mutations known to affect sensitivity to artemisinin derivatives. It is also screening for such mutations in malaria cases detected in the trial and sequencing parasites to identify potential new genetic variants associated with drug resistance.

The impact

The RAMP project will advance a highly promising new antimalarial that has already been licensed for human use. It will:

- Confirm the antimalarial activity of ravidasvir alone and when combined with an existing ACT.
- Quantify its transmission-blocking activity in comparison to primaquine.
- Demonstrate its safety and efficacy in the key target group, young children.
- Generate additional data on the presence of resistance genes across trial sites.

Project at a glance	
Project duration	1 Sep 2026 - 31 Aug 2031
Total project cost	€13 921 281,24
Global Health EDCTP3 funding	€10 298 968,75
Disease area	Malaria
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE
Scientific project leader	KWAME NKUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY KUMASI
Participating countries	France, Ghana, Mali, Egypt, Germany, Gabon, Tanzania, Ethiopia



PvSeroRDT

A point-of-care serological rapid diagnostic test for risk of Plasmodium vivax hypnozoite infection (PvSeroRDT)

The PvSeroRDT project is exploring whether a new diagnostic test for Plasmodium vivax could underpin a test-and-treat strategy for this increasingly important malaria parasite.

The challenge

Most cases of malaria in sub-Saharan Africa are caused by *Plasmodium falciparum* (*P. falciparum*). However, a significant proportion are caused by a related species, *Plasmodium vivax* (*P. vivax*). This species, responsible for more than 500,000 cases a year, is particularly common in areas such as the Horn of Africa and is becoming more important as control of *P. falciparum* improves. Ultimately, eliminating malaria will require effective control of both *P. vivax* and *P. falciparum*.

A key difference between the two parasites is that *P. vivax* lies dormant in the liver before reactivating, leading to a resurgence of symptoms. Conventional malaria diagnostics do not detect this dormant form, which also serves as a reservoir of parasites in the population, contributing to ongoing disease transmission.

P. vivax infections can be treated with **primaquine**. However, primaquine cannot be easily used in population-wide campaigns, because it is harmful to people with an enzymatic deficiency known as G6PD, which is relatively common in sub-Saharan Africa.

The project

The PvSeroRDT project is assessing whether a newly developed rapid diagnostic test for *P. vivax*, which can detect dormant liver forms of the parasite, could be used in a **test-and-treat strategy** targeting entire communities.

Very few *P. vivax* parasites survive in the liver (potentially fewer than 10), so direct detection is challenging. Instead, the PvSeroRDT test detects **antibodies to key *P. vivax* proteins** that persist for several months after infection, covering the period when the parasite lies dormant in the liver. The plan is to use this diagnostic, along with a G6PD test, as part of a community-wide test-and-treat strategy (**PvSeroTAT**) to identify and treat asymptomatic cases of vivax malaria, thereby preventing relapses and reducing disease transmission.

The PvSeroRDT test is a lateral flow test type assay with a reader for interpretation of results, which should be available within 30 minutes. It has been shown to perform well in the laboratory but needs to be tested in the field. It is being evaluated further using stored blood samples and in field trials at sites in Ethiopia, Madagascar and Senegal.

The device is being prototyped in the UK, with final production planned to be transferred to a diagnostics manufacturer based in Senegal. The PvSeroRDT project will include studies to investigate the acceptability and usability of the device, to inform final designs and implementation strategies. National policymakers are being engaged to draw up a roadmap for policy change and implementation. The project is also analysing costs and exploring what product attributes are most important and what policymakers would be willing to pay for different features.

The impact

The PvSeroRDT project is addressing a key challenge on the pathway to malaria elimination. It will:

- Reveal whether the PvSeroRDT test works well in the field and can be used to identify infected but asymptomatic individuals for treatment.
- Identify a pathway to regulatory and policy approvals to facilitate its uptake by countries.
- Provide a boost to the diagnostic manufacturing sector in Africa, with projected demand of up to a million tests a year.

The PvSeroRDT project could usher in a new approach to vivax malaria control. Modelling suggests a successful deployment could reduce the prevalence of *P. vivax* by 60–80%. This would deliver significant public health benefits, particularly in areas where *P. vivax* is most common and *P. falciparum* is becoming better controlled.

Project at a glance	
Project duration	1 Feb 2025 - 31 Jan 2030
Total project cost	€4 062 396,23
Global Health EDCTP3 funding	€4 062 396,23
Disease area	Malaria
Intervention type	Diagnostics
Overarching topic	Digital technologies
Project coordinator	INSTITUT PASTEUR
Scientific project leader	INSTITUT PASTEUR DE DAKAR
Participating countries	France, Senegal, Ethiopia, Switzerland





PATHFINDER

Point-of-care Lab-on-Chip Detection of Host Response in Febrile Illness for Diagnosis and Etiology Research

The PATHFINDER project is using advanced ‘lab-on-a-chip’ technology to provide more refined diagnostic information to guide treatment of fever in children.

The challenge

Diagnosis is fundamental to medical care, but diagnosis of infectious diseases can be highly challenging. Many infections share similar symptoms, such as fever, and testing for a wide range of pathogens individually is inefficient and not necessarily reliable – an organism detected might not be the main cause of symptoms, or a causative agent might be missed if not present at the sampling site.

As a result, in many settings, there is a high rate of **misdiagnosis** or use of non-specific **syndromic treatment**. This means that patients do not necessarily receive the best treatment, and antibiotics are being used when not needed, driving the development of antimicrobial resistance (AMR).

An alternative diagnostic strategy is to **focus on the person (host) rather than the pathogen**. It is now clear that host responses to different types of pathogens vary significantly. In particular, **differences in gene activity** can provide a signature of the type of infection (for example, whether it is bacterial, viral or malaria) and even identify specific pathogens.

However, detecting the host response currently relies on sophisticated **laboratory analyses**. For it to deliver practical benefits, it needs to be packaged into devices that provide affordable, practical solutions suitable for low-resource settings.

The project

The PATHFINDER project is building on ground-breaking research into **host gene activity signatures** associated with infection, combined with innovative ‘**lab-on-chip**’ technology that enables sophisticated molecular analyses to be performed in compact devices suitable for use in routine healthcare settings.

Focusing on **fever in children**, the project is developing an easy-to-use point-of-care device that will generate key diagnostic information from a single blood sample. The results of its analysis will provide the probability that a patient has a bacterial or viral infection, as well as the likelihood of TB or malaria infections.

The project is based on a two-step process. First, RNA transcripts are extracted from blood samples using the **system**. This requires no laboratory equipment or specialist skills and has already been successfully used in rural village settings in Burkina Faso and The Gambia.

The outputs from the RNA processing step are then analysed by a . This channels the sample into **ten microfluidic chambers**, each of which can be analysed separately to generate a wealth of information about gene activity levels. The information generated is analysed on the device to provide the user with the probabilities of different infection types, all within 20 minutes.

The PATHFINDER project is refining the assays, fine-tuning RNA extraction, and comparing the device’s results with equivalent

laboratory tests. ProtonDx, the developer of Lacewing, will incorporate input from key stakeholders, including healthcare workers and community members, into its design specifications.

A **field evaluation** will then be carried out in Burkina Faso and Ghana, in which results will be gathered for 1,000 children with fever, of varying ages. The results will be compared with those obtained from tests currently used clinically, as well as from a wide range of additional laboratory tests. A range of samples from patients with confirmed diagnoses will also be tested to assess diagnostic performance.

The project team will also carry out extensive stakeholder engagement to identify a **regulatory pathway to approval**, approaches to ensure **commercial sustainability**, and an **access plan** for eventual production of the device in Africa. Extensive analyses of study data will provide an indication of its potential impact based on a range of implementation strategies, which will also provide insights into its likely cost-effectiveness.

The impact

The PATHFINDER project could have a profound impact on diagnostic practices in sub-Saharan Africa. It will:

- Provide field data on the ability of the new device to detect tuberculosis and malaria infections in children with fever, and to distinguish between viral and bacterial infections.
- Provide clinicians with information enabling the use of the most appropriate treatments.
- Reduce the inappropriate use of antimicrobials, lessening the pressures driving AMR.
- Generate real-time epidemiological information that can be automatically shared with health authorities.

Project at a glance	
Project duration	1 Oct 2026 – 31 Mar 2030
Total project cost	€3.218.121,12
Global Health EDCTP3 funding	€2.753.896,12
Disease area	Malaria, Tuberculosis, Cross-disease or disease unspecific
Intervention type	Diagnostics
Overarching topic	Antimicrobial resistance (AMR) / drug resistance, Digital technologies, (Other) Emerging technologies
Project coordinator	IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE
Scientific project leader	CENTRE NATIONAL DE RECHERCHE SCIENTIFIQUE ET TECHNOLOGIQUE, INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTÉ
Participating countries	United Kingdom, Burkina Faso, Ghana, Netherlands



MARC SE-Africa

Mitigating Antimalarial Resistance Consortium in South-East Africa

The MARC-SE Africa project is enabling key countries in Africa to track and respond to rising rates of resistance to antimalarial drugs.

The challenge

Sub-Saharan Africa bears the brunt of malaria infections. After a downward trend in the global malaria burden, progress has stalled since the COVID-19 pandemic. Moreover, new challenges are on the horizon – particularly the emergence and spread of malaria parasites with reduced sensitivity to artemisinin or other components of artemisinin combination therapies (ACTs).

ACTs were introduced when malaria parasites developed resistance to previous generations of drugs. However, the slow replacement of compromised drugs led to many unnecessary deaths, highlighting the importance of a rapid response to the emergence of resistance. Several actions can be taken in response to reduced ACT sensitivity, including rotation of different ACT combinations, boosting of ACTs with additional drugs (triple combination therapy), and wider use of low-dose primaquine to reduce parasite transmission.

The project

The MARC-SE project is working to ensure that policymakers in multiple countries in Southern and East Africa have rapid access to comprehensive data on patterns of resistance to antimalarials. Although data are generated on resistance, they are typically collected non-systematically and communicated through scientific papers, a format that is not easy for policymakers to use. This can lead to delays in changes to treatment policy.

The MARC-SE project will begin by mapping the stakeholders involved in malaria policymaking, how they interact with one another, and the evidence they need to guide decision-making. Based on these insights, the project team will develop a data-sharing platform that provides a near-real-time and high-resolution map of patterns of drug resistance. The exercise will also highlight gaps in surveillance where more data are needed.

The project will collate all available data and integrate it within the existing infrastructure of the Worldwide Antimalarial Research Network (WWARN), creating a South-East African regional data resource. Through modelling, risk maps will be generated across 19 countries, illustrating where treatment failure is most likely to develop.

As part of the project, the team will also work with ministries of health to develop a regional action plan, to create a concrete action plan for adaption and implementation of WHO guidance on responding to malaria resistance. The team will also work with

four priority countries to adapt the regional action plan according to their national context. Following policy updates, detailed treatment guidelines and decision aids will be developed, using a novel digital platform (MAGI Capp). At least two countries will be supported through detailed treatment guideline development.

The impact

The MARC-SE project will deliver multiple benefits to health authorities in Southern and East Africa. It will:

- Provide near real-time data on patterns of resistance within a country and highlight areas at highest risk of treatment failure.
- Facilitate rapid revision malaria treatment policy in light of changing patterns of resistance.
- Facilitate rapid development of treatment guidelines and implementation of new policies.
- Foster closer links and build trust between researchers and policymakers, enhancing the likelihood that research evidence informs policy action.
- Support a coordinated approach across countries, delivering tools that would be beyond the reach of individual countries.

Ultimately, the project will ensure that countries are better prepared for increasing resistance to ACTs, can respond more quickly and with approaches tailored to local settings, and therefore avoid unnecessary deaths due to the continuing use of ineffective treatments against resistant parasites.

Project at a glance	
Project duration	1 Apr 2023 – 31 Mar 2027
Total project cost	€4 170 631,25
Global Health EDCTP3 funding	€4 170 631,25
Disease area	Malaria
Intervention type	Other prevention tools, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies
Project coordinator	UNIVERSITY OF CAPE TOWN
Participating countries	South Africa, United Kingdom, Netherlands, Uganda, Sweden, Norway, Germany, Rwanda





DEFEND

Delftia TsuruhatensTC1 Based–Intervention For Interrupting Malaria Transmission In Mosquitoes: A Novel Trial For Evaluating Alternative Tools For Control Of Vector–Borne Diseases

The DEFEND project is piloting a highly innovative strategy to disrupt the spread of malaria by infecting mosquitoes with a strain of bacterium that is lethal to malaria parasites.

The challenge

Around 280 million malaria infections occurred in 2024 in sub-Saharan Africa, leading to at least 600,000 deaths, most of them of children. **Mosquito vectors** have long been targeted in malaria control strategies, but these require the use of powerful chemicals and drive the development of insecticide resistance.

Alternative strategies are being investigated, including genetically modified mosquitoes resistant to infection with malaria parasites and the release of mosquitoes carrying *Wolbachia* bacteria, which disrupt parasite development.

Another bacterium found in some wild mosquito populations, *Delftia tsuruhatensis* TC1, has also been found to kill malaria parasites without affecting mosquito survival. The supernatant (liquid floating on the surface) collected from cultured TC1 cells is also highly toxic to malaria parasites. The lethal compound in it, **harmane**, is active at extremely low concentrations and does not appear to harm either people or pollinators such as bees.

The project

The DEFEND project is advancing the clinical development of **TC1–based transmission–blocking strategies** and exploring novel approaches to **regulatory approval** to accelerate their introduction.

Studies to date, including laboratory evaluations and enclosed field studies (in a ‘MosquitoSphere’ in Burkina Faso), have generated highly encouraging findings, setting the stage for a large-scale efficacy trial. However, the TC1 intervention is unusual and demonstrating health impact in a trial setting is challenging. A cluster-randomised trial to demonstrate effects on community malaria burden would need to be very large and would be costly and time-consuming.

The project is therefore exploring an alternative approach, based on assessing TC1’s impact at the **individual mosquito level**. In areas of Burkina Faso and Senegal, traps are being used to capture mosquitoes around houses and the numbers infected with malaria parasites are being counted. The number of infected mosquitoes in areas where TC1 has been introduced will be compared with the numbers in control areas. Measured effects on parasite carriage will be used to infer the likely impact of TC1 introduction on malaria burden in local populations.

At the same time, the project team is working on a new type of feeder that will attract mosquitoes, infect them with TC1, or ensure the uptake of harmane. Community consultations are being arranged to assess the acceptability of the approach and any possible obstacles to its use.

A further critical strand of the project involves dialogue with **national regulatory agencies** and **global policymaking groups** to determine which evidence on impact and safety is needed to support licensing and policy recommendations.

The impact

The DEFEND project is advancing the development of an environmentally friendly vector-focused approach to control malaria. It will:

- Reveal whether TC1 and/or harmane reduce carriage of malaria parasites in mosquitoes in real-world settings.
- Provide an estimate of the impact of their use on the community burden of malaria.
- Map out a path to regulatory approval and policy recommendations that could be followed by other similar interventions.

Ultimately, the DEFEND project could add to the basket of interventions available to control one of the most important causes of death in young children in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jul 2025 – 30 Jun 2030
Total project cost	€5 952 881,75
Global Health EDCTP3 funding	€5 952 881,75
Disease area	Malaria
Intervention type	Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, (Other) emerging technologies
Project coordinator	GLAXOSMITHKLINE INVESTIGACION Y DESARROLLO SL
Scientific project leader	CENTRE NATIONAL DE RECHERCHE SCIENTIFIQUE ET TECHNOLOGIQUE, INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTÉ
Participating countries	Spain, Burkina Faso, United Kingdom, Senegal



LASR

Effect of long–acting spatial repellents (LASR) vs indoor residual spraying (IRS) on malaria burden in western Kenya: a cluster–randomised trial

The LASR project is testing whether a newly developed mosquito repellent can reduce the community burden of malaria infections.

The challenge

An estimated 250 million malaria infections occurred in 2022, most of them in sub-Saharan Africa. Despite this substantial burden of disease, there was a substantial improvement around the year 2000, with the prevalence of infection halved. **Vector control** is thought to have been the main cause of this decline, with the use of long-lasting insecticide-treated bed nets (LLINs) accounting for 68% of the decline and indoor insecticide spraying for 13%.

However, the decline in malaria has stalled over the past decade. Use of insecticides has led to concerns about environmental contamination and has driven the emergence of **insecticide resistance** in mosquitoes. LLINs are highly effective when used correctly, but can be uncomfortable, especially in hot weather, and there are indications that mosquito biting behaviour is changing, with feeding occurring outside the periods when people are protected by LLINs.

As a result, there is a need for alternative **passive control measures** to complement LLINs and other interventions such as vaccination. One possible approach is the use of **long-acting spatial repellents (LASRs)** – chemicals that seem to reduce the likelihood of being bitten by mosquitoes and infected with malaria parasites. Although they are known to reduce the burden of malaria in communities, their mode of action is not well understood and therefore requires further investigation to optimise vector control and inform policy decisions.

The project

The LASR project aims to generate high-quality evidence on the efficacy of a new long-acting spatial repellent (LASR) developed by SC Johnson, known as **Guardian**. It is also exploring the mode of action of Guardian to inform the development of next-generation products.

SC Johnson’s ‘Mosquito Shield’ product, which is active for about a month, has been shown to successfully reduce the burden of malaria disease. Additionally, their Guardian product is a significant advance, as it continues to have an effect for up to 12 months, allowing for once-yearly renewal of LASR devices.

The LASR project is organising a clinical trial to compare the use of Guardian with another vector control strategy, indoor insecticide spraying with the commonly used insecticide pirimiphos-methyl, and with standard vector control. The studies will take place in a high-transmission area of Kenya, with vector control measures in addition to the standard malaria control measures typically deployed, such as LLINs and vaccination. Regular community surveys will be conducted to detect malaria

infections in children, and hospital data on malaria cases will also be collected.

Alongside this trial, the project team will carry out a range of studies to provide insights into the **effects of Guardian on mosquitoes**. For example, high-speed video will be used to track **mosquito flight behaviour** near a model human in the presence of a LASR. In addition, effects on a model of **blood feeding activity** and parasite uptake will be compared in the presence and absence of a LASR. Effects on **mosquito reproduction** will also be assessed.

The impact

The LASR study will generate key evidence on a novel vector-control product. It will:

- Show whether the use of Guardian reduces the malaria disease burden and how its efficacy compares with indoor insecticide spraying.
- Assess community acceptability of Guardian and long-acting spatial repellents (LASRs) more generally.
- Generate insights into the potential mode of action of LASR, which would indicate what properties should be optimised in new product development.

Vector control has proven benefits in reducing the burden of malaria. With insecticide spraying being phased out in multiple countries, the LASR study could lead to the registration of a new product that, alongside other measures, would protect children and adults against this feared disease.

Project at a glance	
Project duration	1 Jul 2025 – 30 Jun 2028
Total project cost	€6 032 060,92
Global Health EDCTP3 funding	€6 032 060,92
Disease area	Malaria, Neglected infectious diseases
Intervention type	Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation
Project coordinator	LIVERPOOL SCHOOL OF TROPICAL MEDICINE
Scientific project leader	KENYA MEDICAL RESEARCH INSTITUTE
Participating countries	United Kingdom, Kenya, Netherlands, Belgium





Neglected infectious diseases



ACT-CHIK

Accelerating Clinical Trials for CHIKungunya Vaccine in Africa

The ACT-CHIK project is advancing a new vaccine against the chikungunya virus to address its growing burden on African populations and health systems.

The challenge

Spread by mosquitoes, the **chikungunya virus** causes a variety of debilitating symptoms, including fever, headache, joint pain, and fatigue. In some cases, symptoms can be severe and have long-term musculoskeletal and neurological complications, especially in children.

Chikungunya is now endemic in multiple countries and can also trigger large-scale outbreaks. Given the number of other illnesses that present symptoms like chikungunya, it is almost certainly being under-diagnosed and under-reported in sub-Saharan Africa. It is already having major health and economic impacts on households and health systems in the region, and these are likely to worsen as climate change accelerates the virus's spread.

Two vaccines have been licensed for chikungunya. However, one (IXCHIQ®) had its license suspended by the US Food and Drug Administration (FDA) in 2025 due to safety concerns, and the company withdrew its dossier in the US in Jan 2026, while a second (Vimkunya®) is not licensed for children under 12 years of age.

The project

The ACT-CHIK project is evaluating a **potential alternative vaccine** with several **advantageous features**. Measles-vectored chikungunya vaccine (**MV-CHIK**), developed by Institut Pasteur in Paris, uses a measles virus backbone, which is highly immunogenic in animal models, to deliver chikungunya antigens. It is available as a convenient, highly stable freeze-dried (lyophilised) formulation.

Six phase I and II trials of MV-CHIK have been carried out in Europe and the US, including a safety and immunogenicity study in a chikungunya-endemic country (Puerto Rico). **No safety concerns** have been identified, and the vaccine shows a **promising immunogenicity** profile. Given that chikungunya outbreaks are unpredictable and occur with little warning, it is difficult to carry out a conventional clinical trial to assess a vaccine's protective efficacy. However, neutralising antibody levels are considered an acceptable surrogate for protection and can be used to infer likely clinical efficacy.

The ACT-CHIK project has three key goals:

- To generate safety and immunogenicity data in African populations, through a phase Ib/III trial in a mix of chikungunya endemic and non-endemic settings. Since the vaccine has not been tried in Africans, the trial will first assess safety in different age groups, including children, before progressing to a large-scale immunogenicity and safety study. The clinical trials will be implemented by the University of Rwanda (UR - Rwanda),

Kenya Medical Research Institution (KEMRI - Kenya), IRRUA Specialist Teaching Hospital Board of Management (IRRUA - Nigeria) and Institut Pasteur de Dakar (IPD - Senegal).

- To prepare for technology transfer to enable MV-CHIK to be manufactured in sub-Saharan Africa, at the IPD, sub-Saharan Africa's only WHO-prequalified vaccine manufacturer. A Brazilian manufacturer with experience in vaccine manufacturing, Fiocruz, will carry out a feasibility study and identify what is required to enable IPD to produce the vaccine commercially, in collaboration with Institut Pasteur.
- To develop a regulatory strategy for licensure of MV-CHIK vaccine in Africa.

The impact

The ACT-CHIK project has the potential to deliver significant health and economic benefits to sub-Saharan Africa. It will:

- Demonstrate whether MV-CHIK is safe for use in African adults, adolescents, and children and is sufficiently immunogenic to likely protect against the chikungunya virus.
- Establish a roadmap for technology transfer so that MV-CHIK can ultimately be manufactured in sub-Saharan Africa.
- Identify a regulatory pathway to ensure rapid approval and introductions should positive results be obtained in the trial.
- Contribute to Africa's strategic objective to manufacture 60% of its vaccine needs by 2040.

In addition to its health benefits, an effective vaccine against chikungunya would have multiple economic advantages: protecting households against loss of earnings and healthcare costs, reducing national healthcare costs, and preventing economic losses from people having to take time off work.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2030
Total project cost	€15 927 349,25
Global Health EDCTP3 funding	€15 299 931,75
Disease area	Neglected infectious diseases
Intervention type	Vaccines
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation
Project coordinator	INSTITUT PASTEUR
Scientific project leader	UNIVERSITY OF RWANDA
Participating countries	France, Rwanda, South Korea, Senegal, Brazil, Nigeria, Kenya





EAVI

European–African vaccine initiative (EAVI): Accelerating preventive measures against chikungunya virus in sub-Saharan Africa

The EAVI project is establishing an international partnership to promote the clinical testing of vaccines against neglected tropical diseases in Africa, starting with a recently licensed vaccine against the chikungunya virus.

The challenge

Sub-Saharan Africa bears the brunt of neglected tropical diseases (NTDs), yet has access to relatively few vaccines to control them. This reflects both limited research into such vaccines, as well as a lack of clinical trials of candidate vaccines in sub-Saharan Africa, leading to limited data from African populations and delayed licensing decisions.

One example is a recently licensed vaccine, **IXCHIQ**, which protects against the **chikungunya virus**. Although chikungunya is a growing public health threat in multiple sub-Saharan African countries, the vaccine is not yet widely available in the region. IXCHIQ is a highly immunogenic vaccine that should offer good protection against the virus. However, as it is a live attenuated vaccine, there are concerns about its use in people living with HIV, of whom there are 25 million in sub-Saharan Africa, particularly those whose infections are not well controlled. It is therefore important to demonstrate its safety in African populations.

The project

The EAVI project is establishing a new European–African partnership to **accelerate the development and deployment of new NTD vaccines** in sub-Saharan Africa. IXCHIQ is being used as a pathfinder, with clinical studies generating data on the vaccine in African populations.

The project is organising a **phase IIIb trial** in Kenya and Tanzania of IXCHIQ’s **safety and immunogenicity**. The trial is focusing on adults, and participants will include people living with HIV, providing the first data on the vaccine in this group. Socio-behavioural studies will explore the acceptability of the vaccine within communities in these two countries.

The study also incorporates intensive analyses of **immune responses** in vaccine recipients, including comparisons between HIV-positive and -negative participants. It will assess:

- Seroconversion rates: the proportion of recipients who mount immune responses likely to be protective;
- Cross-reactivity: the ability of blood samples from vaccine recipients to neutralise different strains of chikungunya and related viruses;
- The nature of T-cell and antibody responses following vaccination.

The project team will also explore which structural features of the virus stimulate protective immune responses, to inform future vaccine design. In addition, it will apply state-of-the-art single-cell RNA sequencing technologies to gain deep insights into T-cell and B-cell responses and how they differ between HIV-positive and HIV-negative individuals.

A further focus will be on surveillance and disease prevention, as the chikungunya disease burden is unclear and infections are likely

underreported in sub-Saharan Africa. Community exposure to the virus will be assessed by determining how many community members have circulating antibodies to chikungunya, while insect vectors transmitting the virus will be captured and analysed for the presence of the virus. How the virus genome changes over time will be monitored in trial participants to provide insights into viral evolution. This information will provide a clearer picture of the current and future burden of chikungunya to inform national decision-making on the use of the vaccine.

In addition to these chikungunya-specific studies, the project is carrying out a wide range of activities to lay the groundwork for future NTD vaccine studies in the region. These include developing guidance, master protocols and training materials for future trials, holding discussions with key national stakeholders, and engaging with communities to identify potential barriers to clinical studies.

The impact

The EAVI will generate key data on a newly developed chikungunya vaccine while also laying the ground for future neglected tropical diseases (NTDs) vaccine studies. It will:

- Provide data on the safety and immunogenicity of IXCHIQ in African populations.
- Generate the first data from people living with HIV.
- Collect extensive data on immune responses to the vaccine and how these differ in people living with HIV.
- Establish a framework for the evaluation of other NTD vaccines in the future.

NTDs have a huge impact on the quality of life of people across sub-Saharan Africa, as well as a major economic impact. Creating a framework for NTD vaccine testing in Africa could accelerate vaccine testing, licensing and implementation, reducing the burden of these highly prevalent infections.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2031
Total project cost	€14 031 531,25
Global Health EDCTP3 funding	€13 695 935,00
Disease area	Neglected infectious diseases, Emerging or re-emerging infectious diseases
Intervention type	Vaccines, Surveillance tools, Diagnostics
Overarching topic	Climate crisis or climate adaptation, Environment and biodiversity, Health security
Project coordinator	MEDIZINISCHE UNIVERSITÄT INNSBRUCK
Scientific project leader	THE REGISTERED TRUSTEES OF THE IFAKARA HEALTH INSTITUTE
Participating countries	Austria, Tanzania, Spain, Switzerland, Sweden, France, Kenya



DENSTAR

Dengue Efficacy & Safety Trial in African Region

The DENSTAR project is testing a vaccine that could address the growing challenge posed by the dengue virus in sub-Saharan Africa.

The challenge

Dengue is a debilitating viral disease causing a range of symptoms, including fever, muscle and joint pain, and skin rashes. Mild cases can force adults to miss work and children to lose out on schooling, while severe cases can lead to hospitalisation and even death. Spread by mosquitoes, dengue viral infections have become increasingly common in recent decades (1990 to 2021), leading to tens of millions of cases and tens of thousands of deaths globally. In particular, during 2023–2024, the African region faced an increasing risk. Most dengue infections are asymptomatic or cause nonspecific symptoms that can easily be mistaken for other conditions; therefore, reported cases are likely significantly underestimated. It is estimated that around one in four infected people develops noticeable symptoms.

Four ‘**serotypes**’ of dengue virus are in circulation globally: **DENV1–4**. Infection with one serotype leads to some protective immunity against other serotypes, but this protection wanes over time and leads to a risk of a severe reaction if someone is subsequently infected with a different serotype.

There is currently no specific antiviral treatment, and prevention primarily relies on mosquito control. However, this approach is becoming more difficult due to insecticide resistance, rapid urban growth, climate change, and limited community involvement. Existing vaccines provide only partial protection and can only be used in certain situations. This highlights the urgent need for a safe, effective, and widely accessible dengue vaccine, especially in sub-Saharan Africa, where the risk is rising and access to preventive tools is still limited.

The project

The DENSTAR project is advancing a new **tetravalent dengue vaccine**, DengiAll, that covers all four dengue virus serotypes and generates robust, balanced immune responses, with a low risk of severe reactions following post-vaccination infection. It is also a **single-dose vaccine**, unlike existing vaccines, which require multiple doses, shows good stability, and is relatively simple to manufacture, suitable for technology transfer and is optimised for mass deployment in public health programmes and vaccination campaigns.

A large phase III trial of DengiAll is underway in India in adults, and a phase I/II safety and immunogenicity study is planned for younger age groups. The DENSTAR project is generating complementary **evidence on DengiAll in African adults and children** to confirm that the DengiAll vaccine is safe and effective in this population, building on data generated in India.

First, a **phase I safety study** will be carried out in Mozambique, with vaccination initially in adults and then progressively in younger groups down to age 2. Around 100 recipients will be followed for six months.

Assuming no safety issues are identified, a **phase III trial** will follow as an extension of the first study, in Mozambique and at additional sites in Ghana and the Democratic Republic of the Congo (DRC).

This study is designed to assess immune responses to each of the four Dengue virus (DENV) serotypes and compare them with those observed in the Indian trial. Protective efficacy will therefore be inferred rather than measured directly, which allows for a simpler and shorter trial.

A secondary set of activities focuses on introducing a **dengue human challenge model** in Gabon. This will involve volunteers being directly infected with an attenuated challenge strain of DENV under carefully monitored conditions to determine the effectiveness of prior vaccination. These activities will focus on a naturally occurring attenuated strain of DENV4 isolated in Puerto Rico, where it caused asymptomatic infections. This study will close an important knowledge gap, as existing clinical trial data do not cover protection against DENV4 (which was not circulating when the trials were conducted).

The DENV4 model and challenge will first be developed by collaborators in the US before being transferred to a site in Gabon. Around 30 adult volunteers will be vaccinated with DengiAll and then challenged with DENV4 six months later.

The project will consult with national regulators on the evidence needed for licensing. When results are available, it will **begin the registration** process for DengiAll in the DRC, Ghana and Mozambique.

The impact

The DENSTAR project could have a major impact on dengue control in sub-Saharan Africa. It will:

- Generate data on the safety and immunogenicity of DengiAll in African populations, from which vaccine efficacy can be inferred.
- Advance a vaccine that would be relatively straightforward to manufacture in Africa, which the current manufacturer is willing to facilitate.
- Provide a full data package that should be sufficient to support registration in pathfinder African countries.

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2030
Total project cost	€11 091 138,94
Global Health EDCTP3 funding	€11 091 138,75
Disease area	Neglected infectious diseases
Intervention type	Vaccines
Overarching topic	Climate crisis or climate adaptation, Health security
Project coordinator	SCLAVO VACCINES ASSOCIATION
Scientific project leader	KWAME NKUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY KUMASI
Participating countries	Italy, Ghana, South Korea, Democratic Republic of the Congo, Mozambique, United States, Germany, Gabon





eWHORM

Enabling the WHO–Roadmap 2030

The eWHORM project is using an innovative trial design to assess the efficacy of a promising new therapeutic, oxfendazole, against multiple different parasitic worm infections.

The challenge

Soil-transmitted helminths (parasitic worms) are among the most common neglected tropical diseases (NTDs). An estimated 1.5 billion people worldwide are infected with at least one such parasite. Collectively, they account for a burden of disease at least as great as malaria or TB. They typically affect the most disadvantaged populations in sub-Saharan Africa and can have lasting impacts on children’s physical and cognitive development.

Multiple parasitic worms affect populations in sub-Saharan Africa. Some treatments are available, but they have drawbacks, and drug resistance is a growing concern. For most parasites, few new therapeutics are in development, despite the unmet need.

In collaboration with the EU Horizon 2020 project Helminth Elimination Platform (HELP), an international public–private consortium, eWHORM is aiming to expand the pipeline of drugs targeting soil-transmitted helminths. One of the compounds in the HELP portfolio, **oxfendazole**, has shown promise as a drug that kills multiple parasite species.

Oxfendazole is cheap to manufacture and is already licensed for use in veterinary medicine, so it could be repurposed for human use relatively easily. It could provide a new option for both the treatment of individuals and broader disease control efforts.

The project

To demonstrate the full potential of oxfendazole, the eWHORM consortium is conducting an innovative ‘**basket**’ trial, which will assess its efficacy against multiple parasite species – soil-transmitted helminths, especially *Trichuris trichiura* (whipworm), *Onchocerca volvulus* and *Loa loa* (roundworms), and *Mansonella* spp – in a single study.

Individual sites in African countries – Cameroon, the Democratic Republic of the Congo (DRC), Gabon and Tanzania – will each focus on a species of local importance. The trial will also assess different doses of oxfendazole and its effects on parasite co-infections, which are common in sub-Saharan Africa.

The project is also introducing molecular diagnostic tests for multiple diseases developed in Cameroon, which are based on LAMP (loop-mediated isothermal amplification) technology. Unlike other molecular tests, LAMP assays require no sophisticated laboratory equipment and can therefore be deployed in a wider range of settings.

Finally, eWHORM is improving laboratory infrastructure by developing a **virtual training and assessment tool** to identify filarial and parasitic infections using microscopy, which will be used to train the local staff.

The impact

The eWHORM project could have a major impact on the treatment and prevention of common and debilitating parasite infections. It will:

- Advance the development of a much-needed new drug, generating evidence to support registration of oxfendazole in sub-Saharan African countries.
- Facilitate wider use of innovative new diagnostics, providing additional data on parasite epidemiology.
- Enable a shift towards test-and-treat approaches for soil-transmitted helminth infections in routine care.
- Build capacity for complex adaptive trials in sub-Saharan Africa.
- Provide extensive training to enhance capacity for research on diagnosis, treatment and control of soil-transmitted helminths.

The eWHORM project is aligned with the WHO NTD Road Map, supporting the development of a therapeutic that will ‘accelerate programmatic action’. Its activities could drive forward the NTD elimination agenda, reducing the huge burden of disease caused by soil-transmitted helminths and benefiting millions of people in sub-Saharan Africa.

Project at a glance	
Project duration	1 Apr 2023 – 31 Mar 2028
Total project cost	€7 967 127,50
Global Health EDCTP3 funding	€7 967 127,50
Disease area	Neglected infectious diseases
Intervention type	Therapies, Diagnostics
Overarching topic	Digital technologies
Project coordinator	UNIVERSITÄT SKLINIKUM BONN
Participating countries	Germany, Austria, Democratic Republic of the Congo, Cameroon, Netherlands, Gabon



NeuroSolve

Implementation of superior treatment regimen and improved patient pathway for neurocysticercosis in sub-Saharan Africa

The NeuroSolve project is evaluating a new treatment for patients who develop epileptic seizures when tapeworm larvae become lodged in their brains.

The challenge

After ingesting the eggs of pork tapeworms (*Taenia solium*), larvae develop and can become lodged in various tissues, including the brain. Cysts form around larvae, and if they are in the brain, they may cause seizures, a condition known as neurocysticercosis (NCC).

NCC is a common cause of epilepsy – in areas where *T. solium* is endemic, it can account for 30% of all cases of epilepsy. The exact number of people affected is unclear, but it could be as high as 8 million, and NCC is becoming more common.

Although the WHO has developed treatment guidelines, these are not well implemented in sub-Saharan Africa. One major challenge is the need for brain imaging (CT or MRI) to identify brain cysts, as this technology is not widely available in many settings. Antibody-based tests for NCC are being developed and could help to identify potential cases so that NCC-specific treatments can be given.

NCC can be treated with anthelmintic drugs such as albendazole or praziquantel. However, small-scale studies suggest that a combination of the two may be more effective.

The project

The NeuroSolve project is carrying out multiple activities to evaluate potential improvements in prevention, diagnosis and treatment of NCC. It aims to provide a model for implementation research, to strengthen evidence-based policy and practice by building skills in the generation and use of research evidence to support the successful implementation of medical interventions.

A key activity is a large-scale trial in Tanzania and Zambia to assess the effectiveness of the new combination drug treatment of albendazole and praziquantel at improving quality of life. The trial will compare the combination treatment with the current recommended practice, with patients in both trial arms also receiving supplementary steroids to manage the inflammation triggered by treatment of cysts.

The project will also model the potential impact of antibody-based tests for NCC, based on the characteristics of existing tests or those with improved performance. Based on these findings, a new diagnostic and treatment pathway will be designed and evaluated in a pilot implementation study.

The project will also explore the feasibility of developing a multisectoral One Health NCC prevention programme, including key barriers and enablers. In addition, it will explore the possibility of creating a One Health implementation strategy for Tanzania and Zambia.

The impact

The NeuroSolve project aims to generate key evidence on a potential new treatment for neurocysticercosis (NCC), assess the role of antibody tests in NCC care, and identify factors crucial for the successful implementation of these tools. This information will:

- Provide evidence on the **effectiveness of an albendazole and praziquantel** combination treatment, informing national and global policy.
- Suggest how **antibody testing** could best be integrated into NCC care and what the optimal properties of an antibody test would be.
- Identify factors associated with successful implementation, to **guide the introduction of new treatments and patient pathways**.
- Suggest how a **One Health framework** could reduce the prevalence of human cysticercosis.

An improved treatment could reduce the burden of disease due to NCC. At the same time, greater use of antibody testing could mean more patients receive treatment that addresses the root causes of their epilepsy. The project will also demonstrate to policymakers how implementation research can generate evidence to inform policy and the introduction of new medical interventions.

Project at a glance	
Project duration	1 May 2023 – 30 Apr 2027
Total project cost	€4 234 052,00
Global Health EDCTP3 funding	€4 234 052,00
Disease area	Neglected infectious diseases
Intervention type	Therapies, Diagnostics
Project coordinator	R-EVOLUTION WORLDWIDE SRL - IMPRESA SOCIALE
Participating countries	Italy, Belgium, Tanzania, Zambia, France





STOP2030

STOP 2030: Towards the interruption of transmission of soil-transmitted helminths: Promoting implementation of research results of a fixed-dose combination of co-formulated ivermectin and albendazole

The STOP2030 project is accelerating the introduction of a new treatment for parasitic worm infections, one that could accelerate their elimination in sub-Saharan Africa.

The challenge

Soil-transmitted helminths are a group of parasitic worms that infect an estimated 1.5 billion people globally, with sub-Saharan Africa accounting for a large proportion of the disease burden. Key infections include:

- *Ascaris lumbricoides*, a roundworm,
- *Trichuris trichiura*, whipworm,
- *Necator americanus* and *Ancylostoma duodenale*, both hookworms.

WHO’s 2021–2030 Roadmap for NTDs aims for their elimination as a public health problem, mostly through a strategy of mass drug administration with either **albendazole** or **mebendazole**, targeting children and women of reproductive age. However, these drugs are only partially effective against *T. trichiura*. In addition, they do not effectively treat another common parasite, **Strongyloides stercoralis** (threadworm), which is often found in co-infections with other soil-transmitted helminths. Using albendazole or mebendazole on their own also creates selection pressures favouring the emergence of **drug resistance**.

The STOP Consortium has been working for many years on an enhanced treatment for soil-transmitted helminths: a **fixed-dose combination pill** that includes both albendazole and ivermectin, a second highly effective anti-parasite drug. The EDCTP-funded STOP project’s ALIVE phase 2–3 trial in Ethiopia, Kenya and Mozambique has generated highly positive data on the efficacy and safety of this new combination treatment.

The project

Building on these successes, the STOP2030 project is carrying out a range of activities to support the licensing and introduction of the new fixed-dose combination of albendazole and ivermectin in endemic countries.

Core to the project is a pragmatic effectiveness trial that will provide evidence on the use of the fixed-dose combination in mass drug administration settings. Schools in Ghana and Kenya will be randomised to receive either standard albendazole-based mass drug administration or the fixed-dose combination. The study will track the prevalence of parasite infections at various time points after drug administration. Special safety monitoring systems will be set up in association with schools to detect any adverse events.

In addition, acceptability studies are being organised in Ghana and Kenya. These will examine health worker and caregiver perspectives on the two approaches, as well as on different delivery methods – directly observed administration of albendazole, the new fixed-dose combination, or a three-day course with the final two doses taken at home.

The project will also carry out modelling of different use cases and administration scenarios to assess their potential impact and cost-effectiveness. In addition, it is piloting an approach to monitor the emergence of resistance, based on genome sequencing of breakthrough infections detected in the study, which might indicate reduced drug susceptibility.

The project will generate a package of evidence for policymakers and the WHO, which will be used to advocate for the introduction of the new fixed-dose combination. It will also coordinate submissions for regulatory approvals in Ghana and Kenya, which could form the basis for similar applications in other countries. In late 2025, the Ghana FDA became the first country to authorise the treatment for clinical and programmatic use.

The impact

The STOP2030 project could have a major impact on the **control of soil-transmitted helminths** in sub-Saharan Africa. It will:

- Generate evidence from real-world settings on the effectiveness and safety of the new fixed-dose combination.
- Provide a treatment option that is logistically simple to introduce or integrate into ongoing programmes but offers advantages over currently used drugs, having activity across a wider range of parasites.
- Deliver a package of evidence to facilitate regulatory approval and to support global and national policymakers’ decision-making.

Ultimately, the albendazole–ivermectin fixed-dose combination could offer an improved option for controlling soil-transmitted helminths, providing broader protection and accelerating the elimination of diseases that affect many millions of people, especially children, in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jul 2023 – 30 Jun 2027
Total project cost	€5 046 435,75
Global Health EDCTP3 funding	€3 553 502,25
Disease area	Neglected infectious diseases
Intervention type	Therapies, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	LABORATORIOS LICONSA SA
Participating countries	Spain, United Kingdom, Ghana, Kenya, India, United States



STROGHAT

Stop transmission of gambiense human African trypanosomiasis

The STROGHAT project will determine whether a new drug, acoziborole, can be used in a ‘screen-and-treat’ approach for control of human African trypanosomiasis.

The challenge

Enormous progress has been made in the control of human African trypanosomiasis (HAT), a potentially fatal infection with trypanosome parasites. Elimination is possible, but new approaches to disease control will be needed as cases become ever more rare.

Historically, the treatment of the most common form of HAT – gHAT, caused by infections with *Trypanosoma brucei gambiense* – relied on relatively toxic drugs such as melarsoprol. To avoid over-use of a potentially harmful drug, patients underwent a complex assessment procedure, based on screening for antibodies, microscopic analysis of blood samples to identify parasites and, to confirm late-stage disease, analysis of a lumbar puncture sample. As well as being complex and time-consuming, this approach also missed about half of all gHAT cases.

The development of less harmful drugs, including agents active against both early-stage disease and severe late-stage disease, have opened up the possibility of treatment based on simple screening. In particular, the drug acoziborole, developed by Novartis and the Drugs for Neglected Diseases Initiative, has been shown to have an efficacy of 98% against gHAT and a good safety record, and could form the basis of a ‘screen-and-treat’ approach to gHAT control, with at-risk populations screened for antibodies and immediately treated if they test positive.

The project

The STROGHAT project will assess whether a screen-and-treat approach is safe, effective and acceptable. Focusing on the Nord Equateur region of the Democratic Republic of the Congo (DRC), it will target 63 villages in which cases of gHAT have recently been identified. Mobile teams will offer to screen all people in these villages and offer acoziborole to those testing positive, without waiting for microscopy results. In addition, rapid diagnostic tests will be offered at 30 sites already taking part in gHAT surveillance.

The approach will be applied for three years, with careful monitoring for adverse reactions, after which the incidence of gHAT will be reassessed. If it has been reduced below a certain threshold, this would indicate that the parasite is on the path to extinction.

The impact

The STROGHAT project will:

- Evaluate effectiveness of a ‘screen-and-treat’ approach to rapidly reduce gambiense human African trypanosomiasis (gHAT) prevalence in an entire focus.
- Extend acoziborole safety documentation.
- Analyse the costs of this new approach.

STROGHAT intends to provide the first evidence for recommending ‘screen-and-treat’ to national HAT control programmes. Through facilitated diagnosis, increased acceptability and access to treatment, STROGHAT will contribute to achieving the goal of stopping gHAT transmission by 2030, as defined by the World Health Organisation.

Project at a glance	
Project duration	1 Jul 2023 – 30 Jun 2028
Total project cost	€4 001 936,25
Global Health EDCTP3 funding	€4 001 936,25
Disease area	Neglected infectious diseases
Intervention type	Therapies, Diagnostics, Surveillance tools
Overarching topic	Digital technologies
Project coordinator	INSTITUUT VOOR TROPISCHE GENEESKUNDE
Participating countries	Belgium, Democratic Republic of the Congo, France





3SI-CONTROL

Integrated Anthelmintic–Based control of Taenia solium cysticercosis/taeniasis, Soil–transmitted Helminthiasis and Schistosomiasis: safety, effectiveness and implementation strategies

The 3SI–CONTROL project is assessing whether it is safe and effective to administer multiple antiparasitic drugs simultaneously and how to implement this integrated strategy to help control some of the most common neglected tropical diseases affecting sub–Saharan Africa.

The challenge

Neglected tropical diseases are responsible for an enormous global burden of disease, affecting many millions of the poorest people globally, particularly children. **Soil–transmitted helminths**, a group of common parasitic worms, affect around 1.5 billion people, including more than 250 million in sub–Saharan Africa, while over 200 million people worldwide – more than 90% of them in Africa – are affected by **schistosome** (flatworm) infections. Although rarely deadly, these infections have multiple debilitating effects on health and can significantly impair child growth and development. The pork tapeworm **Taenia solium**–related morbidity is strongly associated with neurocysticercosis (NCC), a major cause of epilepsy and various neurological disorders within endemic regions.

Mass drug administration is the cornerstone of soil–transmitted helminth control, typically with **albendazole or mebendazole**. Recently, with EDCTP funding, a **fixed–dose combination** of albendazole with a second anti–parasite drug, **ivermectin**, has been shown to have significant benefits, demonstrating greater efficacy against *Trichuris trichiura* (whipworm) and extending protection to include *Strongyloides stercoralis* (threadworm). Separately, mass drug administration with **praziquantel** is used to control schistosomes. For *T. solium* there are currently no countries routinely implementing control. Nevertheless, praziquantel also impacts the adult tapeworm, and as such, integration of disease control should be considered.

The project

The 3SI–CONTROL project is assessing whether it is possible to combine the new fixed–dose combination of albendazole and ivermectin with praziquantel, as part of integrated mass drug administration campaigns targeting multiple parasites.

While efficacy is well–established for the individual drugs and initial results from trials of the new fixed–dose combination are highly promising, the **safety of multi–drug mass drug administration**, as well as its **effectiveness in real–world settings**, needs to be rigorously demonstrated. There is a risk that an inflammatory response to *T. solium* larvaemight generate neurological symptoms in people with brain cysts.

The 3SI–CONTROL project is therefore carrying out a trial in Tanzania and Zambia that will involve around 10,000 people aged 5 years and older. Areas in the two countries will randomly introduce the fixed–dose combination and praziquantel, either given simultaneously or 14 days apart. Participants will be followed for 45 days to check for any adverse reactions, with any neurological symptoms being subject to in–depth analysis.

Moreover, the impact of joint administration on the community prevalence of *T. solium*, soil–transmitted helminths and schistosomes will be assessed in Zambia. In addition, the project includes a One Health dimension – impacts on the presence of tapeworm larvae in pig populations will also be assessed; typically, around one in three pigs are affected, acting as a source of human infections.

The project also includes a solid implementation research component, identifying potential barriers and facilitators to the introduction of the integrated control programmes in Tanzania, Zambia and Mozambique, along with cost–effectiveness assessment and long–term impact modelling. This work will be used to develop country–specific implementation plans. Prototype testing of the implementation strategies will be conducted in Zambia, Tanzania, and Mozambique, followed by optimisation of the implementation strategies. Finally, the project will also develop general guidance for introductions and policy briefs.

The impact

The 3SI–CONTROL project will provide key policy–relevant data on an integrated approach to parasitic worm control. It will:

- Demonstrate whether the new fixed–dose combination and praziquantel can be safely administered together.
- Provide evidence of their impact on multiple parasitic worm infections.
- Generate practical guidance to accelerate the development and implementation of integrated multi–parasite control programmes.
- Build capacity in three Global South countries

If safety is sufficiently guaranteed, the project could pave the way to integrated mass drug administration campaigns, providing people with protection against multiple parasitic worm infections, including tapeworm infections, which are currently not routinely targeted for mass control. This could enhance the quality of life and development of millions in sub–Saharan Africa.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2029
Total project cost	€5 500 000,00
Global Health EDCTP3 funding	€5 500 000,00
Disease area	Neglected infectious diseases
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Environment and biodiversity
Project coordinator	UNIVERSITEIT GENT
Scientific project leader	UNIVERSITY OF DARES SALAAM
Participating countries	Belgium, Tanzania, Mozambique, Spain, Zambia



TEBULA

Telacebec to Control Buruli Ulcer and Leprosy in Africa (TEBULA)

The TEBULA project is advancing a potentially revolutionary new treatment for two neglected mycobacterial diseases: leprosy and Buruli ulcer.

The challenge

In addition to tuberculosis, mycobacteria cause other diseases that have a significant impact in sub–Saharan Africa, including **leprosy** (caused by *M. leprae*) and **Buruli ulcer** (caused by *M. ulcerans*). Although not as common or deadly as TB, leprosy and Buruli ulcer still have a major impact in many parts of sub–Saharan Africa. Both are associated with long–lasting and disfiguring **skin lesions**, leading to discrimination, social stigma, and reduced quality of life and economic opportunities.

Mycobacteria are hardy bacteria and difficult to kill, so drug treatments tend to be long and complex. Although effective, current treatments for leprosy require patients to take a cocktail of different drugs for up to 12 months, while Buruli ulcer treatment is based on a course of three pills taken at different times of the day for 2 months. Treatments also have side effects, including skin discolouration, which can exacerbate stigmatisation.

Recently, a new drug has been discovered, **telacebec**, that is highly active against mycobacterial infections. The drug inhibits energy–generating biochemical pathways in mycobacteria. Both *M. leprae* and *M. ulcerans* are highly sensitive to telacebec, as genome shrinkage during their evolution has led to the loss of genes encoding alternative energy–generating systems.

The project

The TEBULA project is exploring whether telacebec is also effective for leprosy and Buruli ulcer, building on research into its use as a possible treatment for tuberculosis.

Phase I and II studies have already shown that telacebec is safe. A phase II trial of telacebec for Buruli ulcer has started in Australia, and results from this study will inform activities of the TEBULA project in sub–Saharan Africa.

The primary aim of the project is to evaluate shorter, simpler treatments for the two conditions. This would make it easier for patients to adhere to treatment regimens and reduce the pressure on health systems. For Buruli ulcer, a clinical trial in Benin, Côte d'Ivoire, and Ghana will compare the time required for lesions to heal when patients receive a shortened 4–week course of telacebec versus standard 2–month antibiotic treatment. The study will also explore patient perspectives on treatment and its impact and will have a practical focus, examining factors that may influence the introduction of telacebec into routine care.

For leprosy, the team is organising a phase II study to identify the optimal dose of telacebec to include in multi–drug treatment regimens. This study, in Benin, Côte d'Ivoire and Ethiopia, will compare different doses of telacebec as well as daily and monthly dosing – the latter is anticipated to be effective and would greatly simplify treatments. Because current treatment is highly effective, telacebec is not expected to improve clinical outcomes. The trial is therefore assessing multiple clinical, patient–related and health systems issues to identify the potential benefits of telacebec use.

The impact

The TEBULA project will accelerate the development of a potentially transformative drug for two neglected skin conditions. It will:

- Show whether telacebec is clinically effective against Buruli ulcer and leprosy.
- Reveal whether simplified treatment regimens can be introduced.
- Indicate whether patients experience improved quality of life with telacebec–based treatments.

By simplifying and shortening treatment for Buruli ulcer and leprosy, telacebec could reduce pill burden and treatment duration, improve treatment adherence, accelerate recovery, minimise the risks of stigmatisation and mental health impacts, and reduce demands on health systems.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2029
Total project cost	€6 069 390,00
Global Health EDCTP3 funding	€5 768 415,00
Disease area	Neglected infectious diseases
Intervention type	Therapies
Project coordinator	FONDATION RAOUL FOLLEREAU
Scientific project leader	KWAME NKUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY KUMASI
Participating countries	France, Ghana, United Kingdom, Spain, Côte d'Ivoire, Ethiopia, Cameroon, Belgium





EMINENCE

Eliminating onchocerciasis with Moxidectin in endemic hotspots of Central Africa

The EMINENCE project is exploring whether a newly developed drug, moxidectin, could accelerate the elimination of onchocerciasis (river blindness).

The challenge

The parasitic roundworm *Onchocerca volvulus* infects an estimated 20 million people, almost all of them in sub-Saharan Africa. Spread by blackflies, Onchocerca infections can cause a range of symptoms, including blindness. This infection is commonly known as 'river blindness' because people living along watercourses are particularly vulnerable to infection, as this is where blackflies are most found.

Onchocerciasis has been targeted for elimination, and control currently relies primarily on mass drug administration with ivermectin. Although ivermectin kills microfilariae larvae, the stage of the Onchocerca life cycle when it is transmitted between people, it is much less active against adult worms, which can live for up to 20 years. It will therefore take more than a decade of mass drug administration campaigns to interrupt transmission. Onchocerciasis persists in several hotspots in Central and West Africa, where transmission intensity is high and ivermectin coverage is incomplete.

A further challenge is that mass drug administration with ivermectin cannot be used in areas where a second parasitic roundworm, Loa loa, is also present. Rapid killing of L. loa can trigger a potentially lethal physical reaction in the brain. Onchocerciasis hotspots in Gabon and large areas of other countries, covering 15 million people, are therefore excluded from ivermectin-based mass drug administration programmes.

The project

Because of these challenges, the search is on for additional strategies to accelerate the elimination of onchocerciasis. The EMINENCE project is evaluating the use of **moxidectin** as an alternative to ivermectin in high-transmission areas and regions where *L. loa* coexists with *O. volvulus*.

Phase II and III trials have shown that moxidectin is more active than ivermectin against microfilariae. It also appears to have more impact on adult worms. Although licensed only for use in children over the age of 12 years, an EDCTP2-funded trial has demonstrated its suitability for use in younger children.

This potential advantage needs to be confirmed in programmatic field trials, which is a core aim of the EMINENCE project. A phase IIb trial is being organised to compare annual or biannual use of either moxidectin or ivermectin in hotspot areas of Cameroon. The trial will assess effects on parasite carriage, levels of *Onchocerca* antibodies, and the presence of *Onchocerca* in blackfly vectors; it will also compare effects on adult worms.

In addition, the project is evaluating the safety of moxidectin use in *L. loa* endemic areas in the Republic of Congo and Cameroon. A dose-finding phase II trial is underway, testing progressively higher doses of moxidectin in progressively heavier *L. loa* infections to identify the highest dose that could be used in campaigns.

Alongside these trials, the project team is gathering the views of key stakeholders, including health workers and community members, on the use of moxidectin. It will also carry out an economic analysis to highlight the financial implications of introducing moxidectin and generate materials to help countries introduce it into mass drug administration campaigns.

The impact

The EMINENCE project is a key step in the development of moxidectin as a potential agent for onchocerciasis control. It will:

- Reveal whether the superior performance of moxidectin over ivermectin is also seen in key sub-Saharan African locations.
- Demonstrate whether moxidectin can be used safely in *Loa loa* endemic areas.

If the benefits of moxidectin are confirmed, its introduction could extend the use of mass drug administration campaigns and accelerate the elimination of a common and debilitating neglected tropical disease having a major impact on health and quality of life across a swathe of sub-Saharan Africa.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2030
Total project cost	€5 205 730,25
Global Health EDCTP3 funding	€4 986 011,25
Disease area	Neglected infectious diseases
Intervention type	Therapies, Surveillance tools
Project coordinator	INSTITUT DE RECHERCHE POUR LE DÉVELOPPEMENT
Scientific project leader	ASSOCIATION INSTITUT SUPERIEUR DE RECHERCHE SCIENTIFIQUE ET MEDICALES
Participating countries	France, Cameroon, United Kingdom, Congo



TreatPreg

Enhanced preventive antiparasitic treatment for better health of African pregnant women and their babies

The TreatPreg project is assessing whether a mix of anti-parasite drugs can be given together during pregnancy to prevent anaemia and adverse birth outcomes.

The challenge

Parasite infections can be particularly dangerous during **pregnancy**. An estimated one in four maternal deaths is due to parasite infections, which can also cause a range of adverse birth outcomes such as stillbirth, prematurity and low birth weight. Many of these effects are mediated by parasites' sequestration of iron, leading to **anaemia**.

Because of these effects, the WHO recommends that pregnant women be offered a range of preventive treatments against **malaria** (intermittent preventive treatment in pregnancy, for example, with sulfadoxine-pyrimethamine), **soil-transmitted helminths** (albendazole or mebendazole) and **schistosomes** (praziquantel).

Although there is strong evidence that these interventions improve maternal health and reduce neonatal mortality, they are only partially implemented in sub-Saharan Africa. Key issues include health workers' concerns about giving drugs to pregnant women and the differing dosing and schedules of the recommended treatments.

The project

The TreatPreg project aims to improve the uptake of preventive treatments during pregnancy by gathering evidence on the safety and efficacy of combined anti-parasite treatments.

Each treatment is known to be safe for use in pregnant women on its own. However, there is limited evidence of their use together, although albendazole and praziquantel have been used together in pregnant women and young children; co-administration appears to have no impact on safety or efficacy. Given what is known about how the drugs are metabolised, there is no reason to think that their use together will raise safety concerns or diminish efficacy.

To confirm this in practice, the TreatPreg project is conducting a clinical trial in which praziquantel is administered alongside either albendazole or mebendazole during an antenatal care visit at which preventive malaria treatment is provided. The study, conducted in Benin, the Republic of the Congo, Gabon, and

Ghana, will assess safety and tolerability, including impacts on maternal health, birth outcomes, and the health of young infants.

The trial will include pharmacokinetic studies to assess whether co-administration affects blood levels of the individual drugs. A cost-effectiveness analysis will also be carried out.

The impact

The TreatPreg project will address key barriers to implementing evidence-based strategies to protect maternal health. It will:

- Demonstrate whether preventive treatment for three critical types of parasite infection can be safely given to pregnant women at the same time.
- Provide further evidence on their benefits to pregnant women and their offspring.

Generating this evidence would provide a strong impetus to expand access to preventive anti-parasite treatments during pregnancy, helping to reduce the number of maternal and neonatal deaths in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2030
Total project cost	€4 783 240,00
Global Health EDCTP3 funding	€4 783 193,75
Disease area	Neglected infectious diseases, Malaria
Intervention type	Therapies
Overarching topic	Women's health, Co-morbidities and non-communicable diseases
Project coordinator	EBERHARD KARLS UNIVERSITÄT TUEBINGEN
Scientific project leader	CENTRE DE RECHERCHES MEDICALES DE LAMBARÉNE
Participating countries	Germany, Gabon, Spain, Ghana, Benin, Congo, United Kingdom





WINGS-4-FGS

(W)Initiative for womeN and GirlS affected by Female Genital Schistosomiasis

The WINGS-4-FGS project is carrying out multiple activities to raise awareness, enhance detection and improve treatment of female genital schistosomiasis – a common but poorly recognised infection affecting girls and women in sub-Saharan Africa.

The challenge

Schistosomiasis, infection with parasitic flatworms, is one of the most common neglected tropical diseases. Schistosome infections can cause a range of symptoms, including effects on the urogenital system, as seen with **Schistosoma haematobium**. As well as short-term symptoms such as ulcers, **female genital schistosomiasis (FGS)** can have longer-term impacts on sexual and reproductive health and may increase the risk of HIV infection and cervical cancer.

Although it affects around 50 million women globally, most of them in sub-Saharan Africa, awareness of FGS is low. It is often mistaken for a sexually transmitted infection, leading to mistreatment, stigmatisation and a reluctance to seek treatment.

If identified, adult worm infections can be treated with **praziquantel**. However, genital symptoms are caused by an inflammatory response to granulomas, as schistosome eggs become trapped in the urogenital system and encased in a fibrous casing; these are not resolved by treatment with praziquantel.

The project

The WINGS-4-FGS project is carrying out a coordinated set of activities to raise awareness of FGS, improve detection, enhance treatment, and integrate FGS care into wider sexual and reproductive health services.

- **Awareness:** Awareness-raising and training activities are being carried out among health workers and communities in Côte d'Ivoire, the Democratic Republic of the Congo (DRC), Ghana and Malawi.
- **Diagnosis:** A two-step community-based screening strategy is being piloted: initial screening for schistosome infections using microscopy or a urinary test is followed by analysis of a self-collected genital swab to check for signs of FGS.
- **Treatment:** Alongside praziquantel, **anti-inflammatory drugs** may have additional benefit by alleviating genital symptoms. A clinical trial in Côte d'Ivoire, the DRC, Ghana and Malawi will test whether widely available steroids or non-steroidal anti-inflammatory drugs, when added to praziquantel treatment, help to resolve genital lesions.

- **Service integration:** The project will carry out studies to identify potential barriers and enablers of the integration of FGS detection and treatment into existing sexual and reproductive health services for women.

The impact

The WINGS-4-FGS project has the potential to improve multiple aspects of care of a condition that often goes unrecognised but can have a major impact on women's quality of life. It will:

- Ensure more health workers are aware of the symptoms of FGS and how it should be treated.
- Determine whether community-based self-sampling is a more acceptable and feasible way to detect cases.
- Show whether safe and readily available anti-inflammatory drugs can alleviate the symptoms of FGS.
- Provide insights into how improved FGS care could be integrated into existing sexual and reproductive health services.

FGS is a neglected aspect of a neglected tropical disease. Ultimately, the WINGS-4-FGS project should ensure that more women gain access to appropriate treatment and care, reducing the impact the condition has on reproductive health and quality of life.

Project at a glance	
Project duration	1 Jul 2025 - 30 Jun 2029
Total project cost	€5 036 364,69
Global Health EDCTP3 funding	€5 036 364,69
Disease area	Neglected infectious diseases
Intervention type	Therapies, Diagnostics, Other prevention tools
Overarching topic	Women's health
Project coordinator	LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER
Scientific project leader	UNIVERSITY OF HEALTH AND ALLIED SCIENCES
Participating countries	United Kingdom, Ghana, Malawi, Germany, Democratic Republic of the Congo, Côte d'Ivoire, Rwanda



MAMS4CL

A multi-arm, multi-stage trial for cutaneous leishmaniasis – MAMS4CL

The MAMS4CL project is establishing a clinical trial platform to test improved treatments for cutaneous leishmaniasis, a parasitic disease that causes significant suffering in East Africa.

The challenge

Cutaneous leishmaniasis is not the deadliest form of infection with the **Leishmania** parasite (visceral leishmaniasis is more severe), but it nevertheless has a major impact, particularly in East Africa, where it is most common. It leads to **chronic scarring skin lesions** that can interfere with daily life, affect employability and generate social stigma. The condition can therefore have a major impact on people's quality of life and mental well-being.

The limited number of treatments available for cutaneous leishmaniasis adds to its impact. The most effective therapy involves repeated intramuscular injections with a powerful drug, **sodium stibogluconate**, which is painful and can trigger a variety of side effects. It is likely that fewer than 1 in 10 patients with cutaneous leishmaniasis actually receive treatment.

The good news is that several new treatments are in development. However, even if sufficient trial capacity existed, it would be very costly to test all in separate trials.

The project

To overcome this bottleneck and advance potentially more effective therapies for cutaneous leishmaniasis, the MAMS4CL project is establishing the infrastructure for a '**multi-arm, multi-stage'** (MAMS) trial. It focuses on Ethiopia, a country with a particularly high disease burden.

A MAMS study enables multiple drugs to be compared in a single study. A consultation is being organised to determine the final set of compounds to be evaluated, but several options have some positive data available. These include:

- **Miltefosine:** a more convenient oral medication, but one with significant gastrointestinal side effects.
- **Liposomal formulations of amphotericin B:** already used to treat visceral leishmaniasis.
- **Paramomycin:** used alongside sodium stibogluconate to treat visceral leishmaniasis.
- **Combinations** of the above drugs.

In the first stage of the MAMS trial, initial safety and efficacy data will be collected on the five selected options. A maximum of two options meeting pre-set safety and efficacy criteria will then

progress to stage 2, where a full comparison will be made against the current treatment, sodium stibogluconate.

The project will also include pharmacokinetic studies to identify drug levels associated with successful responses, providing additional information on optimal dosing. Other work will include discussions with local communities on their understanding of the condition and perceptions of current treatments.

The impact

The MAMS4CL project will create a platform for evaluating existing and emerging treatments for cutaneous leishmaniasis. It will:

- Enable multiple possible treatment options to be tested in a single trial.
- Generate directly comparable data on the safety and efficacy of the different options.
- Establish a platform for the rapid evaluation of newly developed agents.

The MAMS4CL project will accelerate the development of new treatments for this common, neglected tropical disease and, potentially, identify a safer and more effective alternative to an existing treatment with significant drawbacks.

Project at a glance	
Project duration	1 Aug 2025 - 31 Jul 2029
Total project cost	€5 499 999,25
Global Health EDCTP3 funding	€5 499 999,25
Disease area	Neglected infectious diseases
Intervention type	Therapies
Overarching topic	Co-morbidities and non-communicable diseases
Project coordinator	LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER
Scientific project leader	ARMAUER HANSEN RESEARCH INSTITUTE
Participating countries	United Kingdom, Ethiopia, Sweden, South Africa, Belgium, Switzerland





FAME

Repurposing fusidic acid as a short-course Onchocerca volvulus macrofilaricide: A randomised controlled open-label parallel group intervention phase IIA/b pilot trial

The FAME project is assessing whether a repurposed antibiotic could improve control of onchocerciasis (river blindness).

The challenge

Onchocerciasis, an infection caused by the roundworm parasite **Onchocerca volvulus**, is a neglected tropical disease most commonly found in Central Africa. In addition to skin conditions, it can lead to visual impairment and blindness. The parasite is spread by blackflies, which reproduce in flowing water, so many cases of disease are found close to watercourses – hence the label ‘river blindness’.

Onchocerciasis has been targeted for elimination, predominantly through the use of mass drug administration campaigns with **ivermectin**. However, this is likely to take more than a decade even if high coverage is achieved. In addition, there are large areas of Central Africa where ivermectin cannot be used safely because of the risk of co-infection with another parasitic worm, **Loa loa**: killing **L. loa** can trigger a powerful inflammatory response that may lead to neurological damage and even death.

Recently, an alternative control strategy has begun to emerge. The parasite depends on a commensal bacterium **Wolbachia** for survival. Hence, targeting **Wolbachia** is an effective way of eliminating **O. volvulus**. Antibiotics such as **doxycycline** are highly effective against both microfilariae, larval stages transmitted between people via blackflies, and the adult worms that generate microfilariae. Furthermore, the killing effects of doxycycline are relatively slow, so there is less risk of triggering neurological damage in co-infections.

Despite these promising developments, doxycycline is unlikely to be a long-term solution: it needs to be given for extended periods and is not suitable for young children or pregnant women.

The project

The FAME project is evaluating a possible alternative to doxycycline, **fusidic acid**, a naturally occurring antibiotic used in topical creams, which is off-patent and safe for use in children and pregnant women.

The first step is to establish a suitable dose for use in a large-scale field trial. A **dose-finding study** is being carried out in Cameroon, with effects on **Wolbachia** compared with a four-week course of doxycycline. This study is being conducted alongside community consultations to assess the approach's acceptability and any potential barriers to its introduction.

The project is also exploring ways to **enhance the efficiency of clinical studies**, for example, by evaluating a potential new method for assessing treatment responses. Current methods depend on biopsies of nodules containing adult parasites, which are then stained and examined by two different expert observers. Using an extensive library of slides, the project will develop and validate an **AI tool** to classify stained sections.

In addition, the project will evaluate an alternative method, based on a less invasive **skin biopsy**, to assess **Wolbachia** levels in microfilariae. The assumption is that changes in **Wolbachia** levels in microfilariae will likely mirror those occurring in adult parasites. This method would allow the efficacy of treatments to be assessed much more rapidly.

An additional goal is to refine a **pharmacokinetic/pharmacodynamic model** to provide a more accurate indication of the drug levels required to kill **Wolbachia** effectively. This would guide pre-clinical studies on **Wolbachia** killing and increase the likelihood that results from pre-clinical research translate to humans.

The impact

The FAME project will advance the development of an affordable compound that could make a significant contribution to onchocerciasis control. It will:

- Provide an initial indication of the efficacy of fusidic acid and the optimal dose for human use.
- Generate new tools to accelerate the assessment of anti-**Wolbachia** disease control strategies.
- Enable a full clinical development plan to be created for fusidic acid.

If studies confirm the early promise of fusidic acid, this would open the door to large-scale trials and ultimately provide a new approach to onchocerciasis control that could drive forward its elimination in Central Africa.

Project at a glance	
Project duration	1 Sep 2025 - 28 Feb 2029
Total project cost	€5 121 718,75
Global Health EDCTP3 funding	€5 121 718,75
Disease area	Neglected infectious diseases
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies, (Other) emerging technologies
Project coordinator	LIVERPOOL SCHOOL OF TROPICAL MEDICINE
Scientific project leader	UNIVERSITY OF BUEA
Participating countries	United Kingdom, Cameroon, Germany, Morocco, Switzerland



IVM-KIDS

Accelerating a pediatric formulation of ivermectin for the control of Neglected Tropical Diseases

The IVM-KIDS project is developing a child-friendly formulation of ivermectin to ensure young children can benefit from this key drug for parasite control.

The challenge

Ivermectin is one of the world's most widely used antiparasitic drugs. It is active against a wide range of parasites that cause neglected tropical diseases, including onchocerciasis, lymphatic filariasis and some soil-transmitted helminth infections. Collectively, these diseases affect more than a billion people, most of them in sub-Saharan Africa.

Ivermectin is commonly used in mass drug administration campaigns. It can be used on its own, but there is also growing evidence of the additional benefits of combination drug use alongside **albendazole**, which is also active against soil-transmitted helminths.

However, unlike albendazole, ivermectin is not approved for use in children less than 5 years old or weighing less than 15 kg. This is partly because of limited **safety data** in this age group and partly because of the **risk of choking** on currently used tablets.

Theoretical safety concerns arose because of fears that the immaturity of the blood-brain barrier in young children might allow ivermectin to cross into the brain. However, recent research suggests that the key protein preventing ivermectin access to the brain in adults is also present in young children. In addition, when young children have been exposed to ivermectin, no safety issues have arisen.

The project

The IVM-KIDS project is developing a **dispersible ivermectin tablet** for young children and undertaking a range of studies to demonstrate its safety and efficacy.

The largest study of the project, planned for Ghana, Kenya, the Democratic Republic of the Congo (DRC) and Tanzania, is designed to demonstrate the safety of the new tablet when given alongside albendazole. Around 4,500 children weighing 5–15 kg will be recruited to this study.

A sub-study involving 1,200 children will test the efficacy of the new ivermectin tablet, focusing on **Trichuris trichiura** (whipworm) infections, which are only partially susceptible to albendazole. Finally, a pharmacokinetic study in 400 children will assess circulating drug levels to ensure that dosing is appropriate.

Alongside these studies, consultations will be carried out with children and caregivers to assess the palatability and acceptability of the new formulation.

The impact

The IVM-KIDS project will expand access to a key antiparasitic drug. It will:

- Develop an ivermectin tablet suitable for young children that dissolves in the mouth (orodispersible).
- Confirm that the new tablet is safe, efficacious and acceptable to children and caregivers.
- Generate the evidence required to support licensing applications.

Ultimately, the IVM-KIDS project could enable millions of children under 5 years of age to gain access to ivermectin, preventing parasite infections that can have a major impact on physical and cognitive development, and are associated with neurological complications, including epilepsy, in sub-Saharan Africa.

Project at a glance	
Project duration	1 Sep 2025 - 31 Aug 2029
Total project cost	€5 498 750,00
Global Health EDCTP3 funding	€5 498 750,00
Disease area	Neglected infectious diseases
Intervention type	Therapies
Overarching topic	Climate crisis or climate adaptation
Project coordinator	LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER
Scientific project leader	KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY KUMASI
Participating countries	United Kingdom, Ghana, Spain, Democratic Republic of the Congo, Kenya





EpiGen Ethiopia

Building scalable pathogen genomic epidemiology for Ethiopia

The EpiGen Ethiopia project is bringing together multiple partners to strengthen the country’s capacity to detect and track known and emerging pathogens.

The challenge

Ethiopia, the second most populous country in sub-Saharan Africa, is affected by multiple infectious diseases. These infections account for an estimated 85% of the country’s health problems. Ethiopia has introduced the WHO’s Integrated Disease Surveillance and Response (IDSR) system to track 19 priority infectious diseases across more than 900 districts.

Implementing the IDSR system is challenging for several reasons, including limited expertise and insufficient infrastructure. Furthermore, because it relies on microbiological methods, the IDSR approach does not provide comprehensive coverage of all pathogens.

Genomic approaches, based on whole-genome sequencing of pathogens, can provide more information across a wider range of pathogens to guide public health responses. Primarily in response to the COVID-19 pandemic, genome surveillance has become more widely used in sub-Saharan Africa. However, further development is required to underpin national surveillance systems.

The project

The EpiGen Ethiopia project is bringing together academic and public health institutions in Ethiopia, as well as regional and European partners, to create a national genomics-based surveillance system.

To this end, 30 sites within the existing IDSR network, including six regional public health laboratories, will share samples with two national sequencing centres, Ethiopia’s national public health institute (EPHI) and the Armauer Hansen Research Institute (AHRI), along with linked clinical and epidemiological data. Genome sequencing capacity will be built at additional sites, and the EPHI data management platform will be strengthened and adapted to integrate TB diagnostic data into a single repository. The project will extend the platform to include data from malaria diagnostic tests and assess the feasibility of integrating additional point-of-care tests, such as for typhoid fever.

The project will build on experience in Kenya, where dashboards have been created using location- and time-tagged data, enabling near-real-time disease information to be viewed by policymakers and other stakeholders on mobile phones. The information generated will be available to support policymaking and local treatment decision-making.

Data visualisation tools will be co-developed with national policymakers to ensure that they meet user needs. These efforts will also benefit from input from experts at the Africa Centre for Disease Control and Prevention (Africa CDC), which has

experience in dashboard development. The Africa CDC is a core project partner, and the project’s work will feed into the Africa CDC’s African Pathogen Genomics Initiative. This linkage will also help to disseminate learnings and tools emerging from the project across sub-Saharan Africa.

The project will also generate a biobank of samples to support further research and establish a comprehensive training programme to build capacity in sequencing, bioinformatics and data management.

The impact

The EpiGen Ethiopia project will establish the foundation for a genomics epidemiology platform for infectious disease surveillance in Ethiopia. It will:

- Enhance the country’s ability to gather information on pathogens and use it in clinical practice and disease control.
- Bring together many partners in a community of practice, catalysing local innovation in the application of genomic technologies to infectious disease surveillance.
- Provide a model that can be replicated in other countries, via links with the Africa CDC.
- Create a centre of excellence in the Horn of Africa and promote wider adoption of genomic technologies.

A functioning genomic surveillance system will deliver multiple benefits to Ethiopia, including the potential to limit indiscriminate use of therapeutics and reduce the drivers of drug resistance, to target disease control efforts where they are most needed, and to support research into the key factors driving the spread of key infectious diseases.

Project at a glance	
Project duration	1 Jun 2023 – 31 May 2028
Total project cost	€5 499 097,50
Global Health EDCTP3 funding	€5 499 097,50
Disease area	Neglected infectious diseases, Diarrhoeal diseases, Tuberculosis
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies, Health security
Project coordinator	STICHTING AMSTERDAM INSTITUTE FOR GLOBAL HEALTH AND DEVELOPMENT
Participating countries	Netherlands, Germany, Ethiopia, Spain



SkincAIr

Early detection and management of SKIN-related negleCted tropical diseases using Artificial Intelligence in sub-Saharan afRica (SkincAIr)

The SkincAIr project is developing an easy-to-use AI-based tool to support the diagnosis of skin conditions caused by neglected tropical diseases.

The challenge

Many neglected tropical diseases affect the skin. Globally, almost 2 billion people have skin conditions linked to such infections, causing stigma, isolation and discrimination alongside their direct effects on health.

Assessment of skin conditions could therefore provide a rapid and convenient way to diagnose neglected tropical diseases, enabling the right treatment to be offered to patients. However, in most sub-Saharan African countries, there are shortages of specialist dermatologists who could make such diagnoses.

The project

The SkincAIr project aims to overcome this barrier using **AI-based image analysis** of skin lesions. Its aim is to create an **AI-driven app** for use in primary care settings to characterise skin lesions and provide a diagnosis to guide subsequent care.

Working in Ethiopia, Nigeria and the Democratic Republic of the Congo (DRC), the project is collating a large database of several thousand images of skin lesions associated with multiple neglected tropical diseases affecting sub-Saharan Africa, drawing on material at 12 hospitals in participating countries. These images are being carefully annotated by dermatologists and will be used to train an AI image recognition system.

The diagnostic app based on this AI system will be co-developed with health workers and other stakeholders using a rapid prototyping and revision approach. It will also incorporate **educational materials** for health workers, and information gathered through the app will be integrated into the standard health informatics platform (DHIS2) used locally. Each image will be geotagged, providing policymakers with epidemiological data on each neglected tropical disease.

The project will also conduct a validation study to assess diagnostic accuracy by comparing the tool’s predictions with those of expert clinicians. Impacts on diagnostic performance of health workers will then be assessed in the three participating countries through a before-and-after comparison following the introduction of the new tool.

The impact

The SkincAIr project has the potential to have a major impact on the care of neglected tropical diseases in sub-Saharan Africa. It will:

- Provide a tool for diagnosis of neglected tropical diseases in frontline health facilities, based on their characteristic skin manifestations.
- Ensure that patients receive a rapid diagnosis and are started on the appropriate treatment as soon as possible.
- Lead to more rapid patient recovery and reduce the likelihood of social stigmatisation and other psychosocial harms.
- Reduce the risk of further transmission due to untreated infections in the community.

With neglected tropical diseases affecting many millions of people in sub-Saharan Africa, the SkincAIr project could have a substantial impact on health and quality of life – particularly among some of the poorest populations in Africa, who are at particular risk of such diseases.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2030
Total project cost	€4 926 027,20
Global Health EDCTP3 funding	€4 926 027,20
Disease area	Neglected infectious diseases
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Digital technologies
Project coordinator	UNIVERSIDAD POLITECNICA DE MADRID
Scientific project leader	KENYA MEDICAL RESEARCH INSTITUTE
Participating countries	Spain, Kenya, Estonia, Senegal, Ethiopia, Nigeria, France, United Kingdom, Democratic Republic of the Congo





MultiplexAI

The Intelligent Autonomous Microscope: An AI platform for multiplex parasite diagnosis at the point of care

The MultiplexAI project is developing an easy-to-use add-on for conventional microscopes that deploys artificial intelligence (AI) models to detect multiple parasite infections in different biological samples.

The challenge

Parasitic diseases, from malaria to neglected tropical diseases (NTDs) such as filariasis and trypanosomiasis, affect hundreds of millions of people worldwide, especially in low- and middle-income countries (LMICs). In many of these regions, diagnosis still relies on conventional optical microscopy.

Optical microscopy is the gold-standard method for diagnosing parasitic diseases, but it holds **important limitations**. The process is labour-intensive, depends heavily on the expertise of trained specialists, and results can vary significantly between observers. Shortages of skilled personnel and limited laboratory resources contribute to delays and misdiagnosis.

These challenges affect patient care and pose a public health challenge: delayed or incorrect diagnoses can worsen disease outcomes, increase transmission, and place additional strain on already fragile health systems.

Recent advances in **AI offer new opportunities to address this challenge**. AI systems can analyse medical images and automatically identify patterns associated with parasites, improving point-of-care diagnosis and accelerating treatment for patients.

The project

MultiplexAI is transforming standard microscopes into intelligent digital diagnostic systems.

The system combines three main components:

- **A low-cost 3D-printed adaptor** that connects a smartphone or tablet to the microscope eyepiece to capture images of samples.
- **A mobile application with embedded AI models** that analyse microscopy images directly on the device, detecting, differentiating and quantifying parasites in real time.
- **A cloud-based telemedicine platform** where images and results can be securely stored, visualised and reviewed remotely by experts, enabling quality control, second opinions and improved epidemiological surveillance.

Together, these components upgrade existing microscopes into connected diagnostic tools that can support healthcare workers at the point of care.

The AI models are being trained using real-world data to recognise multiple parasites that provide clinically relevant information.

The project will **evaluate the technology** in both laboratory and clinical settings across several countries in sub-Saharan Africa (Nigeria, Mozambique, Ethiopia, and Côte d'Ivoire) comparing its performance with established diagnostic methods. In parallel, social science and health economic studies will **assess usability, acceptability, and cost-effectiveness** in real healthcare environments. Finally, a **go-to-market strategy** will be implemented to deliver the final validated product to healthcare communities worldwide.

The impact

MultiplexAI aims to make accurate parasite diagnosis more accessible and scalable by bringing AI-powered image analysis to routine microscopy. The project will:

- Provide a practical way to upgrade existing microscopes with AI-assisted diagnostics.
- Enable faster and more accurate detection of parasite infections, supporting timely treatment.
- Allow a wider range of healthcare workers to perform reliable microscopy analysis.
- Strengthen digital laboratory networks and epidemiological surveillance, while expanding local capacity to develop and use AI-enabled health technologies across sub-Saharan Africa.

By improving the speed and accuracy of parasite detection, the system could enable earlier diagnosis and treatment, reducing the risk of severe infection, limiting transmission, and strengthening health systems in regions where parasitic diseases continue to pose a major global health burden.

Project at a glance	
Project duration	1 Jun 2025 – 30 Nov 2028
Total project cost	€4 999 266,25
Global Health EDCTP3 funding	€4 999 266,25
Disease area	Neglected infectious diseases, Malaria
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Digital technologies
Project coordinator	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA
Scientific project leader	AHMADU BELLO UNIVERSITY
Participating countries	Spain, Nigeria, Mozambique, Ethiopia, Côte d'Ivoire, Italy, United Kingdom



DIDIDI

Digital dashboards in diagnostic innovations

The DIDIDI project is developing automated systems and AI tools to provide a more rapid assessment of parasitic worm burdens.

The challenge

Key neglected tropical diseases, **soil-transmitted helminths** (parasitic worms) and **schistosomes** (flukes) affect around 1.5 billion people, most of them in Africa. They are targeted for elimination, with control relying mainly on mass drug administration campaigns.

Monitoring progress towards elimination is essential but challenging. In addition to the presence of parasites, it is important to track the intensity of infection, or individual worm burdens. This generally relies on manual **microscopic analysis of stool samples** to quantify the number of parasite eggs present. This is labour-intensive and time-consuming.

The project

The DIDIDI project is assessing whether **automation and AI technologies** can accelerate the analysis of stool samples to characterise parasitic worm infections.

A prototype system has been developed based on a very low-cost (below €220) **3D-printed microscope** that can be transported in a backpack to field locations. It has a modified stage that automatically scans stool samples and is controlled by a simple mobile phone app, which also enables AI software to interpret the image and provide a numerical count of eggs, distinguishing between those from **five** different types of parasitic worms and schistosomes, in faecal samples.

The DIDIDI project is working with the microscope manufacturer to refine its design to make it more robust for use in African field settings. In addition, automatic scanning will be extended to the third dimension so the full volume of stool samples can be analysed. The accompanying app interface and decision-support module will be co-designed with users.

The new version will then be evaluated at **six schools in Kenya and Uganda**, in areas where parasitic worms and schistosome infections are common. The aim is for each microscope to process 100 samples a day, or 400 a week (with a day for associated support and transport activities). Results from several microscopes may be processed by networking information through a single mobile phone. Findings will be compared with the results of parallel testing using gold-standard microscopy techniques analysed by local health workers, as well as by lateral flow assay test results and molecular testing.

As well as testing individuals, the project is exploring the use of **community-wide sampling** to track parasite burdens. Latrine pits will be tested to determine whether the information on village-level parasite prevalence over the period of mass drug administration is useful to policymakers.

Individuals' and community results will be delivered directly to national electronic medical records and to standard health information systems in both Uganda and Kenya, with digests presented to policymakers via a digital dashboard. **Health economic analyses** will be carried out to provide insights into the cost-effectiveness and budget impact of both individual-level and community-focused approaches.

Finally, the project is also collating **local meteorological data** from a range of sources to determine whether there are correlations between meteorological determinants and parasite prevalence. This could provide valuable insights into how disease burdens might be affected by recent changes in weather patterns, associated with climate change, which could help to optimise community treatment campaigns.

The impact

The DIDIDI project could support the more effective control of key neglected tropical diseases in sub-Saharan Africa. It will:

- Show whether a new portable, higher-throughput microscopy technology can reliably determine the intensity of infection of schistosomes and soil-transmitted helminths in individuals or communities, in low-resource settings.
- Provide data that could both support the treatment of individuals and guide local and national control efforts.
- Generate insights into how worm infections are being impacted by changes in meteorological patterns in East Africa.

By refining microscopy tools and integrating AI image analysis, the DIDIDI project could greatly increase the amount of information on parasitic worm burdens available to policymakers, helping them to assess the effectiveness of control efforts and prioritise areas for more intensive intervention.

Project at a glance	
Project duration	1 Mar 2026 – 28 Feb 2030
Total project cost	€4 995 384,38
Global Health EDCTP3 funding	€4 995 384,38
Disease area	Neglected infectious diseases
Intervention type	Diagnostics, Surveillance tools, Other prevention tools
Overarching topic	Climate crisis or climate adaptation, Digital technologies
Project coordinator	UNIVERSITY OF GLASGOW
Scientific project leader	UGANDA NATIONAL HEALTH RESEARCH ORGANISATION
Participating countries	United Kingdom, Uganda, Netherlands, France, Kenya, Germany





IMPACTING

Integrated Multi-vector-borne diseases Platform to Assess how global Change impacts Transmission using Innovative systems modelling, Novel monitoring tools, and transmission blockinG micro-organisms

The IMPACTING project is collecting data on a host of insect vectors that spread infections to help better predict the risk of infectious disease outbreaks.

The challenge

Climate change and environmental disruption are having a profound impact on the spread of infectious diseases, including in sub-Saharan Africa. Changing temperatures and weather patterns are affecting the distribution of vectors that spread key diseases, and changing land use is disrupting ecosystems, bringing these vectors into closer contact with people.

These effects are hugely significant, as vector-borne diseases account for an estimated 700,000 deaths a year, mostly of young children. Although epidemiological studies can provide insights into the current distribution of disease and areas at risk, understanding how these are likely to change and which areas will be at greatest risk in the future is critical to inform public health planning.

The project

Focusing on Cameroon, Kenya and Mozambique, the IMPACTING project is undertaking a range of activities to highlight areas most at risk of future outbreaks of vector-borne disease.

It is exploring diseases linked to a range of insect vectors, including:

- **Mosquitoes:** Malaria, dengue, chikungunya, yellow fever.
- **Tsetse flies:** Human African trypanosomiasis (sleeping sickness).
- **Blackflies:** Onchocerciasis.
- **Ticks:** Congo-Crimea haemorrhagic fever.

At multiple sites, project team members are sampling the environment to determine the prevalence of different species of vectors. This information will be used to map the existing distribution of vectors and model how their distribution will change in response to climatic or environmental changes. This work requires several innovations, including the development of new traps and attractants to capture insect vectors more effectively.

A second strand of the project focuses on environmentally friendly approaches to **disrupting disease transmission** by insect vectors. It has recently become clear that the presence of some commensal bacteria can inhibit pathogen development inside vectors. Infecting insects with these bacteria could therefore block transmission without harming the vectors themselves, thereby removing selection pressure to drive resistance – a constant challenge for pesticide-based vector control strategies. The project will initially focus on two species of transmission-blocking commensals, *Serratia* and *Microsporidia MB*, and develop strategies to identify further candidates.

A third strand of work focuses on **community engagement**. The project team aims to involve community members, including women and young people who are often excluded from these

activities, in the co-creation of strategies for community-based vector surveillance and vector control.

Based on these activities, the team plans to work with policymakers to develop a multifunctional, multi-disease dashboard to visualise high risk areas under different climate and environmental scenarios, to inform preventive and rapid-response activities.

The impact

The IMPACTING project is addressing the growing challenge posed by climate and environmental change to health in sub-Saharan Africa. It will:

- Provide better methods for monitoring the distribution of insect vectors of key infectious diseases.
- Identify and begin evaluating commensal-based approaches to control the transmission of vector-borne diseases.
- Involve communities in the development of grass-roots activities to disrupt disease transmission.
- Provide health officials with tools for monitoring vector-borne disease and identifying areas at high risk of outbreaks.

Through these activities, the IMPACTING project will equip policymakers and communities with tools to better predict the impacts of climate change and other environmental factors on vector-borne diseases and to intervene more effectively to reduce the burden of such diseases.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2029
Total project cost	€6 153 640,63
Global Health EDCTP3 funding	€6 113 862,50
Disease area	Neglected infectious diseases, Malaria, Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools, Other prevention tools
Overarching topic	Climate crisis or climate adaptation, Digital technologies, Environment and biodiversity, (Other) emerging technologies, Health security
Project coordinator	CENTRE DE COOPERATION INTERNATIONALE EN RECHERCHE AGRONOMIQUE POUR LE DÉVELOPPEMENT – C.I.R.A.D. EPIC
Scientific project leader	THE INTERNATIONAL CENTRE OF INSECT PHYSIOLOGY AND ECOLOGY
Participating countries	France, Kenya, Cameroon, Portugal, Mozambique, Madagascar, United Kingdom, Switzerland, Australia



PEP4LEP 2.0

PEP4LEP 2.0 – Chemoprophylaxis for leprosy: comparing the effectiveness and feasibility of a community-based intervention to a health centre-based intervention in Ethiopia, Mozambique, and Tanzania

The EDCTP2-funded PEP4LEP project has received additional funding to complete its study of two possible models for the delivery of preventive leprosy treatments and care of other skin diseases.

The challenge

Despite much progress in disease control, leprosy remains a common problem in certain sub-Saharan African countries. Although rarely lethal, it can have a major impact on quality of life, leading to injuries that can be highly disabling and stigmatising, and prevent people from earning a living.

Leprosy develops over a long period of time, and stigmatisation often leads people not to reveal their infection status. These factors lead to delays in care seeking and provide opportunities for infections to be transmitted to family members and social contacts.

The risk of leprosy transmission can be significantly reduced by post-exposure prophylaxis (PEP), which involves providing antibiotics after exposure to contacts of patients to prevent infection. This approach has been shown to be highly effective, but it is not clear how it can best be implemented within health systems in sub-Saharan Africa.

In addition, leprosy is one of more than a thousand diseases that affect the skin, including several neglected tropical diseases, such as leishmaniasis, Buruli ulcer and lymphatic filariasis. Globally, almost a third of the world's population is affected by skin diseases, and in parts of sub-Saharan Africa, skin conditions make up more than 10% of primary healthcare consultations. Since most countries have very few specialist dermatologists, there is interest in developing primary care systems that cover multiple skin conditions, an integrated approach to skin condition management that is recommended by the WHO.

The project

Funded through the EDCTP2 programme, the PEP4LEP project was set up to compare two ways to identify people who might benefit from PEP for leprosy. The first was based on 'skin camps' – temporary community-based clinics where community members coming into contact with patients could be assessed for leprosy and other skin conditions, receiving PEP when necessary. The second approach was similar but involved community members attending **existing health facilities**. A cluster randomised trial was organised in Ethiopia, Mozambique and Tanzania, with areas in the three countries randomised to one of the two models.

The project was badly affected by the COVID-19 pandemic, which disrupted the organisation of skin camps. In addition, a core outcome being assessed in the project was the delay in diagnosis of leprosy cases, which was itself affected by the disruption of health services during the pandemic.

Global Health EDCTP3 funding is enabling the PEP4LEP 2.0 project to complete its study and also to recruit additional cases so that the specific effects of the pandemic can be assessed. In addition, the project is now capturing data on the longer-term impacts of the two models through extended follow-up and is carrying out a cost-effectiveness analysis. The project is also consulting with healthcare workers and community members to assess the acceptability of the two models and to gather insights into the practicalities of implementation.

The impact

The PEP4LEP 2.0 project will provide key data on possible ways to implement post-exposure prophylaxis (PEP) for leprosy prevention and management of skin diseases. It will:

- Generate high-quality data on the impact of PEP on the leprosy disease burden in real-world, high-burden settings.
- Provide an indication of the effectiveness and cost-effectiveness of the two models of PEP delivery.
- Identify key factors associated with the effective implementation of each model.
- Strengthen skills in diagnosis and integrated management of skin diseases at the community level.

Identification of an effective model for community-based management of skin conditions could have a major impact on the quality of life of millions of people in sub-Saharan Africa affected by leprosy and a host of other neglected tropical diseases affecting the skin.

Project at a glance	
Project duration	1 Apr 2024 – 31 Mar 2026
Total project cost	€1 780 303,75
Global Health EDCTP3 funding	€1 780 303,75
Disease area	Neglected infectious diseases
Intervention type	Other prevention tools
Overarching topic	Digital technologies
Project coordinator	NEDERLANDSE STICHTING VOOR LEPRABESTRIJDING
Scientific project leader	ARMAUER HANSEN RESEARCH INSTITUTE
Participating countries	Netherlands, Ethiopia, Germany, Mozambique, Tanzania, Canada, United States





Diarrhoeal diseases

ComBac-Africa

Combating Multidrug-Resistant Gram-Negative Bacteria in Africa through Diagnostic and Antimicrobial Stewardship

The ComBac-Africa project is working to improve access to new antibiotics in sub-Saharan Africa, incorporating measures to ensure their judicious use and limit the risk of drug resistance.

The challenge

Sub-Saharan Africa faces the dual challenge of limited access to some antibiotics as well as some of the world's highest levels of antibiotic resistance. Of particular importance are Gram-negative bacteria living in the gut, including *Klebsiella pneumoniae* and *Acinetobacter baumannii*, that are resistant to key classes of antibiotics (carbapenems and third-generation cephalosporins). These bacteria are an important cause of severe hospital-acquired infections.

While efforts are needed to **improve access** to newer antibiotics that are active against such drug-resistant bacteria, introductions must be carefully managed to ensure their use only when clinically required, to avoid the overuse that would drive the development of **antibiotic resistance**. This depends on the capacity of health systems to identify the causes of infections and on their sensitivity to different antibiotics, so that patients can be prescribed the most appropriate drug.

In addition, **infection prevention and control** measures need to be optimised to prevent the spread of hospital-acquired infections and reduce the need for antibiotics in hospital settings.

The project

The ComBac-Africa project is organising a range of activities to enhance access to a group of new antibiotics – **ceftazidime-avibactam**, **ceftazidime-avibactam**, and **aztreonam-avibactam** – while also promoting stronger hospital infection prevention and control systems and **antibiotic stewardship** programmes.

Focusing on hospitals in Côte d'Ivoire, Guinea-Bissau, and Nigeria, the project is building institutional capacity in microbiological diagnostics by providing new equipment and training. It will work with clinicians in each hospital to strengthen infection prevention and control activities and antibiotic stewardship programmes. Newly developed clinical algorithms will help clinicians optimise the detection and management of serious infections.

These activities will be informed by a programme of work to understand the **local epidemiology of Gram-negative bacteria**, which is generally not well characterised in sub-Saharan Africa. This will include whole-genome sequencing of clinical isolates, enabling the tracking of the transmission pathways of individual cases and suggesting where interventions should be targeted to reduce the risk of transmission.

To determine the impact of these activities, a clinical research study will run in parallel, comparing factors such as clinical outcomes and antibiotic usage before and after the intervention.

The impact

The ComBac-Africa project could lead to significant improvements in the management of severe infections in hospitals across sub-Saharan Africa. It will:

- Help to establish healthcare practices that match patients to the appropriate treatment, improving clinical outcomes and avoiding overuse of antibiotics.
- Strengthen hospital capacities in key areas of infection prevention and control and antibiotic stewardship.
- Provide a mechanism to facilitate the introduction of multiple new antibiotics into sub-Saharan African healthcare systems.
- Explore a range of options to ensure sustainable access to these new antibiotics, including pooled procurement and technology transfer for local manufacture.

As well as enhancing the treatment of serious infections in the three participating countries, the ComBac-Africa project will generate important learning that will facilitate the wider, well-managed introduction of new antibiotics, increasing access to vital, life-saving treatments without misuse that would undermine their potency.

Project at a glance	
Project duration	1 May 2025 – 30 Apr 2029
Total project cost	€5 869 998,75
Global Health EDCTP3 funding	€5 869 998,75
Disease area	Diarrhoeal diseases, Lower respiratory tract infections, Cross-disease or disease unspecific
Intervention type	Therapies, Diagnostics, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Environment and biodiversity
Project coordinator	UNIVERSITÄT DES SAARLANDES
Scientific project leader	OBAFEMI AWOLowo UNIVERSITY
Participating countries	Germany, Nigeria, Guinea-Bissau, Portugal, Côte d'Ivoire, South Africa





HUNADIA

Next-gen cholera treatment for faster recovery, lower mortality and better outbreak control

The HUNADIA project is assessing whether a newly developed drug can alleviate the symptoms of cholera, speeding up recovery and shortening or potentially even preventing hospital stays.

The challenge

Recent years have seen a resurgence in **cholera** (acute watery diarrhoea caused by infection with the bacterium *Vibrio cholerae*). Contamination of water sources can cause explosive outbreaks of diarrhoeal disease that may lead to deaths and place enormous strains on health systems. Globally, up to 4 million cases are estimated to occur each year, leading to tens of thousands of deaths. Sub-Saharan Africa accounts for more than half of all cases and the overwhelming majority of deaths.

Cholera can be prevented by **good water, sanitation, and hygiene (WASH)** infrastructure and practices, but in many resource-poor settings and during humanitarian emergencies, outbreaks remain common. Although oral cholera vaccine (OCV) can prevent disease, it is in short supply and vaccine protection wanes over time.

Treatment of cholera is mostly based on the use of oral rehydration solution (ORS) and zinc to replace fluids and electrolytes. Antibiotics may also be given, although they have minimal immediate impact on symptoms.

While beneficial, these treatments do not address the key mechanism underlying the most dangerous symptoms of cholera: massive fluid loss. This is due to a toxin released by *V. cholerae* (**cholera toxin**), which acts on a protein, known as CFTR, that regulates fluid flow in the gut. Cholera toxin leads to the persistent activation of CFTR, leading to a massive outflow of water into the gut, generating the acute watery diarrhoea typical of cholera.

The project

The HUNADIA project is carrying out a **major international trial** to determine whether a newly developed drug, known as **VR-AD-1005 (VR)**, can provide an additional tool for cholera management by directly targeting the action of cholera toxin.

Developed by a biotech company in Spain, **VR inhibits CFTR**, which turns off the tap held open by cholera toxin. VR has two components: a compound that inhibits CFTR, and a second component that helps the drug stick to the intestinal wall, preventing it from being washed away (which typically happens with oral anti-diarrhoeal drugs).

In animal models, VR led to a 70% reduction in stool volume (faecal matter excreted) and 30% reduction in mortality. Furthermore, in a phase II clinical trial in Bangladesh, where cholera outbreaks are seasonal, VR halved the time to hospital discharge, significantly reduced stool volumes, and reduced the need for intravenous fluid infusions.

To extend these highly promising findings, the HUNADIA project is conducting a **larger-scale phase III trial**, recruiting 1,200 patients in Cameroon, the Democratic Republic of the Congo (DRC), Malawi, Mozambique, Tanzania, and Zambia, as well as in Bangladesh. Patients will receive local standard of care for cholera plus either VR or a placebo.

The trial will be a **multi-centre adaptive trial**, since it is difficult to predict where and when cases of cholera will arise. Recruitment at different sites will be activated when local outbreaks occur. The trial will also include the potential to vary other parameters, such as sample size or dose (under clearly defined circumstances). A smaller number of cases will be recruited in the community to determine whether VR can be used early to prevent hospitalisation.

The trial will assess multiple aspects of patients' symptoms and use of health system resources. Data will be used to develop a **comprehensive impact and health economic assessment** that examines the implications for both households and health systems.

In addition, the trial will use the data collected to explore the **impact of climate and environmental variables** on the risk of cholera outbreaks.

The impact

The HUNADIA project could have a transformational impact on the treatment of cholera. It will:

- Reveal what impact a newly developed drug, known as VR-AD-1005 (VR), has on the severity and duration of clinical symptoms of cholera.
- Whether early use of VR can reduce the risk of hospitalisation.
- Identify the potential impacts of VR administration on the use of health resources, including hospital stays, use of intravenous fluids and antibiotics.
- Provide a rigorous assessment of the cost-effectiveness of VR use.

VR has the potential not only to benefit patients by reducing the severity and duration of cholera cases, but also to deliver health system benefits by reducing demand during outbreaks, freeing up hospital beds, and providing savings on medical supplies – to the extent that it may deliver overall cost savings.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2030
Total project cost	€5 628 262,50
Global Health EDCTP3 funding	€5 628 262,50
Disease area	Diarrhoeal diseases
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation
Project coordinator	HUNAZINE BIOTECH SL
Scientific project leader	CENTRE FOR INFECTIOUS DISEASE RESEARCH IN ZAMBIA LIMITED
Participating countries	Spain, Zambia, Netherlands, Malawi, Mozambique, Bangladesh, Kenya, Cameroon, Tanzania, Democratic Republic of the Congo



TARGET

Targeted antibiotic therapy for high-risk children with watery diarrhoea and malnutrition

The TARGET project is assessing whether antibiotic treatments can improve outcomes for young children affected by both diarrhoeal disease and malnutrition..

The challenge

Young children in low-resource settings are prone to frequent episodes of acute watery diarrhoea, which can be severe enough to lead to hospitalisation and death. Although an estimated 25–50% of cases are likely to be caused by bacterial infections, WHO does not currently recommend antibiotic treatment in such cases, due to a lack of evidence that it would be beneficial and concerns that antibiotic use would drive antimicrobial resistance. Even so, most children do receive antibiotics, but often not ones likely to be effective on the causes of gut infections.

The case for antibiotic use would be stronger if children most likely to benefit could be identified, so antibiotics could be used sparingly and where they are specifically needed. Unfortunately, there are no simple tests to distinguish between viral, bacterial and parasite gut infections, and testing individually for particular pathogens is not feasible in most settings in sub-Saharan Africa.

Diarrhoeal disease is the biggest risk factor for death among children with malnutrition. Such children are also more likely to have disease caused by bacterial infections. A recent trial therefore assessed whether antibiotic treatment would reduce hospitalisation or death in young children with acute watery diarrhoea plus either dehydration, severe stunting or moderate wasting. A small benefit was seen for the group as a whole, but a much larger effect was noted when analysis focused only on children with malnutrition, in whom the risk of hospitalisation and death was cut by more than a third.

The project team calculated that fewer than 20 children would need to be treated to prevent a case of hospitalisation or death, lower than the comparable figure for other conditions (such as pneumonia) for which WHO recommends antibiotic use. Furthermore, the trial did not recruit children with severe acute malnutrition (who should already receive antibiotics) so in practice the number needed to treat is likely to be even smaller.

The project

On the back of these findings, the TARGET project is now carrying out a trial with a specific focus on young children with acute watery diarrhoea and malnutrition. At sites in Kenya and Tanzania where malnutrition is common, 2800 children will be recruited and randomised to one of two antibiotics with known efficacy against intestinal pathogens – **azithromycin and ciprofloxacin** – or standard care alone.

The project will characterise the causes of infection and also evaluate a point-of-care **stool haemoglobin assay** which shows promise as a simple way to detect bacterial infections in care settings.

When infections do not respond to treatment, bacterial isolates will be sequenced to identify potential antimicrobial resistance genes. The presence of such genes in the wider gut microbiome will also be tracked.

The epidemiology of diarrhoeal disease is likely to be significantly affected by **climate change**. The project is collaborating with another EU-funded project (**SPRINGS**) which is developing methods to predict how the distribution of organisms causing diarrhoeal disease will be affected by a changing climate. The TARGET project is installing equipment to generate deep data on local environmental conditions, to determine how these affect the pathogens detected locally. This information will help to predict which other sites might expect to see a similar distribution of gut pathogens because they share similar environmental conditions.

The impact

The TARGET project could have a major impact on the treatment of diarrhoeal disease in young children in sub-Saharan Africa. It will:

- Demonstrate whether a highly vulnerable group – young children with acute watery diarrhoea and malnutrition – benefit from use of widely available antibiotics.
- Evaluate whether a simple point-of-care test could be used more generally to detect bacterial gut infections requiring antibiotic treatment.
- Generate additional information on the presence of antimicrobial resistance genes and their sharing with species present in the healthy gut microbiome.

Targeted treatment of acute watery diarrhoea in young children with malnutrition could save lives and reduce the risk of hospitalisation, which can have a catastrophic impact on household finances and adds to the financial pressures on health systems. By ensuring that antibiotics are targeted where most needed, the project could also improve outcomes without adding to the pressures driving the development of antimicrobial resistance.

Project at a glance	
Project duration	1 Jul 2026 – 31 Dec 2030
Total project cost	€5 799 966,25
Global Health EDCTP3 funding	€5 799 966,25
Disease area	Diarrhoeal diseases
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance; Climate crisis or climate adaptation
Project coordinator	STICHTING AMSTERDAM UMC
Scientific project leader	KENYA MEDICAL RESEARCH INSTITUTE
Participating countries	Netherlands, Kenya, Tanzania, France





CryptoT&T

A cryptosporidiosis point-of-care test-and-treat strategy in children with diarrhoea

The CryptoT&T project is developing a test to detect *Cryptosporidium* intestinal parasite infections, which could usher in targeted drug treatment for this common diarrhoeal disease.

The challenge

Diarrhoeal diseases continue to be a leading cause of death among young children in low- and middle-income countries. Such diseases are caused by a wide range of bacteria, viruses and parasites. One of the most common is *Cryptosporidium*, a single-celled parasite.

Cryptosporidium appears to cause more disease than once thought. The landmark international GEMS study, for example, identified *Cryptosporidium* as the third most common cause of diarrhoeal disease in young children, and one of three infections associated with an increased risk of death in children less than two years old. An estimated 2.9 million cases occur each year in sub-Saharan Africa, leading to more than 200,000 deaths in Africa and South Asia.

These deaths are avoidable, as an effective and affordable treatment for *Cryptosporidium* already exists, **nitazoxanide**. Currently, however, the drug is not widely used as the symptoms of *Cryptosporidium* infection are the same as many other diarrhoeal diseases, and there are no affordable diagnostics that could be used to identify cases caused by *Cryptosporidium*.

The project

The CryptoT&T project aims to overcome this barrier by using a microscope-based approach for identifying *Cryptosporidium* in faecal samples. **LED microscopy** of faecal samples treated with a particular stain (auramine-phenol) is a relatively simple technique requiring minimal training. Moreover, LED microscopy has already been introduced in many parts of sub-Saharan Africa to detect mycobacteria.

The project is exploring whether LED microscopy could be used as part of a **test-and-treat strategy**: patients with diarrhoeal disease would be routinely screened and provided with nitazoxanide when *Cryptosporidium* is detected. A recent study in Ethiopia showed that the technique has high sensitivity, but a larger study is needed to demonstrate that the test-and-treat strategy improves clinical outcomes, specifically in reducing the duration of cryptosporidiosis-induced diarrhoea.

As a treatment is available, a placebo-controlled trial would not be ethical. The project therefore uses a 'stepped wedge' design, in which the intervention is introduced over time, with areas scheduled for late-stage implementation serving as control sites. Ultimately, all facilities within the trial area will be using the strategy by the end of the study.

The key to success will be the speed at which results are generated, since the goal is to enable treatment to begin while a patient is at a health facility. One way to decrease the total turnaround time could be to use **faecal smears** rather than stool samples. The project will therefore run a study in parallel to compare the results obtained with the analysis of faecal smears and stool samples.

The study will run in a diverse set of sites around Addis Ababa and different provinces of Mozambique to provide data from different types of settings. It will also estimate the cost implications of the test-and-treat strategy and carry out a cost-effectiveness analysis. The project aligns with the UN Sustainable Development Goal 3 and the WHO initiatives to reduce the burden of diarrheal diseases.

The impact

The CryptoT&T project has the potential to impact the treatment of diarrhoeal disease significantly. It will:

- Generate critical data on the feasibility and cost-effectiveness of a test-and-treat strategy for *Cryptosporidium* infections.
- Facilitate the introduction of an affordable and targeted drug treatment, nitazoxanide.
- Strengthen surveillance systems and provide additional data on the prevalence of *Cryptosporidium*.
- Reduce the unnecessary use of antibiotics, the driving force of antibiotic resistance.

If the expected clinical impacts are seen, the CryptoT&T project could lead to much wider use of nitazoxanide, reducing the short-term impact of *Cryptosporidium* infections and, over the longer term, the harms associated with growth faltering triggered by repeated enteric infections.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2028
Total project cost	€4700 000,00
Global Health EDCTP3 funding	€4700 000,00
Disease area	Diarrhoeal diseases
Intervention type	Diagnostics, Other prevention tools
Project coordinator	UNIVERSITETET I BERGEN
Scientific project leader	ARMAUER HANSEN RESEARCH INSTITUTE
Participating countries	Norway, Ethiopia, Mozambique



ODIN

Strengthening Environmental Surveillance to Advance Public Health Action

The ODIN project is establishing an infrastructure for genomic surveillance based on monitoring for the presence of pathogens and antimicrobial resistance (AMR) genes at environmental sites.

The challenge

Conventional surveillance relies on analysis of clinical samples. An alternative strategy, increasingly used, is monitoring wastewater or environmental samples. This approach does not provide information about specific clinical cases, but it is a convenient way to identify which pathogen strains are present in a community and how their numbers change over time.

Genomic sequencing enables the identification of multiple pathogens and strains in the same sample. Different pathogen strains can also be distinguished, and information can be gathered on the presence of antimicrobial resistance (AMR) genes.

Wastewater surveillance has been widely used to monitor SARS-CoV-2 and is increasingly being applied to a wider range of pathogens. Key challenges include interpreting large volumes of raw sequence data, presenting analyses so policymakers can act on them, and managing sequence data and associated metadata (e.g., sampling time and location).

The project

The ODIN project is introducing infrastructure and processes to pilot wastewater and environmental surveillance in Burkina Faso, the Democratic Republic of the Congo (DRC), and Tanzania. Sampling sites will be established at two cities of differing sizes in each of the three countries, targeting a variety of wastewater outlets and environmental water sources. The focus pathogens in each country will be agreed with local policymakers.

The project will also create a **mobile surveillance laboratory** – a converted bus that will be equipped with portable Nanopore sequencing technology and other molecular tools. When wastewater sampling detects an increase in a particular pathogen, the mobile surveillance laboratory will be deployed to conduct more detailed analyses to identify potential sources of infection and routes of transmission within the community.

Other aspects of the project include an extensive training programme and the development of a framework for data sharing, within and between countries. It will work closely with national public health institutes and laboratories to build capacity within national systems. Team members will collaborate with policymakers to design semi-automated bioinformatics tools and dashboard visualisations, ensuring sequencing activities inform programme planning as quickly as possible.

The project will also address emerging scientific questions, such as the abundance of different strains and species of *Vibrio*, the bacteria that cause cholera. Data from environmental monitoring will be integrated with local health data to determine how the two might best be used together to detect and track outbreaks. The environmental sampling data will also be used to develop water and sanitation safety plans in study areas.

The impact

The ODIN project will establish pilot capabilities for wastewater and environmental surveillance in three countries. It will:

- Provide public health officials with experience in setting up and managing environmental genomic surveillance systems.
- Create new tools to guide public health responses to water-borne pathogens.
- Offer additional opportunities to detect and respond rapidly to new outbreaks.

With waterborne diseases responsible for the bulk of infectious diseases in Africa, genomic environmental surveillance could provide an essential early-warning system and a means to monitor the effectiveness of public health interventions.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2027
Total project cost	€5 210 037,50
Global Health EDCTP3 funding	€5185 037,50
Disease area	Diarrhoeal diseases, Cross-disease or disease unspecific
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies, Environment and biodiversity, Health security
Project coordinator	LUNDS UNIVERSITET
Participating countries	Sweden, Democratic Republic of the Congo, Tanzania, Belgium, Finland, Burkina Faso, United Kingdom, Norway





GREAT-LIFE

Linking Infectious disease Front-liners’ control Efforts with central public health authorities in The African Great Lakes Region

The GREAT-LIFE project is building a genomics-based infrastructure to track existing and new infectious disease threats and antimicrobial resistance (AMR) genes in the Great Lakes region of Africa.

The challenge

To respond to existing and emerging diseases, national health authorities need to have a good understanding of the pathogens circulating in their countries. Surveillance systems typically focus on individual pathogens, which is inefficient, can lead to the neglect of important disease-causing microbes, and does not help to identify emerging pathogens. Moreover, surveillance systems generally focus on a limited number of sites, which rarely include remote rural settings where new infections are particularly likely to emerge.

New genomic technologies can address these surveillance challenges. Portable sequencing technologies, such as Nanopore, can now be used almost anywhere, generating DNA sequence data that can reveal the presence of multiple pathogens.

The Great Lakes region, which encompasses parts of Rwanda, the Democratic Republic of the Congo (DRC), Burundi, Uganda, Kenya and Tanzania, is densely populated, mostly rural and includes many displaced people. The region is a biodiversity hotspot and, with people living in close proximity to both domestic animals and wildlife, there is a high risk of spill-overs of infections from animals to humans. However, little surveillance is carried out in the region, so limited information is currently available about the causes of infectious disease and AMR.

The project

The GREAT-LIFE project is introducing systems to support the use of genomic surveillance in eight countries centred around the Great Lakes region. The project aims to maximise the value of this information, by enabling it to inform immediate clinical decision-making, to provide national authorities with data on the prevalence of particular pathogens and AMR genes, and to help track emerging infections.

The GREAT-LIFE project team has developed tools to support the collection and analysis of data generated using the Nanopore sequencing platform. The technology generates huge amounts of data, which requires the use of sophisticated bioinformatics tools to generate usable information. The GREAT-LIFE team has developed software that facilitates local analysis on a laptop and compresses the data so that it can be transmitted more easily to centralised data repositories.

Building on pilot work in Tanzania, the technology will be introduced at six or more sites in participating countries. The project is exploring three applications of the technology:

- Analysis of patient samples to identify the causes of diarrhoeal disease, to inform immediate treatment and longer-term public health responses.

- Characterisation of AMR genes in environmental samples, focusing on rural locations and camps for displaced people.
- Detection of new pathogens that emerge during the project.

To ensure that the data is communicated in a form that is useful to policymakers, the team is working with representatives of ministries of health and other stakeholders at different levels of the health system to identify key data needs, preferred reporting processes, and the design of outputs to support decision-making. Field data will be transferred to an existing central repository in Tanzania. Genomic data will be combined with sampling metadata and epidemiological data in a form that can be shared with global databases.

The impact

The GREAT-LIFE project will introduce genomic surveillance across multiple countries and generate evidence in areas that typically do not contribute to surveillance, leading to significant data gaps. It will:

- Support local data analyses, potentially facilitating tailored treatment of individual patients.
- Provide detailed insights into pathogens and AMR genes, supporting the updating of treatment guidelines and informing national public health responses to combat diarrhoeal disease, AMR and epidemics.
- Build capacity in multiple countries to apply genomic technologies in surveillance.
- Support multi-country coordination and sharing of experiences.

Crucially, the GREAT-LIFE project will provide rapid insights into changing trends, enabling rapid action to be taken to mitigate the risk of epidemics of known or new pathogens, limiting potential health and economic impacts.

Project at a glance	
Project duration	1 Jul 2023 – 30 Jun 2028
Total project cost	€5 207 500,00
Global Health EDCTP3 funding	€5 207 500,00
Disease area	Diarrhoeal diseases, Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools, Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies, (Other) emerging technologies, Health security
Project coordinator	DANMARKS TEKNISKE UNIVERSITET
Participating countries	Denmark, Tanzania, Rwanda, United Kingdom, Netherlands, Uganda, Burundi, Kenya



CARE-Africa

Novel Interventions to Identify and Control Diarrhoeal Diseases in sub-Saharan Africa

The CARE-AFRICA project is developing an innovative AI-based tool to guide diagnostics and treatment of diarrhoeal diseases in children under 5 in sub-Saharan Africa, using a combination of local and globally sourced data.

The challenge

Diarrhoeal diseases remain a common cause of ill-health and death in sub-Saharan Africa, particularly among children. In addition to their immediate health impacts, diarrhoeal diseases have multiple long-term consequences, affecting growth, development, schooling and economic prospects in adulthood.

Management of diarrhoeal diseases is a major challenge. A multitude of different viruses, bacteria and parasites can all cause diarrhoea, and identifying the underlying cause of symptoms can be difficult. Outcomes can vary widely, too – some infections rapidly self-resolve while others may progress to severe disease with a risk of death. Again, it is difficult for clinicians to judge which children are most at risk.

The project

The CARE-AFRICA project is developing and evaluating an **AI-based tool to guide clinical decision-making**, based on analysis of patient data entered by a clinician and automated retrieval of regional and national data on other factors likely to affect the risk of diarrhoeal diseases, such as environmental, climate, socioeconomic and demographic data. The tool is designed to integrate these data sources and provide a clinician with a likely diagnosis and a recommended treatment.

In addition to presenting the probabilities of infection and co-infection with a range of different pathogens, the tool also calculates the likelihood that the infection will be resistant to particular antibiotics, which informs its treatment recommendations. It also provides a clinician with an explanation of its results and recommendations. Results will be generated within 5 minutes in healthcare environments, and the system can retain information offline until an internet connection is established (for use in more disadvantaged areas).

To develop the tool, the CARE-AFRICA team will train AI agents on multi-scale and multi-modal data sources, so they learn the associations between a wide range of variables and different causes of diarrhoeal disease and types of drug resistance. To underpin this training, the project is collating historical data from Ethiopia and Uganda and collecting new data from a set of sentinel sites in contrasting locations. The tool's interface and functionality are being developed in close collaboration with end-users. It is being designed to run on a tablet device.

Once trained and validated, the tool will be initially tested in a pilot study in eight facilities in Ethiopia and Uganda. A revised version will then be tested more extensively across 40 facilities, with results obtained for approximately 4,700 children.

In a second strand of the project, the team will develop models based on the training data to provide dynamic predictions of diarrhoeal disease risk. This will give policymakers a tool for exploring how case numbers might be affected across different scenarios, for generating risk maps to target interventions, and for exploring potential impacts. Community consultations will be organised to gather data on community-level risk factors for diarrhoeal disease and barriers to care, which will also be incorporated into the model.

The impact

The CARE-AFRICA project has the potential to radically change the assessment of diarrhoeal disease cases in children in sub-Saharan Africa. It will:

- Create a sophisticated clinical decision-making support tool that requires minimal input from clinicians yet draws on a wealth of data sources to make assessments of the likelihood of different disease aetiologies.
- Provide an immediate assessment of the likelihood of antibiotic resistance, without specific susceptibility testing, which typically takes days to deliver results.
- Reduce antibiotics' misuse by matching antibiotic use to the likely susceptibility profile of an infection.

If validated, the new tool could ensure that children are more likely to receive an appropriate treatment for diarrhoeal disease – speeding up recovery times, reducing unnecessary use of antibiotics and thereby relieving pressures driving antimicrobial resistance, and optimising use of health system resources.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2029
Total project cost	€4 808 785,75
Global Health EDCTP3 funding	€4 808 785,75
Disease area	Diarrhoeal diseases
Intervention type	Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies
Project coordinator	KING'S COLLEGE LONDON
Scientific project leader	THE INFECTIOUS DISEASES INSTITUTE LIMITED
Participating countries	United Kingdom, Uganda, Ethiopia, Italy, Spain, South Africa





PRoRota

Safety, effectiveness and cost-effectiveness of probiotics as adjunct preventive therapy for childhood diarrhoea and antimicrobial resistance in Africa: A double blinded randomised controlled trial

The PRoRota project is assessing whether probiotic supplements can boost responses to rotavirus vaccination and reduce the risk of diarrhoeal disease in young babies.

The challenge

Diarrhoeal diseases are responsible for almost one in ten deaths of young children – more than a thousand deaths a day globally. Diarrhoeal diseases are caused by a wide range of pathogens, but the greatest disease burden is associated with **rotavirus** infections.

This burden has been significantly reduced over the past decade through the widespread introduction of rotavirus vaccination. However, the performance of rotavirus vaccines is markedly lower in countries in sub-Saharan Africa.

There is some evidence that this effect may be related to the composition of bacterial communities in the gut (the gut **microbiota**), which appears to affect responses to oral vaccines in low-income countries. ‘Healthy’ gut bacteria may prevent colonisation by pathogenic bacteria, protecting against gut damage, and may also stimulate gut immune responses.

These findings have led to speculation that **supplementary probiotics** – live, non-pathogenic bacterial cultures – might temporarily shift the gut microbiota and boost immune responses when given alongside rotavirus vaccines. However, limited data are available.

Probiotics may also have other benefits. There is some evidence that they enhance recovery from diarrhoeal disease when used as a treatment. When given prophylactically, they may also limit the diarrhoea linked to antibiotic use. And they may reduce the risk of colonisation with antibiotic-resistant strains of gut bacteria.

The project

The PRoRota project is generating rigorous data on the benefits of probiotic supplementation in young babies, as part of a holistic disease-prevention approach that also incorporates vaccination and improved water, sanitation and hygiene (WASH) practices.

In Côte d’Ivoire, Malawi and Tanzania, the project is recruiting 4,000 newborns and comparing a combined intervention against the usual standard of care. The intervention includes four four-weekly courses of a commercially available probiotic supplement, at birth, 6, 10 and 14 weeks, plus rotavirus vaccination and WASH advice (based on a pre-trial study examining current WASH practices).

The babies are being followed for six months. A wide range of data is being collected, including the number of episodes of diarrhoeal disease, cases of rotavirus diarrhoea, hospital visits and hospitalisations due to diarrhoeal disease. The strength of immune responses following vaccination will be monitored, as

will changes in weight and growth, and the presence of drug-resistant gut bacteria and microbiota diversity.

Data on the impacts of probiotic supplementation on these outcomes will be used to estimate the intervention’s cost-effectiveness and the costs of implementation.

In addition, the project is collecting data on a wide range of **climate-related variables** at study sites. These will be used to explore associations between various climate factors and the risk of diarrhoeal disease, to support the development of a predictive model to identify diarrhoeal disease hotspots based on environmental context.

The impact

The PRoRota project will generate robust data on a potentially impactful intervention to prevent diarrhoeal disease in babies. It will:

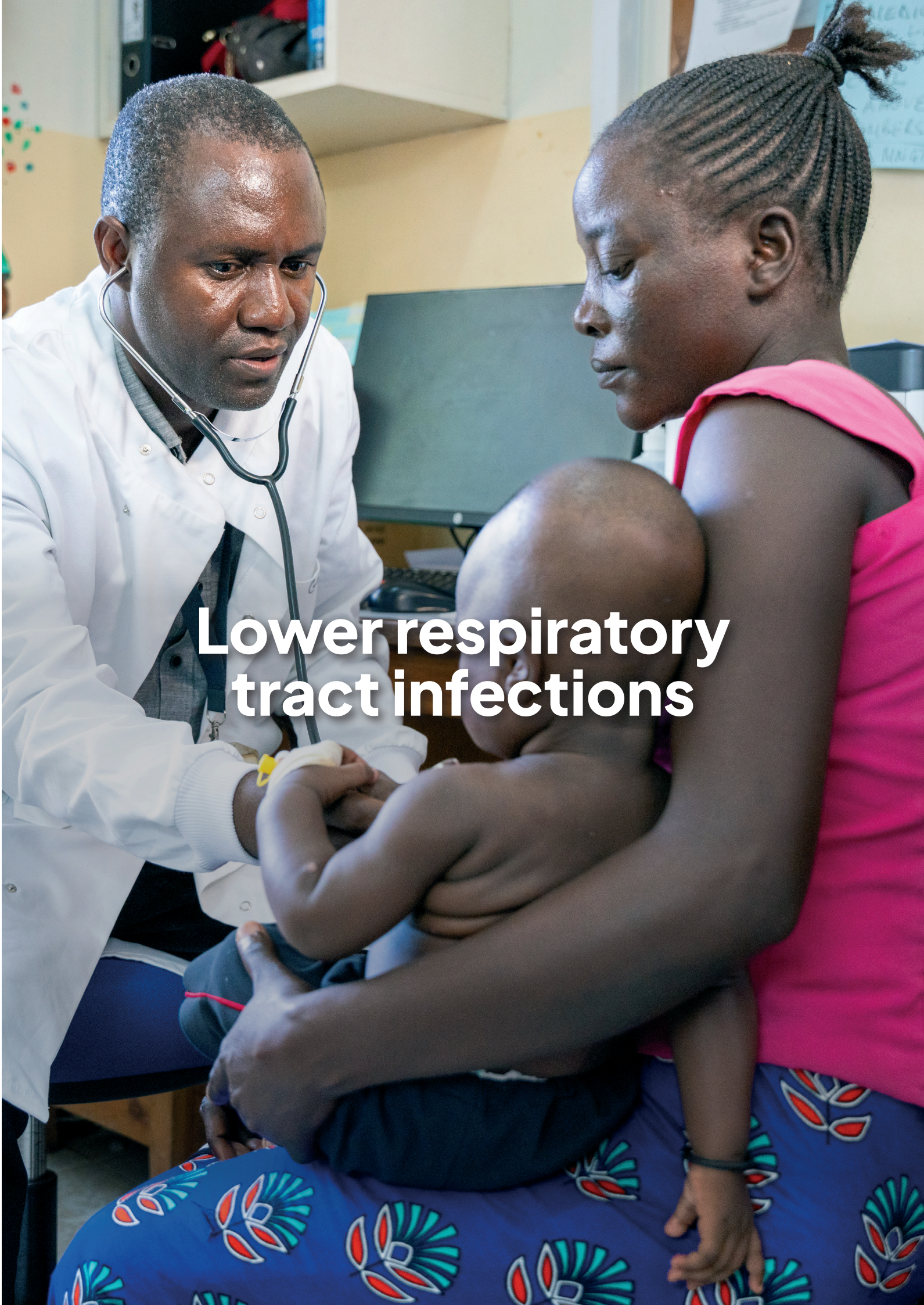
- Reveal whether probiotic supplementation leads to improved immune responses to rotavirus vaccines.
- Show whether supplementation leads to a reduction in the risk of diarrhoeal disease.
- Identify the likely cost-effectiveness of supplement use.
- Develop a model for identifying diarrhoeal disease hotspots and the potential impacts of climate change on diarrhoeal disease risk in different locations.

If shown to be effective, probiotic supplementation is a relatively simple intervention that could have immediate benefits in preventing episodes of potentially severe diarrhoeal disease, while also reducing the long-term impacts on childhood growth and development caused by repeated gut infections.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2030
Total project cost	€5 834 000,00
Global Health EDCTP3 funding	€5 299 998,75
Disease area	Diarrhoeal diseases
Intervention type	Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation
Project coordinator	UNIVERSITETET I BERGEN
Scientific project leader	TRAINING & RESEARCH UNIT OF EXCELLENCE LIMITED
Participating countries	Norway, Malawi, Tanzania, Côte d’Ivoire



Lower respiratory tract infections





OPT-bCPAP

Oxygen Optimisation Therapy through BCPAP for management of childhood pneumonia in general hospitals of LMICs

The OPT-bCPAP project is supporting the rollout of an innovative low-cost approach with the potential to prevent the deaths of thousands of young children from pneumonia.

The challenge

Pneumonia is responsible for the deaths of an estimated 750,000 children under 5 years of age every year, 14% of all deaths in this age group. Countries in sub-Saharan Africa have some of the highest mortality rates from pneumonia, including Nigeria (first) and Ethiopia (fourth).

Pneumonia is caused by a range of bacterial and viral pathogens and is responsible for a huge number of deaths, which are preventable if the condition is recognised early and care is optimised. The main challenge in pneumonia is **hypoxaemia** – low bloodstream oxygen levels – and providing children with supplementary oxygen can make the difference between life and death.

In severe cases in high-income countries, mechanical ventilators are used to deliver oxygen under pressure to the lungs, which ensures that air sacs in the lungs (alveoli) remain inflated. In low-resource settings, a lower-cost alternative is provided by **bCPAP (bubble continuous positive airway pressure)**, which uses simple, readily available materials to deliver oxygen under pressure. Oxygen is delivered via modified nasal prongs, which can be fitted by nurses.

Although several studies in low- and middle-income countries have demonstrated dramatic improvements in survival associated with bCPAP use, in some cases by up to a third, a trial in Malawi found an increased risk of harm. This likely reflects an issue with the implementation of the new approach, highlighting the importance of conducting implementation research to identify key factors associated with the successful introduction of bCPAP into routine clinical practice.

The project

The OPT-bCPAP project is supporting the introduction of bCPAP (bubble continuous positive airway pressure) at sites in high-burden countries (Ethiopia and Nigeria) and in Malawi. It is drawing on the experience of trials that have been carried out in Bangladesh, Ethiopia and Ghana, which demonstrated the potential survival benefits associated with bCPAP use.

During rollout, the project team is monitoring a range of factors that could potentially affect the success of bCPAP. These include adherence to treatment guidelines, healthcare-seeking behaviour and timeliness of treatment, the prevalence of respiratory syncytial virus (RSV, an important non-bacterial cause of pneumonia), levels of resistance to commonly used

antibiotics, and the pharmacodynamics/pharmacokinetics of antibiotic treatments. Antibiotic resistance or inadequate antibiotic treatments could be factors contributing to poor clinical outcomes.

The project is being carried out in close collaboration with national policymakers, and data is also being generated on the cost-effectiveness of the bCPAP approach.

The impact

The OPT-bCPAP project is generating data on one of the biggest killers of young children in sub-Saharan Africa. It will:

- Provide policymakers with key evidence on the clinical impact of bCPAP (bubble continuous positive airway pressure) on child survival and its cost-effectiveness.
- Identify the main factors associated with the successful implementation of bCPAP in routine care in a range of sub-Saharan African countries.
- Generate guidance and other materials that could be used to support implementation in other settings.
- Reveal other potential factors affecting survival, including those linked to antibiotic use, that could be used to optimise the treatment of pneumonia.

By identifying key factors associated with the implementation of bCPAP, the OPT-bCPAP project will increase the likelihood of successful introduction of an affordable technology that could potentially save the lives of thousands of young children every year.

Project at a glance	
Project duration	1 Jun 2024 – 31 May 2029
Total project cost	€4 641 691,25
Global Health EDCTP3 funding	€4 641 691,25
Disease area	Lower respiratory tract infections
Intervention type	Therapies
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	UNIVERSITY OF CAPE TOWN LUNG INSTITUTE PTY LTD*
Scientific project leader	ARMAUER HANSEN RESEARCH INSTITUTE
Participating countries	South Africa, Ethiopia, Sweden, Malawi, Nigeria



ASPIRE

Antimicrobial Stewardship, Prevention of Infection and Resistance in Africa

The ASPIRE project is assessing whether improved infection prevention and control, coupled with more personalised antibiotic use, can reduce pressures driving antimicrobial resistance in hospitals in sub-Saharan Africa.

The challenge

Antimicrobial resistance is a growing challenge globally, particularly in sub-Saharan Africa. An increasing number of infections no longer respond to standard antibiotic treatments, requiring the use of alternative antibiotics that may be more expensive or not readily available in sub-Saharan Africa. Drug-resistant infections are harder to treat, associated with worse outcomes for patients, and are more expensive for health systems to manage, due to longer hospital stays and the need for more expensive treatments.

Drug-resistant infections are a particular challenge in hospital settings, with some strains of bacteria, causing **hospital-acquired infections**, having become well-adapted to survive and spread in such environments.

The rise of antimicrobial resistance is highlighting the importance of **infection prevention and control**. To do this, it is essential to reduce the need for antibiotics and to use them more precisely, with the right antibiotic at the right dose.

The project

The ASPIRE project is exploring a set of interventions, focusing on infection prevention and control and ‘antibiotic optimisation’ (tailoring of individual treatments), to improve clinical outcomes and rationalise antibiotic use at four hospitals in Ethiopia and Ghana.

- Infection prevention and control: The project will coordinate a baseline assessment of infection prevention and control policies and practices at each hospital, and explore the knowledge, attitudes and practices of hospital staff. These insights will be used to develop tailored interventions designed to improve infection prevention and control, focusing on hand hygiene (staff and hospital visitors) and surface cleaning.
- Antibiotic optimisation: The project will build the capacity of hospitals to both monitor bloodstream antibiotic levels in patients and to determine the antibiotic sensitivity of pathogens responsible for serious bacterial infections. Using this information, clinicians can adjust antibiotic dosing to ensure successful treatment outcomes.

The impact of these interventions will be assessed in a clinical trial. This will reveal:

- whether the interventions reduce pathogen detection in the hospital environment;
- whether clinical outcomes improve for patients receiving optimised treatments;

- and whether the new processes affect antibiotic use within hospitals.

Measuring antibiotic levels in individual patients is a technically complex approach that could only be adopted in a limited number of well-resourced hospitals in sub-Saharan Africa. However, by collecting data on patients’ characteristics, treatments, and outcomes, the project aims to develop tools that hospital clinicians in the region could use to tailor treatment and optimise antibiotic use based on readily measurable patient and pathogen characteristics.

The impact

The ASPIRE project will have multiple short- and long-term impacts on patient care. It will:

- Demonstrate whether an enhanced focus on infection prevention and control can reduce the number of hospital-acquired infections.
- Show whether antibiotic optimisation improves patient outcomes and leads to more rational use of antibiotics.
- Generate tools that would enable less well-resourced facilities to apply some of the learning acquired.

Ultimately, the project should improve treatment success at the hospitals in the study and suggest ways to protect the long-term potency of antibiotics through more appropriate use.

Project at a glance	
Project duration	1 Apr 2025 – 31 Mar 2028
Total project cost	€2 840 208,75
Global Health EDCTP3 funding	€2 840 208,25
Disease area	Lower respiratory tract infections, Other childhood infectious diseases, Cross-disease or disease unspecific
Intervention type	Therapies, Other prevention tools, Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies, Environment and biodiversity
Project coordinator	LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN
Scientific project leader	JIMMA UNIVERSITY
Participating countries	Germany, Ethiopia, Ghana, Norway





IMCI-PLUS

Point of care ultrasound for pediatric lower respiratory tract infections in sub-Saharan Africa

The IMCI-PLUS project is promoting greater use of point-of-care ultrasound to improve the detection of bacterial respiratory infections that require antibiotics.

The challenge

Respiratory tract infections are the leading cause of morbidity and mortality in sub-Saharan Africa.

A major challenge in patient care is that many different infections can cause the same symptoms. With few diagnostics available in most sub-Saharan African settings, treatment is rarely targeted at a specific pathogen. Moreover, as viral chest infections are more common than once thought, this is leading to significant **overuse of antibiotics**: in sub-Saharan African hospitals, most children with respiratory tract infections receive antibiotics, but it is likely that only one in ten actually need them. This overuse is a poor use of scarce resources and a major driver of antimicrobial resistance.

It is not feasible to use a raft of pathogen-specific diagnostic tests on patients with respiratory symptoms, but a tool that could distinguish between viral and bacterial infections could help to target antibiotic use. There is accumulating evidence that **point-of-care ultrasound (POCUS)** can reliably distinguish the two, and may also be able to pick up tuberculosis infections, which are commonly missed.

The project

The IMCI-PLUS project has been designed to provide evidence on the clinical impact of POCUS in sub-Saharan African hospitals and the feasibility of its routine use in managing respiratory tract infections. Previous work has shown that POCUS equipment is relatively easy to use, but health workers are not always confident in their interpretation of the images generated. The project is therefore also developing an **AI tool** to support automated image analysis and provide decision-making guidance to clinicians.

The project is carrying out a randomised controlled trial in three African countries – Senegal, South Africa and Tanzania – comparing clinical outcomes when POCUS or standard management of patients with respiratory symptoms is used. It will also focus on other key metrics, such as levels of antibiotic use.

ATB-focused sub-study will similarly compare WHO-recommended diagnostic algorithms (one based on chest X-ray results and one on POCUS) to determine whether POCUS could replace chest X-rays, which are not available at most primary healthcare facilities.

The project will also conduct consultations with a wide range of stakeholders, including health workers, patients and policymakers, to explore the acceptability of POCUS and factors likely to affect its adoption in routine practice.

The impact

The IMCI-PLUS project will generate evidence from real-world African settings on a promising technology with wide potential applicability. It will:

- Demonstrate whether using point-of-care ultrasound (POCUS) to investigate respiratory tract infections leads to better clinical outcomes.
- Reveal whether POCUS drives more targeted use of antibiotics.
- Identify key factors associated with the successful implementation of POCUS in routine clinical care.

As well as demonstrating whether POCUS saves lives and reduces antibiotic use, the project will also build confidence in POCUS use, potentially leading to its wider deployment in African health systems.

Project at a glance	
Project duration	1 Apr 2024 – 30 Sep 2028
Total project cost	€4 371 990,00
Global Health EDCTP3 funding	€4 371 990,00
Disease area	Lower respiratory tract infections, Tuberculosis
Intervention type	Diagnostics, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies
Project coordinator	WITS HEALTH CONSORTIUM (PTY) LTD
Participating countries	South Africa, Tanzania, Rwanda, Netherlands, Senegal, Switzerland



AFRICAI-RI

A Pan-African Research Infrastructure for Collaborative Biomedical Imaging and Artificial Intelligence in Respiratory Care

The AFRICAI-RI project is establishing a digital infrastructure to support the development of AI-based image analysis tools to automate diagnosis of key diseases, beginning with common lung conditions.

The challenge

Diagnosis can be one of the most challenging areas of medicine, including for infectious diseases. Many infections share similar symptoms, and health facilities may lack the analytical tools needed to distinguish between them. These challenges are compounded by a **shortage of specialist clinicians** in sub-Saharan Africa. As a result, many conditions in the region are being under-diagnosed.

There are hopes that **AI-based systems** could overcome these bottlenecks. For example, they could be used to support **automated analysis of medical images**, using devices suitable for health workers without extensive specialist training. However, such AI tools need to be trained on large quantities of well-annotated images, and sub-Saharan Africa currently lacks large-scale medical image repositories.

The project

The AFRICAI-RI project is establishing a regional platform for the collation and analysis of medical images from across sub-Saharan Africa, to underpin the development of AI-based image-analysis tools for disease diagnosis. With an initial focus on lung conditions, it will provide a model that could be adapted in other areas of medicine.

The project is building on several recent developments, including the creation of an **African Network for AI in Biomedical Imaging** and a proposal to create a **pan-African medical image repository**. A secure data repository, Health Data Research West Africa, has been established in The Gambia under the auspices of the EDCTP-funded West Africa Network of Excellence for Clinical Trials in TB, AIDS and Malaria (WANETAM) network. This hub has established a robust **data governance framework** and **data-sharing protocols**.

The AFRICAI-RI project is using this hub as the basis for a larger secure image repository. It will apply the approach of **federated data analysis**, through which data remain within a secure local data centre but can be analysed remotely from a central hub, enabling pooled data analyses. Through the federated approach, the benefits of data sharing can be gained without data needing to be transferred to a central site, which can create data-security and data-governance challenges, particularly for international projects.

The project is focusing on regionally important **lung conditions**, particularly pneumonia in children and TB in children and adults, and two types of imaging data – **chest X-rays and ultrasound**. The latter is a relatively new technology with potential to be used at lower-level health facilities. The initial focus will be on four diagnostic use cases:

- TB detection using chest X-rays in adults with additional health conditions, including HIV infections.
- TB detection using chest X-rays in children.
- TB detection in adults using ultrasound.
- Pneumonia detection in children using ultrasound.

During the project, implementation studies will be organised for two of these use cases (pediatric chest X-ray and adult chest ultrasound). Using data already part of electronic health records, **‘in silico’ trials** will enable the results of AI tools to be compared with the conclusions reached by specialist clinicians looking at the same source material.

Images will be shared by ten institutions across participating countries. Computing power will be strengthened at each site to enable them to participate, and data standards and a submission portal are being established to facilitate sharing of data in a consistent format. The project will also issue an open call that will enable three other institutions from sub-Saharan Africa to join the consortium.

The project has a strong focus on **ethical frameworks and policy issues**. An extensive multidisciplinary co-creation process will be organised to establish appropriate governance and operational guidelines, including management of intellectual property and ways to ensure academic recognition for centres whose images are included in third-party data analyses.

Validation of the repository will be tested through six-month **‘data challenges’**, addressing specific clinical diagnostic issues in areas of interest, which will be open to up to 15 teams for each of two challenges. In addition, a **‘hacking challenge’** will be organised to test security.

The impact

The AFRICAI-RI project will establish a large-scale international medical image repository in sub-Saharan Africa. It will:

- Create a repository of around 75,000 annotated images related to lung conditions during the project.
- Support work to develop AI-based tools for diagnosis of important lung conditions in adults and children.
- Validate the performance of new diagnostic tools using existing health data.
- Demonstrate the workability of region-wide data-governance and data-sharing mechanisms.

Project at a glance	
Project duration	1 Sep 2025 – 31 Aug 2029
Total project cost	€4 999 075,00
Global Health EDCTP3 funding	€4 999 075,00
Disease area	Lower respiratory tract infections, Tuberculosis
Intervention type	Diagnostics
Overarching topic	Digital technologies
Project coordinator	UNIVERSITAT DE BARCELONA
Scientific project leader	FUNDAÇÃO MANHIÇA
Participating countries	Spain, Mozambique, Democratic Republic of the Congo, Ethiopia, Malawi, Nigeria, Greece, Uganda, United Kingdom, Senegal, Netherlands, Gabon, Ghana





PROTECT

PPreparing for Optimal Phase III/IV maTErnal Group B StreptococCal vaccine Trials in Africa (PROTECT)

The PROTECT project is creating a network of sites in East Africa to monitor the safety of vaccines administered during pregnancy.

The challenge

Although child mortality has been in decline, deaths in the neonatal period have not fallen as markedly as previously predicted. As newborns have underdeveloped immune systems, many deaths are due to infections. **Vaccination of pregnant women** offers a way to protect this vulnerable group, since maternal antibodies can cross the placenta and enter the foetal bloodstream.

A maternal vaccine is already available for **respiratory syncytial virus (RSV)**, a common cause of severe pneumonia in young infants. Another is in development to prevent **group B streptococcal (GBS) infections, which can cause deadly bloodstream infections in neonates**.

As with all new interventions, it is essential that the safety of new vaccines given to pregnant women is carefully monitored, even after their safety has been demonstrated in clinical trials. However, routine safety monitoring systems are rudimentary in many African settings, and often exclude adolescent girls and pregnant women.

The project

The PROTECT project is supporting maternal vaccine development by creating an **international platform for tracking the safety of new vaccines** used in African populations. Drawing on newly introduced electronic health record systems, it is helping to establish 12 sentinel safety surveillance sites in Kenya, Malawi, Mozambique and Uganda.

To support the development of this safety monitoring infrastructure, the project is adapting a **standard international framework** for recording potential safety issues. It is also developing a **software tool** to automatically extract relevant information from the electronic health records of pregnant women and newborn babies.

Other important project activities include strengthening **GBS surveillance** to provide additional African data on the burden of GBS disease. This will also enable the effectiveness of a GBS vaccine to be assessed when it is introduced. The project will also evaluate a new **GBS diagnostic** that could provide additional data on GBS disease burden and could also be introduced into routine clinical practice.

Finally, the project is undertaking an extensive **programme of engagement** with communities and healthcare workers to

explore perceptions of maternal vaccination and participation in research and to identify potential barriers and enablers. These activities will also be used to co-create a **communications toolkit** to support recruitment into maternal vaccination trials.

The impact

The PROTECT project will establish an international platform for gathering data on the effectiveness and safety of maternal vaccines used in routine care. It will:

- Enable a network of sites to conduct phase III and IV maternal vaccination trials.
- Provide an infrastructure for tracking the safety of vaccines and other medical interventions in pregnant women.
- Generate additional data on the group B streptococcal (GBS) disease burden in Africa to inform national decision-making on vaccine introduction.
- Create materials to support recruitment of women into clinical studies.

Through these impacts, the project will accelerate the development and evaluation of GBS and other maternal vaccines, helping to protect mothers and newborns from severe bacterial infections that currently kill hundreds of thousands of babies a year.

Project at a glance	
Project duration	1 Mar 2024 - 28 Feb 2027
Total project cost	€3 271 990,50
Global Health EDCTP3 funding	€3 271 990,50
Disease area	Lower respiratory tract infections
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Health security, Digital technologies, Women's health
Project coordinator	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA
Scientific project leader	MU JHU CARE LIMITED
Participating countries	Spain, Uganda, Belgium, Mozambique, Malawi, Kenya, Germany



PediSEP1

Risk stratified care to reduce antibiotic use and AMR transmission in African hospitals

The PediSEP1 project is testing an approach to identify low-risk children who can be safely discharged from the hospital, allowing clinical attention to focus on those most in danger and reducing unnecessary use of antibiotics.

The challenge

Infections are a very common cause of death in young children. The majority of infections are self-limiting, but in the early stages, it can be difficult to distinguish infections likely to progress to severe disease from those at low risk. Symptoms may provide limited clues, and diagnostic or prognostic tests may not be available. As a result, clinicians tend to take a **'safety-first'** approach, providing high levels of care to a large proportion of sick children.

This has several consequences. For example, it leads to **overuse of antibiotics**, driving the development of **antimicrobial resistance**. It also puts children at risk of developing a hospital-acquired infection, which can then spread in communities once children are discharged. It leads to overcrowding in hospitals and to inefficient use of scarce healthcare resources.

The project

The PediSEP1 project is developing a simple prognostic tool that would enable clinicians to judge the likely severity of infection soon after hospital admission. Low-risk children could then be rapidly discharged, and clinical attention could be focused on the highest-risk cases.

Although some efforts are currently made to stream cases by severity, this is rarely done systematically. Low-risk children are often looked after by clinicians with limited pediatric training, and there are no formal guidelines on the de-escalation of treatment and discharge.

Focusing on first-level referral hospitals in Kenya, Malawi, and Uganda, the PediSEP1 project is analysing existing data from multiple studies to identify key early factors associated with severe disease. These will be integrated into a clinical algorithm that can be used in the early stages of hospitalisation to assess the risk of deterioration, enabling cases to be classified as low-, medium-, or high risk and managed accordingly.

The emphasis is on clinical and other measures that can be easily assessed in low-resource settings. The algorithm will be co-designed with health policymakers and clinicians, and consultations will be held with caregivers to check its acceptability.

Once developed, the tool will be evaluated in a clinical trial using a stepped-wedge design, whereby all sites gain access at different time points, with later sites serving as controls for the early adopters. This design will also enable the study of

factors associated with successful implementation. The main outcome measure will be safety, to ensure that early discharge does not increase the risk of death. The project will also explore other key factors, including antibiotic use and hospital-acquired infections. Potential impacts on the health system will then be modelled to guide policymaking.

As part of this work, the project will also investigate a new approach for collecting data on hospital-acquired infections, based on systematic faecal sampling at specified times, to augment existing surveys of antibiotic use.

The impact

The PediSEP1 project could have a major impact on how children with infections are cared for in lower-level hospitals in sub-Saharan Africa. It will:

- Create a simple-to-use tool for assessing the risk of deterioration soon after admission.
- Enable the lowest-risk children to be rapidly and safely discharged, ensuring they are less likely to develop a hospital-acquired infection.
- Allow clinicians to focus on the most severely affected children.
- Ensure that antibiotics are used more appropriately.

Most immediately, the PediSEP1 project will lead to more efficient use of scarce healthcare resources, with care focused on the sickest children. In the long term, it will reduce antibiotic use and the incidence of hospital-acquired infections, thereby helping to prevent the rise of antimicrobial resistance.

Project at a glance	
Project duration	1 Jul 2025 - 30 Jun 2030
Total project cost	€5 998 992,50
Global Health EDCTP3 funding	€5 998 992,50
Disease area	Lower respiratory tract infections
Intervention type	Other prevention tools, Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies
Project coordinator	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD
Scientific project leader	TRAINING & RESEARCH UNIT OF EXCELLENCE LIMITED
Participating countries	United Kingdom, Malawi, Kenya, Italy, Uganda, United States





Emerging and re-emerging infectious diseases



INTEGRATE

The Integrate study: An adaptive platform trial for the development of a new intervention to combat Lassa fever in Africa

The INTEGRATE project is creating a clinical trial platform able to support efficacy studies on multiple Lassa fever therapeutics.

The challenge

Lassa fever, a viral haemorrhagic fever spread by contact with rodents carrying the virus or with infected patients, affects large parts of West Africa, particularly Nigeria. An infection with epidemic potential, it kills around 12% of hospitalised patients. Overall, it is responsible for an estimated 5,000 to 10,000 deaths every year. An increasing number of outbreaks have occurred in recent years.

Only one specific treatment exists, ribavirin, but there are significant doubts about its efficacy, and it can have significant side effects. Four drugs are under development. The most advanced, favipiravir, a licensed drug developed to treat influenza, has shown significant promise in preclinical and early clinical studies.

With no vaccine yet available for Lassa fever, cases apparently on the increase, and doubts about the efficacy of existing treatment, more therapeutics are urgently needed.

The project

Several European and African institutions have worked together for more than 15 years to better understand Lassa fever infections and improve detection. One objective has been to build the capacity of clinical sites in Nigeria, enabling them to conduct pharmacokinetic studies and undertake the phase IIa SAFARI clinical study, which is evaluating the efficacy and safety of different doses of favipiravir compared to ribavirin.

Building on these efforts, the INTEGRATE project is further strengthening trial capacity so that additional clinical studies can be performed. In particular, it is establishing a multisite clinical trial platform able to conduct an adaptive trial of candidate Lassa fever therapeutics. The project is beginning with a head-to-head comparison of favipiravir versus ribavirin, informed by the results from the SAFARI trial, but will be able to introduce new drugs into the trial should they become available.

The project will also undertake an extensive programme of community engagement to ensure community support for the trial. Factors such as the stigma associated with Lassa fever infections could affect people's willingness to take part in trials, and there is a need to understand the full range of factors that could potentially affect participation.

Preparatory work has been carried out at additional sites in Benin, Guinea, Liberia and Nigeria so that they can contribute to the trial. Clinical trials capacity is being developed not just by links to European institutions but also by drawing on the expertise of a regional centre of research excellence, CERMEL in Gabon, providing an example of South-South capacity-building.

The impact

The INTEGRATE project will have a major impact on drug development for Lassa fever. It will:

- Provide key evidence on the efficacy and safety of favipiravir as a possible alternative to ribavirin.
- Drive improvements in care of Lassa fever patients at clinical sites.
- Accelerate the evaluation of additional drugs showing promise against Lassa fever.
- Reduce the costs and timescales of subsequent drug trials by providing an established platform and protocol.
- Build clinical trial capacity and expertise in Nigeria and other parts of West Africa.

As favipiravir has already been licensed in some countries, it could potentially be introduced relatively quickly if shown to be safe and efficacious against Lassa fever, ensuring that populations in West Africa rapidly benefit from a new treatment for a major threat to health in the region.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2028
Total project cost	€8 800 000,00
Global Health EDCTP3 funding	€8 000 000,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Therapies
Overarching topic	Health security
Project coordinator	UNIVERSITÉ DE BORDEAUX
Participating countries	France, Nigeria, Germany, Côte d'Ivoire, Gabon, United Kingdom





EBO-PEP

The EBO-PEP project: EBOla Zaïre Post-Exposure Prophylaxis, preparedness and efficacy evaluation during outbreak in Central and West-Africa

The EBO-PEP project is evaluating whether monoclonal antibodies can protect close contacts of people with Ebola virus infections.

The challenge

Ebola virus infections arise periodically in multiple sub-Saharan African countries. Outbreaks are associated with very high mortality, with the close contacts of infected patients being the most at risk.

Vaccines have been developed for the most common Ebola virus infection, **Zaire ebolavirus**, and the r-VSV-ZEBOV vaccine is now widely used in 'ring vaccination' strategies to contain outbreaks. However, vaccination does not generate immediate protection, leaving those who have already been exposed to infected patients at high risk of infection and disease.

Monoclonal antibodies, which can block infection of cells by Ebola viruses, offer a complementary prevention strategy. Because they provide immediate protection, they could be of particular value to close contacts of patients. Two monoclonal antibodies, ansuvimab and REGN-EB3, have been approved by the US Food and Drug Administration (FDA) for the prevention of **Zaire ebolavirus** infection.

Monoclonal antibodies have been used in the Democratic Republic of the Congo (DRC) through an emergency use protocol, and no infections occurred in people receiving such post-exposure prophylaxis (PEP). However, these products have not yet been rigorously evaluated in a clinical trial.

The project

The EBO-PEP project is designed to provide reliable data on the efficacy of monoclonal antibody PEP for **Zaire ebolavirus**. Evaluating preventive interventions for Ebola virus outbreaks is challenging, due to their sporadic nature, the need for a rapid response, and their short duration (if they are controlled effectively).

To address these challenges, the EBO-PEP project is establishing an infrastructure that will enable rapid trial launches in response to outbreaks and facilitate the pooling of data from multiple outbreak responses across different countries.

The project is based on a consortium encompassing many of the countries at risk of Ebola virus outbreaks. Initially, it focuses on two particularly high risk countries, the DRC and Guinea. It places a strong emphasis on preparedness, including the development and approval of a standardised clinical trial protocol that can

be immediately implemented when outbreaks occur. Other key activities include ensuring that monoclonal antibody and other trial supplies will be immediately available and the preparation of clinical trial sites.

The project also includes a strand of work on community engagement to identify potential issues that might affect trial conduct and to ensure community support for research activities.

The impact

The EBO-PEP project will generate critical data on the effectiveness of monoclonal antibody PEP for **Zaire ebolavirus**. It will:

- Provide policymakers with key evidence on the effectiveness and cost-effectiveness of monoclonal antibody PEP to inform national Ebola outbreak response strategies.
- Build capacity for clinical care of Ebola virus patients and clinical research on Ebola virus and other emerging infections.
- Provide a model for innovative coordinated, multi-country, multi-outbreak clinical trials for emerging and re-emerging diseases.

If the effectiveness of monoclonal antibody PEP is confirmed, it would provide a way to protect those at highest risk of Ebola virus infection, including household contacts and healthcare workers, leading to reduced mortality and more rapid containment of outbreaks.

Project at a glance	
Project duration	1 Jun 2024 - 31 May 2027
Total project cost	€3 435 775,00
Global Health EDCTP3 funding	€3 435 775,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Therapies
Overarching topic	Health security
Project coordinator	INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMÉDICALE DU ZAIRE
Participating countries	France, Democratic Republic of the Congo, Spain, Guinea, Côte d'Ivoire, Senegal



Ebola PREP-TBOX

Development of a toolbox to improve preparedness strategies on surveillance in human-animal interface and countermeasures to reduce recurrent Ebola impacts

The Ebola PREP-TBOX project is developing a suite of tools to improve detection, treatment and public health responses to Sudan ebolavirus outbreaks.

The challenge

Ebolavirus and other filovirus infections are much feared across the globe and in sub-Saharan Africa in particular, where major outbreaks have claimed thousands of lives. Seen across a swathe of central Africa, outbreaks arise when viruses spill over from animals to people. The virus can then be spread by contact with an infected person. Fatality rates can be very high, so early detection and a rapid response to prevent the spread of infection are critical to an effective public health response.

Multiple strains of ebolavirus circulate. The most common human infections are of **Zaire ebolavirus**, which was responsible for the 2013-2016 West African ebolavirus outbreak. Vaccines are now available to prevent **Zaire ebolavirus** infections. However, a related strain, the **Sudan ebolavirus**, can also infect humans, and no treatment or vaccine has yet been licensed for this species.

Effective control of ebolavirus requires a combination of approaches, including **surveillance** to rapidly identify new cases, **vaccines and treatments**, and **public health measures** to prevent transmission. The latter depend on support from local communities to ensure adherence to disease control measures.

The project

The Ebola PREP-TBOX project is developing a toolbox of interventions to improve preparedness and response to ebolavirus outbreaks, particularly of **Sudan ebolavirus**. It is targeting several key aspects of disease control:

- **Detection:** The project is collating information on previous outbreaks, and integrating multiple other sources of environmental, climate, demographic, socioeconomic and zoological data, to develop **spatiotemporal models** that **identify hotspots** where infections are most likely to occur. This will help countries target more intensive surveillance activities.
- **Surveillance:** An enhanced approach to surveillance will be developed, involving **communities** in case reporting, closer monitoring of the **human-animal interface**, and social listening – automated analysis of communications materials to detect mentions suggestive of ebolavirus infections.
- **Diagnostics:** Currently used diagnostics lack sensitivity, leading to false negatives and undetected cases. Improved diagnostics will be developed, incorporating a **pathogen enrichment step** based on nanomagnetic beads to enhance test sensitivity.
- **Treatments:** **Polyvalent antibodies**, generated by inoculation of horses, are a practical and affordable way to generate therapeutics with a wide spectrum of activity. A formulation covering **Sudan ebolavirus** will be developed. A **'mosaic' antigen** will also be developed, incorporating parts of multiple proteins, to determine whether antibodies protective across

different ebolaviruses (and related viruses such as Marburg virus) can be generated.

- **Community engagement:** An interdisciplinary approach is being adopted, including community studies to better understand current knowledge, attitudes, practices and social dynamics, to raise awareness, and to inform more community-oriented responses.

The project has a strong emphasis on **trans disciplinary**, incorporating experts from many different fields, including social science and One Health.

The impact

The Ebola PREP-TBOX project will provide tools to support countries in their preparation for ebolavirus outbreaks. It will:

- Generate **risk maps** where outbreaks are most likely, and highlight factors associated with human infection, to support prevention and early identification of cases.
- Provide more sensitive **diagnostics** and **new treatment options** for **Sudan ebolavirus** infections.
- Ensure that **communities** are more aware and supportive of the public health measures needed to control ebolavirus outbreaks.
- Strengthen **health systems** so they are better prepared to manage cases of ebolavirus infections.

This combination of advances will lead to earlier detection of ebolavirus outbreaks and help to ensure that they do not flare up into major epidemics that are harder to control.

Project at a glance	
Project duration	1 Oct 2024 - 30 Sep 2027
Total project cost	€2 999 868,67
Global Health EDCTP3 funding	€2 999 868,67
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Therapies, Surveillance tools, Other prevention tools
Overarching topic	Health security, Climate crisis or climate adaptation, Digital technologies, Environment and biodiversity
Project coordinator	EBERHARD KARLS UNIVERSITÄT TUEBINGEN
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MEDICALE
Participating countries	Germany, Congo, Uganda, Spain, Democratic Republic of the Congo, France, Switzerland, United States





EPoCA

Empowering Africa’s Point of Care with Cutting-edge Graphene Biosensing for Rapid Detection and Interconnected Surveillance of Novel Ebola Virus Outbreaks

The EPoCA project is developing an innovative new point-of-care test for Ebola virus infections that will also give insights into infection severity and automatically alert policymakers of new infections.

The challenge

Ebola virus infections call for rapid action – both clinically, to save patients’ lives, and via public health responses, to halt further transmission. Infections have a high fatality rate and are highly contagious, so diagnoses need to be made as rapidly as possible, for example, using point-of-care tests.

New technologies and materials are enabling rapid diagnostics for Ebola and other infectious diseases. One example is **graphene**, ultrathin layers of carbon, which can be modified to incorporate detection systems for biomolecules specific to particular pathogens or produced by patients in response to infection. Following the binding of these biomolecules, changes in the graphene detector’s properties can be converted into an easily interpreted visual signal.

The project

The EPoCA project is using this approach, known as multiplexed field-effect sensor technology (FET), to develop a rapid, sensitive and specific diagnostic test for Ebola virus infection. Over the past 10 years, graphene FETs have been developed for a range of biosensing uses, providing a strong foundation for the adaptation to Ebola detection.

Using standard blood samples, the technology will detect a mix of viral and host biomolecules, including antibodies indicating infection and host biomarkers that provide a measure of infection severity. These results will be generated rapidly – within 30 minutes – so they can inform immediate patient care, including triage based on infection severity.

In addition, the detector will be integrated into an ‘Internet of Things’ device, so that diagnostic information can immediately be shared across the web. This will provide policymakers with near-instant epidemiological information to inform public health responses.

The EPoCA project will develop a prototype device, conduct clinical validation studies, and explore manufacturing scale-up. Clinical validation studies will be carried out with project partners at field sites in the Democratic Republic of the Congo (DRC) and Ghana.

The impact

The EPoCA project is leveraging an exciting area of technology development to create a new tool for Ebola control. It will:

- Develop a practical, easy-to-use diagnostic tool for rapid detection of Ebola virus infections at the bedside.
- Enable patients to be rapidly triaged so severe cases receive priority care.
- Deliver near-real-time epidemiological information to public health officials to support rapid response to outbreaks.
- Provide proof-of-concept for a technology that could have multiple applications in infectious disease control and other areas of healthcare in sub-Saharan Africa.

A graphene FET-based diagnostic for the Ebola virus would improve immediate care of Ebola patients, helping to reduce alarmingly high mortality rates, and also support efforts to control the spread of infections through the community.

Project at a glance	
Project duration	1 Jul 2024 – 30 Jun 2027
Total project cost	€2 926 130,00
Global Health EDCTP3 funding	€2 920 255,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Digital technologies, (Other) emerging technologies, Environment and biodiversity, Health security
Project coordinator	LIBELIUM COMUNICACIONES DISTRIBUIDAS SL
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMEDICALE DU ZAIRE
Participating countries	Spain, Democratic Republic of the Congo, Ghana, Italy, Estonia



ResTick

Resilience Enhancement for Ticks and Tick-Borne Diseases in sub-Saharan Africa

The ResTick project is creating infrastructure to monitor the distribution of ticks and the diseases they spread, including a key potential pandemic threat.

The challenge

Ticks are found throughout the world, including sub-Saharan Africa, and transmit a range of pathogens, including multiple viral infections. Ticks thrive in woodland areas and infect both humans and animals, including wild animals and livestock. Their ecology is being altered by both climate change and changing land use.

In sub-Saharan Africa, a specific concern is a potentially deadly viral infection, **Crimean–Congo haemorrhagic fever (CCHF)**. Frequently acquired following contact with livestock or wild animals, CCHF has a fatality rate of up to 40%. It is also found in areas outside Africa, including southern Europe and different parts of Asia.

Despite the importance of ticks as disease vectors and the threat of CCHF virus outbreaks, the distribution of ticks and how human activities are altering tick populations in the context of climate change are poorly understood.

The project

The ResTick project aims to provide a model approach for monitoring ticks and the presence of CCHF virus, to underpin early warning systems and to inform control efforts. It is adopting a multidisciplinary **One Health approach**, focusing on both domesticated and wild animal reservoirs of the CCHF virus.

The project team aims to characterise around 5,000 ticks a year across multiple sub-Saharan African countries – Benin, Burkina Faso, Côte d’Ivoire, Ethiopia, South Africa, Togo and Uganda – as well as the island of Crete, Greece in Europe. The project’s main focus is on **livestock herders**, a group at high risk of infection. Animals will be examined for ticks, which will undergo acarological characterisation. Molecular techniques will be used to determine tick species and whether they are carrying CCHF virus.

Molecular methods will also be used to determine whether ticks are carrying **acaricide resistance genes**. The presence of such genes will be compared across areas with high and low acaricide use to explore how pesticide use affects tick populations. Additionally, the project will test the role of acaricide resistance in exacerbating the disease transmission with a special focus on CCHFV, as well as the socio-economic impact of this phenomenon on livestock producers in sub-Saharan Africa.

The project is also capturing **migratory birds** that travel between Europe and Africa, to assess whether they might provide a route for the spread of ticks and the pathogens they carry between continents.

To facilitate monitoring activities, the project team is also adapting the ‘Pebble’ diagnostic platform to provide a **point-of-care test** to detect CCHF viral infections. In addition, a **serological survey** will be conducted in human and animal populations to assess exposure to the CCHF virus among populations at risk.

Using the information collected, the project team will develop **mathematical models** of tick and CCHF virus epidemiology to identify high risk areas for spillover infections and to assess how these might be affected by climate change, environmental disruption, and human population movements.

The impact

The ResTick project will close key knowledge gaps in tick-borne diseases, particularly regarding the Crimean–Congo haemorrhagic fever (CCHF) virus. It will:

- Provide rich information on the abundance and distribution of tick species in multiple African countries.
- Deliver new insights into the prevalence of CCHF virus infections and viral epidemiology.
- Provide new tools for detecting CCHF virus infections, to facilitate disease detection and control, and to track infection rates.
- Decipher the role of acaricide resistance on transmission dynamics of CCHF virus and its impact on livelihoods in sub-Saharan Africa.
- Provide policymakers with tools to identify current and potential future high risk areas to inform disease control activities.

Collectively, these project activities will generate a clearer view of tick ecology and the potential impacts of climate and environmental shifts, as well as key insights into the zoonotic lifecycle of the CCHF virus, a pathogen with pandemic potential.

Project at a glance	
Project duration	1 Jun 2025 – 31 May 2028
Total project cost	€6 130 555,00
Global Health EDCTP3 funding	€6 130 555,00
Disease area	Emerging or re-emerging infectious diseases, Neglected infectious diseases
Intervention type	Surveillance tools, Other prevention tools, Diagnostics
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Health security, Digital technologies, Environment and biodiversity
Project coordinator	IDRYMA TECHNOLOGIAS KAI EREVNAS
Scientific project leader	MAKERERE UNIVERSITY
Participating countries	Greece, Uganda, Ethiopia, South Africa, Benin, Togo, Burkina Faso, Côte d’Ivoire, Switzerland



VectorGrid-Africa

Establishing a Network of Permanent Observatories for Mosquitoes and Mosquito-Borne Diseases in East and Southern Africa (VectorGrid-Africa)

The VectorGrid-Africa project is developing a platform that could eventually provide an intimate picture of disease-transmitting mosquitoes across sub-Saharan Africa.

The challenge

Mosquitoes transmit a wide range of infections, most notably **malaria**, but also dengue virus and other rare but potentially dangerous pathogens. Factors such as **climate change** and **changing land use** are having a profound impact on the ecology of mosquitoes, affecting their numbers and distribution, with important implications for the spread of these infections.

Currently, **limited surveillance data** are available for mosquitoes and mosquito-borne diseases in sub-Saharan Africa. Data collection is not standardised, and data are generally not shared to create an overall picture of patterns in the distribution of mosquito populations. Furthermore, there is often limited collaboration between researchers and public health officials, a barrier to the use of research evidence to inform disease control.

The project

The long-term goal of the VectorGrid-Africa project team is to establish a **pan-African platform** for the collection and analysis of data on disease-transmitting mosquitoes. Through a pilot phase, such a platform is being created in five countries in East and Southern Africa – Kenya, Madagascar, Mozambique, South Africa and Tanzania.

The project is establishing **data collection nodes** in each country at sites with varying environmental conditions. At each site, mosquitoes will be collected at specific times of the year and subjected to intensive analysis. This will include:

- Genomic analysis and sequencing, to identify the mosquito species, key genetic traits such as insecticide resistance, and genomic shifts occurring over time.
- Detection of malaria parasites and viruses being carried by mosquitoes.
- Characterisation of mosquito traits.

The project will draw upon innovative **new analytical approaches**. These include genetic techniques that enable multiple types of information to be gained in a single test, including the species of mosquito being analysed, the source of its last blood meal, and whether it is carrying malaria parasites.

In addition, a relatively new technology, **infrared spectral analysis**, will be used to characterise multiple aspects of trapped mosquitoes, including their species, age, infection with pathogens or commensal bacteria, last blood meal, and insecticide resistance. This technology is highly promising as it requires no reagents and can be done with widely available desktop scanners.

At each node, ten **sentinel villages** will be selected, with mosquito collection carried out monthly or twice a year. Data will be collected on an anticipated 300,000 mosquitoes during the project. Linked data will be recorded on environmental

conditions and climate, using local data sources and satellite data. Some clinical data on key infections such as malaria will be collected from facilities in each country.

In Tanzania, the project will also pilot a **One Health approach**. Working with local veterinary officers to gather samples from cattle, the project will generate data on **Rift Valley fever virus**, a highly dangerous pathogen with the potential to be transmitted from livestock and other animals to humans.

The data will be integrated to generate **mathematical models** of mosquito populations and disease transmission. These models will be used to explore the potential impacts of different climate change scenarios and land-use changes. They will reveal possible disease hotspots and enable the evaluation of the impact of different control interventions.

The impact

The VectorGrid-Africa project is piloting an approach that could provide the basis of a comprehensive surveillance system for disease-transmitting mosquitoes. It will:

- Create a platform for the intensive and standardised characterisation of mosquitoes and the pathogens they are carrying in five African countries.
- Strengthen local capacity to use genomics and other new tools to characterise mosquitoes.
- Provide policymakers with information on current mosquito populations plus tools for modelling potential changes linked to climate trends and land-use changes.
- Enable policymakers to anticipate changes in disease patterns and evaluate possible disease control strategies.

Project at a glance	
Project duration	1 Sep 2025 - 31 Aug 2030
Total project cost	€6144 373,98
Global Health EDCTP3 funding	€6144 095,73
Disease area	Emerging or re-emerging infectious diseases, Malaria, Neglected infectious diseases
Intervention type	Surveillance tools
Overarching topic	Climate crisis or climate adaptation, Environment and biodiversity, Health security, Digital technologies
Project coordinator	UNIVERSITY OF GLASGOW
Scientific project leader	THE REGISTERED TRUSTEES OF THE IFAKARA HEALTH INSTITUTE
Participating countries	United Kingdom, Tanzania, Kenya, Mozambique, Madagascar, South Africa



Other childhood infections



IMPROVE-HPV

Understanding vaccination hesitancy and evaluating single dose and gender-neutral vaccination for improving uptake of HPV vaccines in West and East Africa

The IMPROVE-HPV project is exploring ways to improve take-up of vaccines against human papillomavirus (HPV), the main cause of cervical cancer.

The challenge

An estimated 700,000 **cervical cancer** cases occur each year, leading to around 372,000 deaths. The burden of cervical cancer, which affects the lower uterus, is greatest in sub-Saharan Africa, where the incidence of the disease is twice as high as in Asia and four times as high as in North America.

The majority of cases of cervical cancer result from persistent infection with high risk **human papillomavirus (HPV)**. Eliminating cervical cancer as a public health problem will be heavily dependent on the use of HPV vaccines. These are being rolled out globally, with introductions being accelerated by a 2022 WHO recommendation endorsing a single dose of vaccine to girls and boys aged 20 years or younger.

However, **vaccine coverage remains suboptimal** in many countries due to delivery challenges for a novel target group (pre-adolescent and adolescent girls and, in some countries, also boys) and low take-up, often related to concerns or misunderstandings about the vaccine.

The project

The IMPROVE-HPV project aims to increase HPV vaccine uptake in Nigeria and Tanzania. Tanzania has already introduced HPV vaccination and has moved from a two-dose to a single-dose schedule, while Nigeria introduced a single-dose HPV vaccine for the first time.

Tanzania has also been piloting the use of a '**gender-neutral**' HPV vaccination strategy – administration of the vaccine to both girls and boys. HPV infections can also have detrimental effects in men, causing around 60,000 cancers a year. In addition, vaccination of boys could reduce the levels of HPV in circulation in the population, providing additional 'herd immunity' to girls. It could also lead to fewer concerns about vaccination, given that administering the vaccine solely to girls is a source of vaccine hesitancy.

The IMPROVE-HPV project is taking advantage of these national plans to organise clinical studies and consultations to gather evidence on HPV vaccination to support policymaking on vaccine use.

The project is examining a range of HPV vaccine-delivery/provision scenarios, including the use of the two-dose schedule in girls, the introduction or switch to the single-dose approach,

and a gender-neutral approach. It is conducting studies to compare vaccine effectiveness and uptake of different approaches in the two countries.

The project is also exploring the perceptions of health workers and community members regarding different delivery strategies, including two- versus one-dose schedules and girls-only versus gender-neutral strategies.

The impact

The IMPROVE-HPV project will generate valuable evidence on ways to enhance HPV vaccination uptake. It will:

- Demonstrate whether one- or two-dose schedules are associated with significantly higher vaccine uptake.
- Reveal whether gender-neutral strategies lead to enhanced take-up of vaccination in females.
- Shed light on other factors affecting the acceptability of HPV vaccine delivery schedules.

Evidence generated by the IMPROVE-HPV project will enable policymakers to optimise the design of HPV vaccine programmes, to increase uptake and ensure that more women are protected against HPV infection and the development of potentially deadly cervical cancer.

Project at a glance	
Project duration	1 Dec 2024 – 31 May 2028
Total project cost	€4130 342,50
Global Health EDCTP3 funding	€3 613 287,50
Disease area	Other childhood infectious diseases
Intervention type	Vaccines
Overarching topic	Women's health, Co-morbidities and non-communicable diseases
Project coordinator	INSTITUT CATALA D'ONCOLOGIA
Scientific project leader	NATIONAL INSTITUTE FOR MEDICAL RESEARCH
Participating countries	Spain, Tanzania, Nigeria



REACH-OUT

Closing the immunisation gap by reaching zero-dose children through improved equitable and cost-effective vaccine delivery strategies

The REACH-OUT project is developing strategies to ensure that more 'zero-dose' children – those missing out entirely on the benefits of vaccines – are reached by immunisation programmes.

The challenge

Vaccination is a proven lifesaver, and national immunisation programmes in sub-Saharan Africa now deliver dozens of vaccines to protect infants against a variety of deadly infectious diseases, including measles, pertussis and diphtheria. However, reaching every infant is highly challenging. In particular, some communities can be very hard to reach or may be reluctant to take up vaccination services.

So-called **zero-dose children**, who do not receive any infant vaccinations, are at risk of multiple vaccine-preventable diseases. In addition, they often live in communities that have limited access to any kind of health services. Globally, zero-dose children account for a third of all childhood deaths.

There are multiple possible reasons why a community has a high proportion of zero-dose children, including both **supply-side barriers** affecting access to vaccines and **demand-side barriers** affecting take-up. Understanding these reasons is essential if effective ways to reduce the number of children with zero doses are to be introduced by immunisation programmes.

The project

The REACH-OUT project is working with national immunisation programmes and other stakeholders in Kenya, Nigeria and Rwanda to better understand the **root causes of under-vaccination** and to design **locally tailored interventions** to address key issues and increase vaccination rates.

One key challenge is to identify where zero-dose children are most likely to be found and what the determinants of poor vaccination are. The project is addressing these questions in different ways. A range of data will be collated to develop integrated **geospatial and epidemiological models** that create high-resolution maps of ZD prevalence and infection risks. Other geospatial information will also be collated, including the location of immunisation facilities and the distribution of other variables affecting immunisation service delivery and take-up.

It is also gathering and analysing new data to understand the factors influencing the **supply of and demand for immunisation services**. These data include a survey of caregivers on the behavioural and social determinants of vaccination, as well as interviews and focus groups with health providers at different levels of the immunisation programme. This new evidence will be used as a basis to inform the **participatory design of more effective service delivery interventions**. A novel digital tool will also be developed to help health facility workers identify and reach zero-dose children within their catchment area.

Extensive consultations will be undertaken with immunisation experts, local immunisation programme staff, and community representatives to identify potential interventions that could be included in a package. These co-created packages will then be piloted, implemented and evaluated in the three countries.

Impact will be assessed using a **stepped wedge trial design**, in which the package of interventions will be sequentially introduced across different areas, with sites scheduled for later implementation serving as controls for early implementing sites. Multiple measures of impact will be tracked, including total coverage, reductions in zero-dose numbers, and impacts on the equity of vaccination coverage. The trial design also creates an opportunity to study factors associated with the successful implementation of the new interventions. Alongside the trial, a distributional cost-effectiveness analysis will be conducted to assess the value for money of the defined interventions and their equity impacts.

The impact

The REACH-OUT project will generate evidence on the causes of under-immunisation and the effectiveness of strategies to address them. It will:

- Provide new tools to enable programmes to gain a clearer picture of where zero-dose children are likely to live.
- Generate evidence on the effectiveness of a range of interventions to improve access to and take-up of immunisation services.
- Highlight key factors affecting the success of implementation at the scale of such interventions.
- Identify contextual factors that influence impact, to guide adaptation of interventions to other settings.

By enabling immunisation programmes to identify and reach zero-dose children, the REACH-OUT project will ensure that more vulnerable infants receive life-saving vaccines and fewer die unnecessarily from vaccine-preventable diseases.

Project at a glance	
Project duration	1 Jan 2025 – 31 Dec 2028
Total project cost	€5 214 140,50
Global Health EDCTP3 funding	€5 214 140,50
Disease area	Other childhood infectious diseases
Intervention type	Vaccines, Surveillance tools
Overarching topic	Digital technologies
Project coordinator	UNIVERSITA COMMERCIALE LUIGI BOCCONI
Scientific project leader	CIIC-HIN LIMITED
Participating countries	Italy, Rwanda, Nigeria, Kenya, Germany, Belgium





SNIP-AFRICA

Severe neonatal infection adaptive platform trials in Africa

The SNIP-AFRICA project is establishing a research platform with an innovative trial design that will enable multiple treatment options for sepsis in young infants to be assessed simultaneously.

The challenge

Sepsis is one of the most common causes of death of neonates and young infants – globally, it is responsible for more than two million deaths a year. It is one reason why the number of neonatal deaths has shown only a small recent decline, despite a significant fall in wider child mortality.

Sepsis is a clinical challenge because it can be triggered by a range of different infections, requiring different treatments. Some of these infections can be acquired in hospitals, including infections with several Gram-negative pathogens that have become increasingly common in hospital settings and are often resistant to multiple antibiotics and hard to treat.

Because the causes of sepsis vary widely and can differ markedly between hospitals, it is difficult to organise conventional clinical treatment trials, which usually involve testing a single treatment against a specific pathogen. Hence, there is very limited evidence to guide clinical decision-making. This is especially problematic as the standard WHO-recommended treatments for bacterial infections in neonates are becoming less effective in many settings, due to antibiotic resistance.

The project

The **SNIP-AFRICA project** is pioneering a new approach to generate evidence to inform management of sepsis in neonates and young infants in sub-Saharan Africa. It links specialist hospital sites in the region, creating a network through which data can be collected and used in research studies to evaluate the impact of different sepsis treatments.

Within SNIP-AFRICA, a clinical trial called **NeoSep1**, sponsored by the Global Antibiotic Research and Development Partnership (GARDP), is testing different antibiotic treatments for newborn sepsis at the same time. Instead of focusing on a single drug, the trial compares several treatment options, including combinations of off-patent antibiotics and commonly prescribed antibiotics, such as those recommended by the WHO.

At each hospital, doctors and the trial team select the most relevant treatments to be tested, based on local patterns of infection and antibiotic resistance, as well as the condition of the babies being treated. The aim is to **rank these antibiotic options** to guide doctors' clinical decisions across different settings and conditions. The trial will compare options not only in terms of survival, but also side effects, resistance, availability and cost, helping doctors choose the most effective and practical treatments for newborns with sepsis.

A second important component of the SNIP-AFRICA platform is **clinical and microbiological surveillance**. By embedding data collection for research within routine care, the project will also collate a wealth of additional evidence across different sites, for example, on microbial epidemiology, clinical management, use of healthcare resources, and antibiotic prescribing practices in

neonatal units. A real-time **data dashboard** will be developed to support hospital decision-makers, for example, by showing how local causes of sepsis and resistance patterns are changing. In addition, data collection will provide rapid insights into the impact of changes in clinical practice.

Pharmacokinetic studies will also be embedded in the platform to explore how circulating drug levels are associated with treatment success. One such study, conducted at South African sites, will improve understanding of how to dose the antibiotic colistin more appropriately in neonates and children under two years of age.

Adaptive platform trials are relatively new and **complex to manage**. Experience to date suggests that **strong governance structures and decision-making rules** are needed to ensure clarity on how patients will be treated under different scenarios. The SNIP-AFRICA project will establish a strong but lean governance framework. It will also carry out extensive consultation with health service and community stakeholders to understand their perspectives on adaptive trials and ensure support for research activities embedded within clinical care.

The impact

The SNIP-AFRICA project represents a fundamental shift in how research on the treatment of neonatal sepsis is carried out. It will:

- Establish a multicentre platform able to conduct research and evaluate multiple treatment options for neonatal and infant sepsis.
- Evaluate how well different antibiotic combinations work compared to current global standards and reveal which combinations could help improve the survival of neonates and young infants with sepsis.
- Provide a wealth of additional information for clinicians and hospital managers to optimise local clinical management of sepsis.
- Increase awareness and experience of adaptive platform methodologies across multiple sub-Saharan African countries.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2028
Total project cost	€7 168 901,00
Global Health EDCTP3 funding	€7 168 901,00
Disease area	Other childhood infectious diseases, Lower respiratory tract infections
Intervention type	Therapies, Surveillance tools, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Health security
Project coordinator	FONDAZIONE PENTA ETS
Participating countries	Italy, Kenya, Belgium, Uganda, Tanzania, Ghana, United Kingdom, South Africa



UTI-Diag

Diagnostic and Antibiotic Stewardship for Urinary Tract Infections Using Fit-for-Purpose Diagnostic Tools

The UTI-Diag project is exploring whether point-of-care tests could improve detection and management of urinary tract infections (UTIs) and reduce the pressures driving antimicrobial resistance.

The challenge

Urinary tract infections (UTIs) are caused by a range of pathogens and are extremely common, with globally more than 400 million UTI cases each year. The prevalence of UTIs has been increasing over the past two decades, particularly in low- and middle-income countries.

In low-resource settings, treatment is typically syndromic, or diagnosis is made primarily on clinical signs, which is incorrect in about a third of cases. This leads to high levels of antibiotic use, driving the spread of antimicrobial resistance. Disease recurrence is common, for example, occurring in 26–44% of women treated for UTIs.

UTI symptoms are not specific to infections, so the first challenge in clinical care is to determine as quickly as possible whether a patient actually has an infection. Clinical management could also be improved by knowledge about the antibiotic resistance profile of a pathogen, enabling a suitable treatment to be selected.

The project

The UTI-Diag project is exploring whether new diagnostic and sampling technologies could be applied to UTI management in sub-Saharan Africa to enable more targeted antibiotic use and reduce the pressure driving the emergence and spread of antimicrobial resistance.

The project is focusing on four tools that could improve UTI detection and patient care:

- A simple **sample collection and transport** device, based on a card with disks for urine and blood samples, which can be sealed and sent by regular mail. This could be used by patients or clinicians.
- A lateral flow test (**ULTRIPLEX**), which detects two urinary proteins associated with UTIs, is to be used in initial triage to determine whether patients have infections.
- **UTI-Diag**, a battery-operated point-of-care device for molecular detection of **antimicrobial resistance genes**, to guide choice of antibiotic treatment.
- An adapted version of the **AviroPocketClinic digital tool**, which reports the results, aids clinical decision-making, and has built-in communications and training support modules.

The project is carrying out clinical validation studies of these tools at multiple sites in Cameroon and Senegal. Special efforts are being made to investigate their use in marginalised and hard-to-reach communities so that the results are as generalisable as possible. The performance of the tools is being compared with that of multiple other strategies and detection methods. Costing analyses are also being carried out.

The impact

The UTI-Diag project will provide data on one of the most common infections, which, in addition to leading to many deaths, has a major impact on quality of life, places high demands on health systems, and is increasingly difficult to treat due to antibiotic resistance. It will:

- Demonstrate whether the tools being tested, individually or collectively, can lead to more targeted treatment of UTIs.
- Show whether their use improves patient outcomes and leads to more rational use of antibiotics.
- Provide health authorities with information on the prevalence, spread and resistance patterns of infections.
- Generate data on the feasibility of the tools and their costs to inform national decision-making.

The project estimates that, with widespread use of the tools, treatment failures, hospital admissions, and healthcare costs could be reduced by more than 40%, and misdiagnosis could be reduced from around 33% to 5%. This would deliver significant benefits to patients, health systems and the long-term battle against AMR.

Project at a glance	
Project duration	1 Mar 2025 - 31 Aug 2028
Total project cost	€3 944 941,38
Global Health EDCTP3 funding	€3 944 941,38
Disease area	Other childhood infectious diseases, Cross-disease or disease unspecific
Intervention type	Diagnostics, Other prevention tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Women's health, Digital technologies, Climate crisis or climate adaptation
Project coordinator	KAROLINSKA INSTITUTET
Scientific project leader	INSTITUT PASTEUR DE DAKAR
Participating countries	Sweden, Senegal, South Africa, Germany, France, Cameroon, Finland





LINDA-FAMILIA

Implementation of an Integrated Digital Health System for Infectious Diseases in Maternal and Child Health In East Africa

The LINDA-FAMILIA project is enabling four countries in East Africa to introduce and scale up multiple digital health technologies.

The challenge

There are many ways in which **digital technologies** can improve healthcare, from efficient management of patient information to text messaging of reminders of clinical appointments. In many sub-Saharan African countries, however, paper-based health systems remain the norm at service-delivery levels, with information then laboriously entered into electronic systems for reporting.

Although efforts are underway to introduce digital health technologies, implementation is often haphazard. By one estimate, nearly 1,000 separate systems are used in health systems in sub-Saharan Africa.

One area where digital health technologies could have a major impact is in **maternal, neonatal and child health**. Around 200,000 of the 290,000 maternal deaths occurring each year happen in sub-Saharan Africa, which also has the highest neonatal mortality rate in the world, with infections accounting for an estimated one in four of such deaths.

The project

The LINDA-FAMILIA project is working with ministries of health in four East African countries (Ethiopia, Rwanda, Tanzania, and Uganda) to introduce and scale up a dozen evidence-based digital health technologies for maternal, neonatal, and child health.

These applications cover a range of uses, including:

- Capture and storage of patient-related information.
- Coordination of patient referrals.
- Support for clinical decision-making.
- Planning health professionals' work schedules.
- Communication with health service users.
- Data collection, coding and exchange.

The project has a strong focus on integration with existing systems and long-term sustainability. New tools will be integrated within a widely used health information system (DHIS2), drawing on the flexible functionality of individual-level electronic health registries (eRegistries).

The health ministries of each country are part of the project team and will select which digital health technologies to introduce or scale up. They will also help to co-create the specific design of tools introduced nationally. This work will be informed by an initial landscape review, setting out the current state of digital health in each country. A post-project sustainability plan will be developed in each country to ensure continued use of the new tools.

In addition to improving care delivery, digital health systems also offer opportunities for research embedded in routine care. To demonstrate the potential of such research, the project will undertake two studies: a cross-country comparative analysis of maternal and neonatal infectious diseases and a clinical trial to assess the impact of text messaging on antenatal care attendance and facility-based delivery.

The impact

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Project at a glance	
Project duration	1 Aug 2025 - 31 Jul 2029
Total project cost	€4 998 562,50
Global Health EDCTP3 funding	€4 998 562,50
Disease area	Other childhood infectious diseases
Intervention type	Surveillance tools, Other prevention tools
Overarching topic	Digital technologies, Women's health, Co-morbidities and non-communicable diseases
Project coordinator	UNIVERSITY COLLEGE CORK - NATIONAL UNIVERSITY OF IRELAND, CORK
Scientific project leader	THE GOOD SAMARITAN FOUNDATION
Participating countries	Ireland, Tanzania, Norway, Ethiopia, United Kingdom, Uganda, Rwanda



ACROBAT Newborns

Appraising the Critical Role of prognostic Biomarkers in the Assessment and Triage of sick African newborns: Advancing a point-of-care device based on sTREM-1 towards CE marking and implementation

The ACROBAT Newborns project is developing a bedside test to identify newborns at the highest risk of sepsis, one of the most common causes of death in the neonatal period.

The challenge

Infections in the newborn period are common and can pose a serious threat to a baby's health. One of the most concerning consequences of infection is **sepsis**, a massive inflammatory response that can lead to multi-organ failure and death, often at great speed. Globally, an estimated 1.3 to 3.9 million cases of sepsis occur every year in newborns, leading to 400,000 to 700,000 deaths, most on them in sub-Saharan Africa.

In hospitals, a major challenge is to identify babies most at risk of sepsis so that they can be given the most intensive care. An estimated 84% of deaths from sepsis could be prevented with early detection. However, it is difficult to identify at-risk babies based on clinical signs alone, as no reliable predictor of sepsis has been validated yet. Identifying underlying causes of infection is also of limited value since many different types of infection can lead to sepsis.

It is now becoming clear that, whatever its cause, sepsis progresses through a common physiological pathway. Biomarkers associated with early stages of sepsis progression could therefore help clinicians identify high risk babies, without needing to know the underlying cause of their condition.

The project

The ACROBAT Newborns project is focusing on a sepsis biomarker known as **sTREM-1**. This bloodstream marker has been found to be strongly associated with sepsis, and detecting its presence is highly predictive of sepsis development.

Through the Horizon Europe EChLiBRiST project, the project team developed a sepsis risk-prediction tool based on sTREM for use in children called X-TREM. Using just two drops of blood, it provides results within 10 minutes, stratifying patients into low, medium, or high risk to guide patient management (discharge, monitor, admit, and treat). The test platform uses disposable cartridges with a simple-to-operate handheld reader.

During the ACROBAT Newborns project, the team is validating the use of this tool among young infants. The new project will test X-TREM on 4,000 sick newborns and 400 healthy controls at first contact with health systems at sites in Ethiopia, Gabon, Mozambique and Uganda. The study will evaluate its clinical performance in the field, comparing results with a wide range of sepsis-detection algorithms and potential sepsis biomarkers (those already incorporated into products or identified in experimental studies).

The project will track the progress of infants, collect data on vital signs and various physiological parameters, and apply diagnostic tests. This will provide additional valuable information on factors associated with sepsis and poor outcomes, including its association with particular types of infection.

The project is also testing the usability, feasibility and acceptability of the diagnostic device, to generate evidence to inform final designs and to support successful implementation. It will advance product development to an industrial prototype. The project team will also develop a plan to achieve regulatory approvals in target countries, including CE marking, and develop a business plan to advance the product to market.

The impact

The ACROBAT Newborns project will provide clinicians in sub-Saharan Africa with a new tool to identify newborn babies at the highest risk of sepsis. It will:

- Advance product development through to the industrial prototype stage.
- Generate evidence on its predictive performance in field settings.
- Gather feedback on users to inform final designs.
- Provide a detailed economic analysis, potential impact studies and implementation scenarios to inform national and international policymaking.

If its potential is confirmed, X-TREM could have multiple benefits, leading to more targeted use of antibiotics and other healthcare resources and, most importantly, reducing the impact of a condition responsible for around half of child mortality in sub-Saharan Africa.

Project at a glance	
Project duration	1 Jan 2025 - 31 Dec 2029
Total project cost	€4 808 065,00
Global Health EDCTP3 funding	€4 808 065,00
Disease area	Other childhood infectious diseases
Intervention type	Other prevention tools
Overarching topic	(Other) emerging technologies, Co-morbidities and non-communicable diseases
Project coordinator	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA
Scientific project leader	FUNDACAO MANHICA
Participating countries	Spain, Mozambique, Ethiopia, Nigeria, Germany, Uganda, Gabon, United Kingdom





SDx

REConneCteD: Risk-Enhanced Community Care After Discharge

The SDx project is assessing whether digital tools can enable community health workers to maintain contact with vulnerable children discharged from the hospital but at elevated risk of death.

The challenge

Children discharged from the hospital after treatment for a serious infection remain at increased risk of death for several months. In the six months following discharge, mortality rates are typically 5–10%, as high as they are when children are being treated for serious infections in hospitals.

Half of all deaths that occur within 6 months after discharge happen at home, without children receiving further hospital care, and half occur more than a month after discharge. Children living in poverty are at markedly higher risk of death.

It is not feasible for facility-based health workers to monitor discharged children for signs of deterioration or other serious illnesses. However, **community health workers** could link the community and hospitals, enabling the monitoring of high risk children and their referral back to hospitals when necessary.

The project

The SDx team has developed a ‘**Smart Discharge**’ approach to hospital care, based on a digital algorithm integrated into electronic health records, that guides clinical decision-making based on infection severity. Analysing eight easily measured variables, the algorithm categorises children into low-, medium-, and high risk groups, enabling tailored clinical care and discharge plans.

In a trial in six hospitals in Uganda, this approach reduced the mortality rate among children under 5 years of age by nearly a quarter after discharge. This figure could be reduced further if the monitoring of high risk children were extended into the community after discharge.

However, the digital platform used by community health workers (eCHIS) is different to the electronic health record system used in clinical facilities. The SDx team is therefore developing a new module for the eCHIS system to equip community health workers with information on high risk children post-discharge, how to monitor them, and when to refer them back to the hospital. This module is being co-developed with community health workers and other stakeholders to ensure that it integrates into existing work practices.

Following testing for usability, feasibility, and accessibility, an optimised version of the new module will be evaluated in a clinical trial, comparing the use of the new approach with existing post-discharge practices. The trial will focus on children up to 16 years of age discharged after treatment for a serious infection. The key success factor is whether the introduction of the module leads to reduced all-cause mortality at 6 months after discharge.

The trial will also assess various process metrics to gain insights into how the module is used and its impact on care provision. Impacts on community health worker knowledge will also be explored.

The project also incorporates an economic evaluation, and a plan will be developed to promote the integration and continued use in routine care at the end of the trial, for example, by identifying ‘champions’ of the new technology.

The impact

The SDx project could have a significant impact on children’s survival after hospital treatment. It will:

- Demonstrate whether a digital tool, embedded within a standard community health worker health information system, can enable continued monitoring of vulnerable children in the community after discharge from the hospital.
- Provide evidence of whether this community monitoring leads to timely referral of children back to the hospital and improves survival rates.
- Help caregivers identify signs of deterioration and the need for a return to the hospital.

The SDx project could leverage digital technologies to maintain care-system contact with children during one of the most vulnerable periods of their lives, the months following discharge from the hospital, when they are at heightened risk of serious illness and death.

Project at a glance	
Project duration	1 Jul 2025 – 30 Jun 2030
Total project cost	€5 003 298,75
Global Health EDCTP3 funding	€4 999 688,50
Disease area	Other childhood infectious diseases
Intervention type	Other prevention tools
Overarching topic	Digital technologies
Project coordinator	UNIVERSITY OF BRITISH COLUMBIA
Scientific project leader	WORLD ALLIANCE FOR LUNG AND INTENSIVE CARE MEDICINE IN UGANDA (WALIMU)
Participating countries	Canada, Uganda, Kenya, Switzerland



Emergency response actions



Mpox outbreak



PregInPoxVac

Maternal and infant safety and immunogenicity in a phase 3, open-label, randomised, vaccine trial of a two-dose mpox vaccine

The PregInPoxVac project is generating data on the use of the MVA-BN vaccine to prevent mpox infections in pregnant women.

The challenge

The monkeypox virus (MPXV), the causing agent of mpox, can have particularly severe impacts on infants and children, where it can lead to severe complications and high mortality. Also, **pregnant women** are at increased risk, affecting both their health and that of their babies in the womb. Infections during pregnancy can lead to a range of adverse pregnancy outcomes, including neonatal infections, stillbirths, premature delivery and low birthweight.

The **MVA-BN vaccine** offers good protection against mpox infection. However, there are limited data on its use in infants and pregnant women. Additionally, in infants, available safety data in pediatric populations support the rationale for evaluating **a reduced (half) dose**. A lower dose may provide comparable immune responses while potentially reducing reactogenicity, but this needs to be confirmed. This approach will help determine whether a smaller dose can achieve adequate immunogenicity while minimising adverse events in this younger age group.

Given its non-replicating nature, the MVA-BN vaccine is deemed to be safe in pregnant women. However, its safety and immunogenicity in this population still need to be formally evaluated. In addition, it remains unknown whether, and for how long, vaccinated mothers can provide **protection to their newborns**.

In this study, we will assess the presence of antibodies in umbilical cord blood and breastmilk of women vaccinated during pregnancy, as well as the timing of antibody appearance in women vaccinated in the immediate postpartum period. We will also evaluate whether these antibodies are transferred to infants through breastfeeding and how long they persist.

The project

The PregInPoxVac project is collecting data to assess the **immunogenicity and safety** of MVA-BN in infants and in pregnant women. At Boende, Tshuapa Province in the Democratic Republic of the Congo (DRC), an existing clinical trial site, 344 infants of 4 to <24 months will be recruited, of whom half will receive the standard vaccine regimen and half, the half-dose regimen. Further, 359 pregnant women will be recruited into a study to track immune responses following vaccination. 215 pregnant women will be vaccinated during pregnancy and 144 in the immediate postpartum.

As well as analysing **immune responses** after vaccination, the project team is also **tracking birth outcomes** and **monitoring the health of young babies** born to vaccinated women. Afterwards, we will assess the extent to which **vaccine-induced antibodies** are transmitted to the babies via the umbilical cord or breastfeeding. In addition, a qualitative study is being carried out to assess **attitudes towards Mpox vaccination** and **participation in vaccine research** among pregnant women, their families and health workers. This will inform the development

of communications materials for women and their families to encourage vaccination uptake and participation in research studies. Also, a formal **ancillary care policy** will be rolled out and will cover all study and non-study-related adverse events during trial participation.

The PregInPoxVac project has received €5.99 million of co-funding from CEPI.

PregInPoxVac is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The PregInPoxVac project is generating vital data on vaccination of pregnant women and infants to prevent mpox infection. It will:

- Provide further high-quality data on the safety and immunogenicity of the MVA-BN vaccine in pregnant women in Africa.
- Identify whether vaccine-induced antibodies are transmitted to newborns of vaccinated mothers.
- Provide further high-quality data on the safety and immunogenicity of the MVA-BN vaccine in infants in Africa.
- Shed light on the use of half a dose of the MVA-BN vaccine in the infant population
- Shed light on any potential barriers that might prevent the uptake of mpox vaccination by pregnant women.

With infants and pregnant women at risk of multiple adverse outcomes following infection, the PregInPoxVac project will provide policymakers with greater confidence to recommend vaccination of pregnant women and/or infants against mpox.

Project at a glance	
Project duration	1 Aug 2024 - 31 Jul 2027
Total project cost	€1 599 327,50
Global Health EDCTP3 funding	€1 599 327,50
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Vaccines
Overarching topic	Women's health, Health security
Project coordinator	UNIVERSITEIT ANTWERPEN
Scientific project leader	UNIVERSITEIT DE KINSHASA
Participating countries	Belgium, Democratic Republic of the Congo, Italy, Kenya





MpoxVax AFRIVAC

Expanding a prospective, clinical trial examining the immune response of participants receiving Modified Vaccinia Ankara vaccine to Africa

The MpoxVax AFRIVAC project is closing key knowledge gaps on the performance of mpox vaccines in Central Africa.

The challenge

The **MVA-BN vaccine** has been shown to provide good protection against mpox infection and has been widely used, including in sub-Saharan Africa. However, several aspects of the vaccine are not well characterised, including the strength of immune responses generated in **women** and in those with **impaired immune systems** (for example, due to advanced HIV infection), the **durability** of these responses and the length of protection after vaccination.

In Europe, the **MpoxVax trial** evaluating MVA-BN vaccination to prevent mpox infection is collecting important immunogenicity data. However, the study population predominantly comprises Caucasian gay and bisexual men who have sex with men, reflecting the population most affected by the clade IIb mpox outbreak in Europe. As such, the findings may have limited generalisability to Central African settings, where the epidemiology of mpox differs, and women represent a substantially affected population.

The project

The MpoxVax AFRIVAC project uses the European MpoxVax trial as a template, extending recruitment to additional populations in the Democratic Republic of the Congo, Tanzania and Uganda in collaboration with local partners. By using existing trial materials, the project team has been able to rapidly launch the new studies in Africa.

The key aim of the project is to generate data on the **immunogenicity** (the ability to provoke an immune response) of the MVA-BN vaccine and the **durability** of immune responses in African populations, with a focus on women and people living with HIV, who are disproportionately affected by the current mpox outbreak. The studies will also explore other factors, such as age or ethnicity, that could be associated with variation in the strength or duration of vaccine-induced immune responses.

Around 300 people have been recruited from three sites and followed for 48 weeks after vaccination. Analyses are focusing on antibody levels immediately after vaccination and in the following months, providing important information on the magnitude and durability of vaccine-induced immune responses.

The project will also evaluate a previously developed and validated **immunological assay** in African populations. The assay distinguishes immune responses following mpox infection from those induced by vaccination by measuring responses to selected viral antigens, enabling identification of infection- versus vaccine-derived immunity.

Finally, the project is establishing a **regional clinical trials unit** to support research across the three participating countries.

MpoxVax AFRIVAC is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The MpoxVax AFRIVAC project will provide key information on the immune responses generated by the main vaccine being used to prevent mpox infections. It will:

- Generate data on immune responses in sub-Saharan African populations, including women and people living with HIV, which will provide a likely indication of its effectiveness in the general population and in these specific groups.
- Deliver evidence on the durability of protection and whether and when re-vaccination might be required.
- Establish research skills, knowledge and trial infrastructure in a Central African setting to enable future research in emerging infections and host immune response.

With vaccination a key strand of mpox control programmes, the MpoxVax AFRIVAC project will deliver vital evidence for policymakers on how best to use the MVA-BN vaccine.

Project at a glance	
Project duration	1 Oct 2024 - 31 Mar 2027
Total project cost	€1 377 183,75
Global Health EDCTP3 funding	€1 371 783,75
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Vaccines, Diagnostics
Overarching topic	Health security
Project coordinator	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN
Scientific project leader	MAKERERE UNIVERSITY LUNG INSTITUTE
Participating countries	Ireland, Uganda, Tanzania, United Kingdom, Democratic Republic of the Congo



PREGMPOX

Impact of MPXV infection on pregnancy outcome and newborn health

The PREGMPOX project is attempting to find out why mpox virus infections are particularly harmful to pregnant women.

The challenge

Unlike the global mpox epidemic of 2022-2023, which primarily affected young men, the later outbreak centred on the Democratic Republic of the Congo (DRC) and sub-Saharan Africa impacted a broader range of populations, including **women**. Female sex workers, for example, have been badly affected by the newly emerged clade Ib strain of mpox in the DRC and elsewhere.

It has also become clear that mpox infections are particularly severe in **pregnant women**, affecting both women and their unborn babies, increasing the risk of miscarriage, stillbirth and other adverse birth outcomes. The reasons for this susceptibility are not clear.

The project

The PREGMPOX project is tracking a **cohort of pregnant women with mpox infections** to obtain a comprehensive picture of the consequences of infection on maternal health and pregnancy outcomes, and to identify potential factors contributing to increased susceptibility.

An additional strand of the project is focusing on collecting **surveillance data** from clinical facilities and from communities – due to the stigma associated with infections, women may not seek help, which could lead to an under-estimate of community burdens. Stations will be set up in communities to detect cases, supported by the involvement of local community health workers.

The cohort study will monitor for a range of impacts, including stillbirth, low birth weight, prematurity, neonatal infection and deaths. Women's immune responses will also be monitored throughout infection, alongside viral load. In addition, placental samples will be analysed to provide insights into the harmful effects of the virus on **placental development and function**, which could explain poor pregnancy outcomes.

These analyses, with associated clinical data, could reveal key **risk factors** associated with adverse pregnancy outcomes and transmission of mpox infections to babies.

The data will also be used to establish a **register of outcomes**, which will provide a benchmark for assessing the impact of interventions (treatment or vaccination). The project will use this resource in studies of **tecovirimat**, an antiviral treatment,

and **vaccination with MVA-BN**. This part of the study will provide insights into both the safety and effectiveness of these interventions in pregnant women.

PREGMPOX is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The PREGMPOX project will close an important gap relating to the impact of mpox on pregnant women. It will:

- Provide a comprehensive picture of the burden of mpox among women in the DRC.
- Generate detailed data on the impacts of infection on pregnant women and their developing babies.
- Create an information repository on adverse outcomes that can be used as a reference in interventional trials.
- Generate data on the effectiveness of a potential antiviral treatment and vaccination.

Through these routes, the PREGMPOX project will help to guide public health strategies and improve clinical care during pregnancy, potentially reducing both the numbers and severity of neonatal impacts of mpox infection.

Project at a glance	
Project duration	1 Aug 2024 - 31 Jul 2027
Total project cost	€1 250 000,00
Global Health EDCTP3 funding	€1 250 000,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Women's health, Digital technologies, Health security
Project coordinator	UNIVERSITEIT ANTWERPEN
Scientific project leader	UNIVERSITE CATHOLIQUE DE BUKAVU
Participating countries	Belgium, Democratic Republic of the Congo, Germany, Uganda





MPOX-PROBE

Strengthening epidemiological, genomic and community surveillance of Mpox virus (MPXV) at the Congo River border for DRC and RoC

The MPOX-PROBE project is tracking the emergence and spread of mpox on the border between the Democratic Republic of the Congo (DRC) and the Republic of Congo.

The challenge

The natural **animal reservoir** of the mpox virus is not known with certainty, although it is suspected to be native to small mammals, including some types of squirrels. This knowledge gap makes it difficult to plan activities to minimise the risk of ‘spillover’ – the transmission of viruses from animals to people.

In addition, the lack of easy-to-use **diagnostics** makes it difficult to track the spread of new infections, as mpox symptoms overlap with those of other infections.

These factors make it difficult to gain a clear picture of the emergence and spread of new mpox infections, hampering prevention and outbreak response measures.

The project

The MPOX-PROBE project is carrying out a diverse range of activities to enhance mpox surveillance, with a focus on the border between the DRC and the Republic of Congo. The two countries are separated by the Congo River, but there is considerable cross-border travel, which could facilitate the wider spread of the virus.

Key activities include:

- **Enhanced mpox surveillance**, focusing on three border sites. Surveillance activities will include **trapping of animals** and testing those with signs of disease for the presence of the mpox virus, to identify potential natural host species. In patients, blood samples will be analysed to characterise **host responses to infection** (through transcriptomics and assessment of inflammatory responses). Analysis of **serum samples from the wider population** will provide insights into the community prevalence of infection and potential for asymptomatic carriage. Analysis of **air samples** from a range of clinical and public spaces will shed light on the risk of airborne spread of the virus. Notably, studies will include children, pregnant women and people living with HIV.
- **Development of a dynamic transmission model**: Existing and new surveillance data will be used to develop a **model of mpox transmission**, which will highlight potential high risk areas and enable the possible impact of control measures to be explored.
- **Diagnostic development**: A prototype mpox **rapid diagnostic test** will be developed using novel nanoparticle technology. It will be highly sensitive, able to discriminate between different mpox clades, and could potentially be converted into a point-of-care device.
- **Knowledge, attitudes and practices**: A survey and other tools will be used to gather insights from key groups, including members of the public and healthcare workers.

- **Understanding risk factors for infection**: A **case-control study** will compare patients with mpox infections (acquired from an animal source or by human-to-human transmission) with matched controls, to help identify key factors associated with an increased risk of mpox infection.

MPOX-PROBE is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The MPOX-PROBE project will generate substantial new evidence on the emergence and spread of mpox infections in the DRC and the Republic of Congo. It will:

- Identify potential animal reservoirs of the mpox virus.
- Provide a clearer picture of the emergence and transmission of the virus.
- Create new diagnostic tools for identifying and tracking infections.
- Clarify current knowledge and attitudes across key community groups.
- Develop a transmission model to support planning of public health responses.

Through its activities, the MPOX-PROBE project will provide policymakers with information and new tools to better understand the mpox outbreak, how the virus is being transmitted through populations, and how transmission might be affected by different control measures – better equipping policymakers to control the outbreak and protect public health.

Project at a glance	
Project duration	1 Oct 2024 - 30 Sep 2026
Total project cost	€1 301 868,75
Global Health EDCTP3 funding	€1 299 993,75
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance tools
Overarching topic	Health security, Digital technologies
Project coordinator	R-EVOLUTION WORLDWIDE SRL - IMPRESA SOCIALE
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MEDICALE
Participating countries	Italy, Congo, Democratic Republic of the Congo, Spain



ODIN-MPox

Implementing wastewater and environmental surveillance for Mpox in sub-Saharan Africa

Building on the existing Global Health EDCTP3-funded ODIN project, the ODIN-Mpox project is applying genomic technologies to wastewater surveillance to track the spread of mpox.

The challenge

Pathogen surveillance traditionally draws on analysis of **clinical samples** collected from patients. Complementary information can be obtained from environmental samples, which are relatively easy to collect and analyse and can provide a broad overview of where a pathogen is circulating and whether infection levels are rising or falling. One advantage of this approach is that it measures the **total viral ‘load’** in a community, including that deriving from asymptomatic infections.

The **ODIN project** was one of six funded by the Global Health EDCTP3 programme to help build capacity for **genomic surveillance** of priority pathogens in sub-Saharan Africa. It is helping three countries – Burkina Faso, the Democratic Republic of the Congo (DRC) and Tanzania – introduce genomics-based wastewater surveillance.

The project

In response to the mpox outbreak in the DRC and other sub-Saharan African countries, the ODIN-Mpox project is expanding its work to include mpox, having initially focused solely on bacterial pathogens. The project is working closely with national public health laboratories to integrate genomic wastewater and environmental surveillance into routine public health activities.

The project is using the same approach adapted to mpox, with sensitive molecular methods to **quantify the amount of viral genetic material** in wastewater and other environmental samples from a range of locations. This genetic material is also **sequenced** to provide information on the specific mpox virus variants present in samples.

An automated data-processing pipeline is being developed alongside a **dashboard** to communicate results to public health partners as rapidly and accessibly as possible. The project’s work draws on stakeholder consultations and landscaping carried out in the initial ODIN project. This project has also been developing a **mobile laboratory**, which will enable on-the-spot analyses to be carried out in remote locations, and will help to identify sources of pathogen contamination. This, too, will be adapted to facilitate mpox analyses.

ODIN-Mpox is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The ODIN-Mpox project will add a valuable additional dimension to mpox surveillance. It will:

- Provide additional insights into trends in mpox circulation, providing an early warning of hotspots to inform disease control responses, including targeting of vaccination.
- Generate sequence data on mpox and help to identify sub-lineages having the greatest impact, with sequence information shared with global repositories.
- Create tools to provide additional insights into the properties and transmission of the virus, and to track the impact of disease control activities.
- Strengthen the capacity of national public health laboratories to carry out genomic surveillance on viral pathogens.

Using the original ODIN project infrastructure as a springboard, the ODIN-Mpox project will rapidly establish systems to monitor mpox presence in the DRC and two other nearby countries, providing public health officials with key information to guide disease control strategies.

Project at a glance	
Project duration	1 Aug 2024 - 31 Jul 2026
Total project cost	€1 378 272,50
Global Health EDCTP3 funding	€1 378 272,50
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Climate crisis or climate adaptation, Health security
Project coordinator	LUNDS UNIVERSITET
Scientific project leader	UNIVERSITE DE KINSHASA
Participating countries	Sweden, Democratic Republic of the Congo, Finland, Tanzania, Belgium, Burkina Faso, United Kingdom, Norway





IPHER-MPOX

Deciphering host genetics and viral determinants of MPOX epidemiology in the Democratic Republic of Congo

The DECIPHER-MPOX project is identifying host- and virus-related factors responsible for susceptibility to and the severity of mpox infections.

The challenge

During the mpox outbreak in sub-Saharan Africa, exposure to an infected individual may or may not lead to a new infection. Furthermore, when infected, an individual may show no symptoms, experience mild illness, or develop severe disease. It is unclear what factors account for these varying outcomes.

The project

To address this question, the DECIPHER-MPOX project is establishing **cohorts of family contacts** of infected patients. By tracking them over time and comparing those who fall ill with their immediate family relatives (father, mother or siblings), the project aims to identify factors associated with acquiring mpox infection and with more severe disease.

The project is using a variety of technologies to explore **host-related factors** associated with mpox susceptibility or resistance. These include:

- **Whole exome sequencing**, which may reveal **rare genetic variants** having a major impact on susceptibility.
- **Transcriptomics**, which may identify common variants or **signatures of gene activity**, across multiple genes, that are associated with symptom severity.
- **Digital cell sorting**, which could reveal differences in **immune cell populations** associated with disease severity.
- **Viral genome sequencing** to identify variations (strains) within the dominant clade 1b.
- Immunological assays to cross-validate phenotypes of monkeypox virus (MPXV) specific host antibody expression, T cell response and or innate function and how they relate to all the above.

Infectiousness and the impact of infection may also be related to **properties of the mpox virus**. The project will therefore sequence mpox virus isolates to explore links between genetic changes in the virus and its impacts on human hosts.

The research will be carried out in the Kamituga area of South Kivu Province, Democratic Republic of the Congo (DRC), where the newly detected clade 1b strain of mpox is circulating.

DECIPHER-MPOX is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The DECIPHER-MPOX project will provide answers to key virological questions. It will:

- Identify host and virus factors associated with severe disease.
- Help to guide patient care based on the risk of severe disease.
- Provide information on disease mechanisms, which will feed into the development of mpox therapeutics.
- Shed light on potential immunological correlates of protection to inform vaccine development.

Ultimately, a deeper understanding of how contacts are affected following mpox exposure will provide critical evidence to underpin vaccine and therapeutic development, generating new options to prevent and treat mpox disease.

Project at a glance	
Project duration	1 Aug 2024 - 31 Jul 2027
Total project cost	€1 260 000,00
Global Health EDCTP3 funding	€1 260 000,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	NATIONAL HEALTH LABORATORY SERVICES
Scientific project leader	MAKERERE UNIVERSITY
Participating countries	South Africa, Uganda, Canada, Democratic Republic of the Congo, United Kingdom



MBOTE-SK

Tackling and investigating the South-Kivu mpox outbreak

The MBOTE-SK project is embedding research within the response to the new clade 1b mpox outbreak in eastern DRC.

The challenge

In late 2023, mpox cases began to be detected in Kamituga, a densely populated mining area in the east of the Democratic Republic of the Congo (DRC). These were found to be caused by a novel '**clade 1b**' strain of mpox, which was being transmitted by sexual and other close person-to-person contact.

When cases of mpox began to rise significantly, the **MBOTE consortium**, already established and with partners in the DRC and Europe, supported initial efforts to understand and respond to this outbreak in eastern DRC. Much was unknown about the spread and impact of clade 1b mpox, hampering efforts to provide optimal care and control its spread.

The project

The MBOTE-SK project combines support for immediate response to the clade 1b outbreak with research studies that will enhance clinical care and inform control strategies.

The project team is working across five areas, each of which integrates response-support activities as well as associated research studies:

- **Understanding transmission:** Carrying out case-finding activities and mapping cases to clarify **mpox epidemiology** and provide health authorities with up-to-date information about the spread of infection. Research activities will also explore potential drivers of transmission.
- **Genomic surveillance:** Introducing regional **genome sequencing capacity** in eastern DRC to genomically characterise isolates and shed light on the transmission and evolution of the new strain.
- **Case management and diagnostics:** Documenting the **full clinical impact** of clade 1b in different groups, tracking outcomes and identifying risk factors for particular impacts. The project is also supporting the introduction of **decentralised molecular diagnostic tools** at the local hospital and providing a platform for **evaluating rapid diagnostics** for mpox.
- **Community attitudes: Community engagement** activities will raise awareness of mpox and generate insights into community knowledge and attitudes, including stigmatisation. This work will help to reveal hidden cases of mpox in the community.
- **Supporting vaccination:** The project's epidemiological analyses will inform the **targeting of vaccination strategies at high risk populations**. The project is also evaluating the **impact of vaccine campaigns** and assessing vaccine effectiveness.

MBOTE-SK is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The MBOTE-SK project is making a critical contribution to the response to the mpox outbreak in the eastern DRC. It will:

- Provide policymakers with key information on the local spread of clade 1b, to inform the planning of control strategies.
- Identify the full range of clinical impacts of clade 1b, to ensure optimal clinical management.
- Provide insights into community attitudes and 'invisible' transmission in the community, to shape public health interventions and communication strategies.
- Help to target vaccination strategies and generate evidence of their impact.

Collectively, the project's work will support the immediate response to the clade 1b outbreak and generate evidence needed to improve care and control the spread of infection over the longer term.

Project at a glance	
Project duration	1 Aug 2024 - 31 Jan 2027
Total project cost	€2 066 281,25
Global Health EDCTP3 funding	€1 263 076,25
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools, Diagnostics, Vaccines
Overarching topic	Health security
Project coordinator	INSTITUUT VOORTROPISCHE GENEESKUNDE
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMEDICALE DU ZAIRE
Participating countries	Belgium, Democratic Republic of the Congo, France, Canada, Switzerland, United States





JUA KIVU

Joint Understanding and Analysis of clade I monkeypox epidemiology, evolution and immunology in South Kivu

The JUA-KIVU project is generating a clearer picture of the origins and spread of the novel strain of mpox virus (clade Ib) identified in South Kivu Province, eastern DRC.

The challenge

A new strain of clade I mpox, named **clade Ib**, was identified in eastern parts of the Democratic Republic of the Congo (DRC) in 2024. Many aspects of this variant, including its origins, spread and interactions with other infections, remain poorly understood.

The discovery of the **clade Ib mpox virus** emerged from activities undertaken as part of the Global Health EDCTP3-funded GREAT-LIFE project, which is working to build capacity for genomic surveillance in eastern African countries, including Burundi, the DRC, Rwanda, and Tanzania. As part of a capacity-building project, mpox samples from the South Kivu outbreak were sequenced and found to constitute a distinct cluster within the clade I branch of the mpox virus family tree, likely the result of a recent zoonotic spillover that has become established in the human population.

The epicentre of this clade Ib outbreak in the DRC is a densely populated mining area, with multiple bars, a thriving sex industry, and many migratory workers, including regular border crossings. This environment provides opportunities for the extensive spread of the new mpox virus variant.

The project

Through the JUA-KIVU project, the team responsible for identifying the clade Ib mpox virus is carrying out more genome sequencing and other studies to provide additional insights into the outbreak.

Around 200 additional **mpox clinical isolates** have been collected during the outbreak and will be sequenced to shed light on the virus's evolution and the pathways through which it is transmitted.

Other work will focus on the possible **origins of the virus**. Local researchers collected samples from multiple wild animals, bushmeat and hunters before and during the outbreak, which will be analysed for signs of the virus and to pinpoint its emergence in the human population.

The project team is also investigating the **impact of co-infections** on the severity of mpox disease. Co-infections, for example, affecting mpox skin lesions, appear to be a common cause of death in mpox patients. This effect will be systematically investigated through **metagenomic** studies to identify all microbes present in patients' skin lesions and to assess their association with poor outcomes. The **antimicrobial susceptibility** of co-infections is also being investigated.

It is likely that not all clade Ib infections are being detected, as the numbers are based on analyses of cases seen in health facilities. The project is also carrying out **serosurveys** to identify how many people show signs of past infection, with a particular focus on high risk populations such as sex workers, hunters, household

members of patients, and travellers. Samples taken from latrines at multiple **border crossings** are being analysed to provide insights into virus circulation within the wider population. Further data are coming from **wastewater surveillance** activities that were already part of the GREAT-LIFE project.

The JUA-KIVU project team is also assessing **immunological responses to clade Ib infections**, comparing both antibody and cell-based responses to those seen following infection with other mpox virus clades and after vaccination.

JUA-KIVU is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The JUA-KIVU project will provide new insights into the mpox clade Ib outbreak in the eastern DRC. It will:

- Provide a clearer picture of the likely origins of the outbreak.
- Shed light on the extent to which clade Ib virus has been circulating and is currently being transmitted through high risk populations.
- Reveal the extent to which co-infections are driving poor outcomes associated with clade I mpox infection.

These activities will inform the treatment of mpox patients, particularly the management of co-infections, and will also provide policymakers with insights to enable them to plan strategies to control the virus's circulation and prevent new spillovers.

Project at a glance	
Project duration	1 Oct 2024 - 30 Sep 2026
Total project cost	€1 250 000,00
Global Health EDCTP3 funding	€1 250 000,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Health security
Project coordinator	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM
Scientific project leader	STANSILE LTD
Participating countries	Netherlands, Rwanda, Denmark, Spain, Tanzania, Burundi, Democratic Republic of the Congo



MOVIE-TRACE

Addressing Critical Gaps in mpox epidemiology in DRC – The MOVIE and TRACE studies

The MOVIE-TRACE project is clarifying two key aspects of mpox infections: the speed at which the virus is cleared from the body and its infectiousness.

The challenge

Optimisation of control measures to prevent the spread of mpox, including the newly emerged clade Ib mpox virus, depends on a good understanding of **viral transmission**. Key issues include the **time during which the virus replicates and a patient is infectious, and the virus's infectiousness** (how easily it is transmitted to others). The latter is generally characterised by its **'secondary attack rate'**: the proportion of people in contact with a patient who also become infected.

Although these factors were well studied during the global mpox pandemic of 2022–2023, relatively few data are available from sub-Saharan Africa, from groups such as children and women, who were less affected in the global pandemic, and for clade Ib infections.

The project

The MOVIE-TRACE project team collected important data on mpox virus infections during the global pandemic, characterising the **kinetics of viral shedding** from a range of tissues during an infection. Infection kinetics differed significantly across tissue compartments, with skin lesions in particular showing virus shedding for extended periods.

Building on this experience, the team is now conducting two complementary studies in the Democratic Republic of the Congo (DRC) to provide similar insights into clade Ib infections.

- **MOVIE**: To characterise **viral kinetics**, the MOVIE study will recruit 50 newly diagnosed patients, including women and children, and analyse samples from different tissues (skin, blood, urine and nose/throat) at five time points out to 8 weeks, measuring viral load and generating an estimate of the time to viral clearance.
- **TRACE**: To assess **infectiousness** and calculate secondary attack rate, 10 close contacts of each patient will be recruited and followed up to see which go on to develop mpox infections. Comparisons between those who become infected and those who do not could also reveal factors associated with susceptibility to infection.

MOVIE-TRACE is one of nine projects funded through an emergency call for proposals launched in response to the mpox outbreak in the DRC and other sub-Saharan African countries, which was declared a Public Health Emergency of International Concern (PHEIC) by WHO and a Public Health Emergency of Continental Security (PHECS) by Africa CDC in 2024.

The impact

The MOVIE-TRACE project will provide vital information to inform mpox infection control policies and practices. It will:

- Reveal how long patients are likely to be infectious and therefore need to be kept in isolation.
- Shed light on infectiousness and risks for infection, revealing potentially vulnerable groups and informing targeting of public health responses.
- Generate data on infectiousness that will provide a benchmark for assessing the effectiveness of vaccination.

The results of the MOVIE-TRACE project will therefore feed directly into patient management and the design of disease control strategies and will be a valuable input into trials of mpox interventions.

Project at a glance	
Project duration	15 Oct 2024 - 14 Oct 2026
Total project cost	€1 431 182,50
Global Health EDCTP3 funding	€1 430 875,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Health security
Project coordinator	LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMEDICALE DU ZAIRE
Participating countries	United Kingdom, Democratic Republic of the Congo, Spain





EBO-PEP 2026

Filovirus post-exposure prophylaxis, preparedness and efficacy evaluation during outbreak in Central and West Africa

The EBO-PEP 2026 project is assessing whether a licensed antiviral can prevent disease in individuals who have had close contact with patients with Bundibugyo Ebola virus.

The challenge

Before they are diagnosed and isolated, patients with Bundibugyo virus (BDBV) infections are likely to come into contact with various healthcare workers, household members, and others. These individuals may have been exposed to BDBV and are therefore at increased risk of BDBV infection and disease.

Post-exposure prophylaxis (PEP) offers a way to protect such individuals. During the virus’s incubation period, which can last up to three weeks, antivirals, monoclonal antibodies and/or vaccines could be given to boost host defences and prevent the virus from gaining a foothold. PEP has been shown to be highly effective at preventing HIV and other viral infections, and was deployed during earlier Zaire ebolavirus outbreaks, when no cases occurred in PEP-treated individuals.

Options for PEP are limited for BDBV, but there is some evidence that direct-acting broad-spectrum antivirals may inhibit the virus.

The project

The EBO-PEP 2026 project is organising a randomised controlled trial to assess the potential benefits of **obeldesivir-based PEP** for close contacts of BVBD patients. Obeldesivir, a derivative of remdesivir, is a promising option for PEP, as it has shown good activity in pre-clinical studies. Unlike remdesivir, it is an oral drug, making it easier to deliver in challenging outbreak contexts.

The BDBV-focused project builds on the existing Global Health EDCTP3-funded EBO-PEP project, which aims to evaluate PEP for other forms of Ebola infection. It mobilised to launch research during a Zaire ebolavirus outbreak in the DRC in late 2025, but this outbreak was very rapidly contained so no data could be collected. However, the infrastructure, partnerships and community engagement developed for this outbreak have facilitated a rapid pivot to a BDBV research project.

The main BDBV trial will take place in the DRC and be integrated within the national disease control response, with close collaboration with the Ministry of Health and humanitarian actors. Almost 1,000 close contacts of BDBV patients will be randomised to receive either obeldesivir or a placebo, administered daily for 10 days under direct observation. Participants will be monitored for signs of infection and regularly tested for BDBV infection.

Children are at high risk of severe disease, with mortality rates higher than 80% seen in previous Ebola outbreaks. Pregnant women are also at particular risk of severe disease and adverse pregnancy outcomes. A placebo-controlled trial is not considered ethical in these groups. Instead, they will be recruited into a complementary cohort study and provided with remdesivir as PEP. This will provide data on the safety, effectiveness, and feasibility of PEP in these groups, as well as information on the natural history of infection and host responses.

EBO-PEP 2026 is one of four projects funded through an emergency call for proposals launched in response to the Bundibugyo Ebola outbreak in the Democratic Republic of the Congo (DRC) and Uganda in 2026.

The impact

The EBO-PEP 2026 project will generate vital data on the potential benefits of BDBV PEP. It will:

- Show whether obeldesivir can prevent infection or reduce the severity of symptoms when given to close contacts of BDBV patients.
- Reveal whether PEP is acceptable and can feasibly be delivered in outbreak contexts.
- Provide data on the costs and cost-effectiveness of obeldesivir-based PEP.

If shown to be effective, obeldesivir and remdesivir are readily available therapeutics that could be rapidly deployed in PEP programmes to reduce the risk of severe disease in groups at high risk of acquiring BDBV infections.

Project at a glance	
Project duration	1 Aug 2026 – 31 Jul 2028
Total project cost	€12.821.591,33
Global Health EDCTP3 funding	€12.821.591,33
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Therapies
Overarching topic	Health security
Project coordinator	INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMÉDICALE DU ZAIRE
Participating countries	France, Democratic Republic of the Congo, Côte d’Ivoire, Senegal



EPoCA-BVD

Empowering Africa’s point of care with cutting-edge graphene biosensing for rapid detection and interconnected surveillance of Bundibugyo virus disease

The EPOCA-BVD project is developing a sensitive point-of-care test for Bundibugyo virus, based on innovative new materials and biosensing technology.

The challenge

Detection of Bundibugyo virus (BDBV) infections is challenging. Initial symptoms are non-specific and similar to those of other common local infections, including malaria. No validated point-of-care test is available yet, and laboratory confirmation takes several days and requires transport of hazardous biological materials.

Delays in diagnosis can have significant consequences. Unconfirmed cases might not enter isolation, providing opportunities for the virus to spread, or they might be placed in isolation unnecessarily, disrupting daily life, wasting healthcare resources, and absorbing capacity that could be used for patient management.

The project

The EPOCA-BVD project is developing a novel diagnostic, suitable for use in field conditions, that will provide rapid, reliable information on BDBV infections and automatically share data with policymakers.

The project is building on the existing Global Health EDCTP3-funded, which has been using novel biosensing technology to develop a test for other ebolaviruses. The new project will leverage the progress made in this project and the product development pathways established.

The detection technology is based on the **BioGFT platform**. Binding of a target molecule – such as an antigen from a pathogen of interest – triggers electrical changes in a transistor, which can be analysed by embedded AI systems to provide an output communicating the presence or absence of that pathogen. The platform has been enhanced by the use of **graphene**, which increases the platform’s sensitivity.

The technology incorporates a **biorecognition layer**, based on antibodies that bind to specific pathogen antigens. Existing Ebola biorecognition will be adapted to detect BDBV-specific antigens. The device will also be made more rugged for use at field sites, such as peripheral health facilities and field triage sites, and will provide an initial diagnosis within 90 minutes (laboratory confirmation will still be required). The platform is internet-enabled, so data can be immediately shared with central data sources to provide health system managers with up-to-date epidemiological information.

After laboratory testing of performance on biobanked samples, the technology will be evaluated in the field under real-world outbreak conditions. Data will be gathered on its diagnostic

performance compared with gold-standard laboratory methods, as well as on its usability in field settings and its clinical utility (the extent to which results actually inform clinical decision-making). The project aims to test around 200–400 potential cases within a year.

The project will also map out a pathway for the sustainable use of the platform for BDBV detection, including regulatory clearances, plans for technology transfer to support local manufacturing, documentation to support efficient deployment, and agreements for integrating data into national health information systems.

EPOCA-BVD is one of four projects funded through an emergency call for proposals launched in response to the Bundibugyo Ebola outbreak in the Democratic Republic of the Congo (DRC) and Uganda in 2026.

The impact

The EPOCA-BVD project could have a major impact on triage of potential BDBV cases. It will:

- Develop a BDBV-specific diagnostic suitable for use in remote settings with minimal training.
- Generate data on its performance in real-world response settings, including the extent to which it informs clinical decision-making.
- Automatically share diagnostic information to provide up-to-date epidemiological information to guide outbreak control activities.

A rapid point-of-care diagnostic could be a significant benefit to disease control efforts by ensuring patients are isolated and receive supportive care as quickly as possible, helping avoid overcrowding at testing facilities, and enabling earlier identification of contacts for monitoring.

Project at a glance	
Project duration	1 Oct 2026 - 31 Mar 2028
Total project cost	€1.000.000
Global Health EDCTP3 funding	€1.000.000
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance Tools
Overarching topic	Health security
Project coordinator	LIBELIUM COMUNICACIONES DISTRIBUIDAS SL
Scientific project leader	INSTITUT NATIONAL DE RECHERCHE BIOMÉDICALE DU ZAIRE
Participating countries	Spain, Democratic Republic of the Congo, Estonia, Ghana, Italy



Ebola PREP-TBOX Plus

Advancing the preparedness toolbox for One Health surveillance, rapid diagnostics and medical countermeasures against recurrent Ebola outbreaks

The Ebola-Prep TBOX Plus project is developing a toolbox of practical aids to support those battling the Bundibugyo virus outbreak in Central Africa.

The challenge

The Central African Bundibugyo virus (BDBV) outbreak has occurred in a highly challenging setting. The epicentre of the outbreak in eastern Democratic Republic of the Congo (DRC) is a geographically remote area characterised by insecurity, limited healthcare infrastructure and a mistrustful population. Displacement and extensive cross-border movement provide opportunities for dissemination of the virus.

Tracking the spread of infection is held back by the lack of validated point-of-care diagnostics, while limited community-based surveillance is a missed opportunity to catch cases early. The region also lacks IT systems capable of integrating diverse data sources to provide a holistic, up-to-date picture of the spread of infection. Patient care is undermined by the lack of BDBV-specific therapeutics.

Enhancing the response to the outbreak therefore requires an integrated approach that addresses multiple shortcomings.

The project

The Ebola-Prep TBOX Plus project builds on the previously funded by Global Health EDCTP3. Initially focused on developing a toolbox of innovations to control other ebolavirus infections, the new project is shifting its attention to BDBV and to delivering practical aids to support the response to the Central African outbreak.

The project is focusing on four key areas:

- **Community engagement:** Research into current community knowledge, attitudes and practices relevant to BDBV, to support development of culturally appropriate communications materials in local languages, focusing on points of entry and at-risk forest communities in the Republic of Congo. The project will also train frontline workers in community engagement and risk communication.
- **Diagnostic development and evaluation:** The project is establishing a highly sensitive laboratory-based detection system at sites in the DRC, Republic of Congo and Uganda. Through a multisite field trial, it will also evaluate multiple commercial and laboratory-developed tests, including a remote molecular assay developed by the project that can be deployed at sites with minimal laboratory infrastructure, such as district-level health facilities and border posts.
- **AI-enabled surveillance:** The project is enhancing surveillance by facilitating and creating new reporting mechanisms. It is developing a One Health reference glossary and multilingual AI-based system to capture BDBV-related information from a wider range of sources. Focusing on sites in the DRC and Republic of Congo, it is working with communities to enhance **community-based surveillance** through a specially developed app for use by community health workers and other community-based groups.

- **Advancing an antibody-based therapeutic:** The Ebola-Prep TBOX project has been developing a broad-spectrum Ebola antibody-based therapeutic generated by inoculation of horses with a cocktail of viral antigens. The resulting polyclonal antibodies are isolated and processed to generate a preparation capable of neutralising a range of viruses. In this project, the team is using the same development pathway to identify immunogenic BDBV antigens and to develop and test a therapeutic preparation with activity against BDBV.

Ebola-Prep TBOX Plus is one of four projects funded through an emergency call for proposals launched in response to the Bundibugyo Ebola outbreak in the Democratic Republic of the Congo (DRC) and Uganda in 2026.

The impact

The Ebola-Prep TBOX Plus project is developing a range of tools to support a more effective response to the BDBV outbreak. It will:

- Provide evidence-based and culturally appropriate materials to raise awareness of BDBV and infection prevention among vulnerable key populations in Central and Western Africa.
- Develop an innovative new diagnostic and generate data on a range of other potential tools to inform policymakers’ decision-making on diagnostic use.
- Enhance community-level reporting of possible cases and strengthen local surveillance systems.
- Develop a novel antibody-based targeted BDBV therapeutic to the point that it can be tested in people.

Collectively, these activities have the potential to accelerate case detection, enabling treatment and isolation to begin sooner and reducing the risk of further transmission, while also enhancing awareness among hard-to-reach communities and potentially providing a new treatment option for those with confirmed BDBV infections.

Project at a glance	
Project duration	1 Oct 2026 - 31 Mar 2028
Total project cost	€999.972,89
Global Health EDCTP3 funding	€999.972,89
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Diagnostics, Surveillance Tools, Therapies
Overarching topic	Health security
Project coordinator	EBERHARD KARLS UNIVERSITY OF TÜBINGEN
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MÉDICALE
Participating countries	Germany, Democratic Republic of the Congo, Uganda, France, Congo



EboNet

Coordinated operational framework and response to the Bundibugyo virus disease outbreak

The EboNet project is establishing links across multiple Global Health EDCTP3-funded research networks in Africa to ensure a coordinated research response to the Bundibugyo virus outbreak in Central Africa and to strengthen surveillance systems in high-risk areas.

The challenge

The Central African Bundibugyo virus (BDBV) outbreak has affected an area with weak healthcare infrastructure. Furthermore, response strategies face multiple challenges, including insecurity in affected areas, displacement of large numbers of people, frequent cross-border movement, use of traditional burial practices that create opportunities for viral transmission, and high levels of mistrust of healthcare workers from outside the area.

In addition, the lack of a validated point-of-care test makes it difficult to rapidly identify new cases. No tests are suitable for commonly used molecular diagnostic platforms, and PCR kits for molecular testing are not available locally. As a result, policymakers are frequently working with an incomplete and out-of-date picture of a rapidly evolving outbreak.

The project

The EboNet project is bringing together to promote a coordinated research response to the BDBV outbreak, and in particular to enhance surveillance systems so that more complete and up-to-date information is available to those leading country responses.

Research is a crucial aspect of the response to the BDBV outbreak, but given the urgency of the situation, it is essential that research efforts are coordinated and well planned so that they deliver the needed data, are well aligned with outbreak responses, and are conducted efficiently.

The Global Health EDCTP3 programme has funded multiple outbreak and pandemic preparedness networks in sub-Saharan Africa, including the , , , and projects, each of which has conducted studies and has expertise that could be deployed in the BDBV outbreak. The EboNet project is establishing linkages between the networks, which together cover 23 countries and around 100 research institutions, to ensure a coordinated response to the latest crisis.

Project activities include mapping existing surveillance efforts and identifying gaps, providing training on BDBV detection, and developing a platform to share BDBV-related information. The project is also developing target product profiles (TPPs) to guide the development of BDBV treatments and diagnostics, as well as adaptive clinical trial protocols with standardised endpoints and other trial metrics. It will establish the basis for a data-sharing

platform and facilitate access to clinical trial and genomic data relating to BDBV.

The project focuses on the currently affected countries, the DRC and Uganda, as well as neighbouring at-risk countries. All activities are being undertaken in close collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC).

EboNet is one of four projects funded through an emergency call for proposals launched in response to the Bundibugyo Ebola outbreak in the Democratic Republic of the Congo (DRC) and Uganda in 2026.

The impact

The EboNet project will help mobilise the assets and technical expertise held by multiple Global Health EDCTP3-funded research networks to support the BDBV outbreak response. It will:

- Create a collaborative framework enabling multiple African-based researchers and institutions to support research and response activities in a coordinated way.
- Help to harmonise approaches and facilitate data sharing so that data from different studies can be efficiently integrated.
- Avoid unnecessary overlap and optimise research efforts during the outbreak.
- Ensure that less well-developed sites can be involved in research activities.
- Deliver training at scale, leveraging the diverse expertise held across collaborating networks.

The EboNet project will help ensure a coordinated research response to the BDBV outbreak, maximising the utility of the data generated while efficiently leveraging the expertise within existing networks to support response and control activities.

Project at a glance	
Project duration	1 Sep 2026 - 31 Aug 2027
Total project cost	€4.023.512,61
Global Health EDCTP3 funding	€1.000.000
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EDCTP ASSOCIATION
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MÉDICALE
Participating countries	Netherlands, Congo, Ethiopia, Nigeria, France, Ghana, Uganda

Coordination and support actions



PRESERVE

Preparedness, Research and Surveillance Network for infectious Diseases in Central Africa

The PRESERVE project is strengthening pandemic preparedness and responses in Central Africa, with a focus on One Health.

The challenge

Central Africa is a hotspot for emerging and re-emerging infections. Rapidly identifying and responding to new infections is critical to prevent them from expanding into large-scale outbreaks and pandemics. This requires effective **surveillance systems, outbreak response mechanisms**, and strategies to ensure **research on treatments and control measures** can be activated as rapidly as possible during outbreaks.

However, pandemic preparedness in Central Africa faces multiple challenges. These include limited human resources, inadequate laboratory and clinical research infrastructure, including diagnostic capacity, and poor cross-border sharing of data and information.

The project

Initiatives funded by past EDCTP programmes and others have helped to create international multi-disciplinary platforms to boost clinical research and pandemic preparedness capacity in Central Africa. Key networks have been established, including the Central Africa Clinical Research Network (CANTAM), the Central African Training Platform for Clinical Research (CATCR) and the EDCTP-funded pandemic preparedness network PANDORA-ID-NET. The PRESERVE project is building on this foundation to further strengthen regional collaboration and capacity building, with a particular focus on the human-animal interface and One Health approaches.

The project brings together private-non-profit and public partners from Cameroon, the Republic of Congo, the Democratic Republic of the Congo (DRC), Gabon and Zambia, plus four European partners. It will forge close ties with the CANTAM, CATCR, and PANDORA-ID-NET networks, as well as key regional partners, such as the WHO Regional Office for Africa, the Africa Centres for Disease Control and Prevention (Africa CDC), the Coalition for Epidemic Preparedness Innovations (CEPI), and the Gates Foundation.

The project aims to strengthen expertise, training, partnerships and infrastructure in the subregion, with a particular focus on:

- Developing a **disease-agnostic toolbox and adaptive protocol** to enable clinical trials to be launched rapidly when an outbreak is detected.
- Promoting capacity building for **One Health diagnostics and research** through strengthening of the Institute of One Health (INOHA) and expansion of its training programmes.
- **Strengthening national public health laboratories** in the Republic of Congo and Gabon, with additional training and the introduction of rigorous quality management systems.

- **Improving tuberculosis diagnosis**, for example through evaluation of a newly developed tool based on AI analysis of chest X-rays.
- Enhancing **surveillance of arboviruses** (such as dengue, chikungunya, Rift Valley fever, yellow fever and Zika viruses) and vector control activities.
- Extending monitoring of **zoonotic transmission of TB**, through integration into One Health activities.
- Embedding **community engagement** to strengthen participation in clinical research.

The impact

The PRESERVE project will strengthen pandemic preparedness in Central Africa. It will:

- Significantly expand One Health capacity in the subregion.
- Strengthen surveillance systems for vector-borne viral diseases.
- Facilitate the upgrading of laboratories and increase diagnostic capacity.
- Enhance clinical trial sites across the subregion.
- Establish systems for the rapid launch of clinical trials in outbreak contexts.

Collectively, the work of the PRESERVE project partners will build the capacities of countries in Central Africa to monitor the emergence of new infections and to work together to prevent the escalation of outbreaks into major regional public health challenges.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2031
Total project cost	€14 151 489,48
Global Health EDCTP3 funding	€12 484 342,48
Disease area	Emerging or re-emerging infectious diseases, Malaria, Tuberculosis
Intervention type	Diagnostics, Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Environment and biodiversity, Co-morbidities and non-communicable diseases, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MEDICALE
Participating countries	Netherlands, Congo, France, Cameroon, Democratic Republic of the Congo, Germany, United Kingdom, Gabon, Zambia





ACT-PREP

Advancing clinical trials and epidemic preparedness research capacity in Africa (ACT-PREP)

The ACT-PREP project aims to strengthen capacity for conducting clinical trials in sub-Saharan Africa, with a particular focus on research during outbreaks.

The challenge

Countries in sub-Saharan Africa face a multitude of infectious disease challenges, including a high risk of outbreaks of epidemic-prone pathogens. At the same time, countries typically have weak healthcare systems, limited surveillance capacity, and underdeveloped capacity for detecting and responding to outbreaks.

In particular, countries rarely have the capacity to **integrate research activities into outbreak responses** to generate evidence that strengthens control activities and response effectiveness.

Nevertheless, some countries in the region have built strong surveillance, outbreak response and research capacities, and have achieved significant successes in preventing outbreaks from turning into major health crises. There are opportunities for such countries to share their expertise and experience with other countries in the region.

The project

The goal of the ACT-PREP project is to institutionalise **clinical trial preparedness** within national public health systems, as part of broader efforts to strengthen outbreak detection and response. It has a particular focus on HIV/AIDS, malaria, neglected tropical diseases and TB, alongside emerging and re-emerging infections.

The project is providing an extensive range of **short- and long-term training opportunities to strengthen research capacity** for researchers, healthcare professionals, clinical trials support staff, and undergraduate and postgraduate students. This will be based on interactive workshops and online courses, use of massive open online courses (MOOCs), and placements at trial sites and within ongoing trials or surveillance activities. The project partners will provide access to real-life datasets for supervised training exercises.

In particular, the project is training more than 700 senior researchers in advanced methodologies and techniques, setting up mentorship programmes, and developing exchange programmes. It will support the work of 15 PhD students and 10 postdoctoral scientists. In addition, a further 80 clinical trial monitors will be trained.

Capacity for preparedness and rapid response will be built across the network, leveraging existing high-performing sites. In addition to research, it aims to ensure that new tools, such as AI technologies, are integrated into outbreak responses.

Standardised research protocols will be developed so that research studies can be rapidly launched at the onset of outbreaks, supported by training and simulation exercises for responders. Surveillance activities will be enhanced by integrating surveillance data with existing DHIS2 health informatics systems. Community engagement will be strengthened to build trust and support for research activities during outbreaks.

To facilitate the rapid launch of high-quality research during outbreaks, training workshops and benchmarking visits will be organised for ethics review committee members and representatives of regulatory authorities. Guidelines will be updated based on research conducted during outbreaks and epidemics. To improve efficiency, digital systems will be introduced where they are not already used by regulators and ethics review bodies.

Laboratory infrastructure and data management systems will also be upgraded, with a focus on sites in countries with less well-developed clinical research capacity. At least **five laboratories will be upgraded** during the project.

Collaborations will be strengthened across academia, public health bodies and ministries of health, with the project also working closely with the Africa Centre for Disease Control and Prevention (Africa CDC). The project will create a platform for sharing resources, data and protocols, and establish an extensive community of practice for researchers and health workers delivering trials during outbreaks.

The impact

The ACT-PREP project will strengthen regional capacity to detect, prevent and manage infectious disease outbreaks. It will

- Strengthen capacity to launch clinical trials rapidly when outbreaks occur.
- Streamline regulatory and ethics review processes to enable rapid launch of clinical studies while safeguarding participants' interests.
- Build a highly trained workforce able to be deployed to different sites when outbreaks occur.

Project at a glance	
Project duration	1 Jun 2026 - 31 May 2031
Total project cost	€19 389 911,80
Global Health EDCTP3 funding	€12 751 864,50
Disease area	Emerging or re-emerging infectious diseases, HIV/AIDS, Neglected infectious diseases
Intervention type	Surveillance tools, Diagnostics, Cross-intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	MAKERERE UNIVERSITY
Participating countries	Netherlands, Uganda, Somalia, Democratic Republic of the Congo, Tanzania, Ethiopia, Sweden, Germany, Rwanda, Senegal, South Sudan



EACCR4

Eastern Africa consortium for clinical research 4

The EACCR4 project is strengthening clinical research capacity across a wide range of sites in East Africa.

The challenge

Despite some progress, sub-Saharan Africa remains underrepresented as a location for clinical trials. This has multiple implications, including a lack of data on the efficacy and safety of new interventions in African populations and delays in introducing new medical innovations in African countries.

Strengthening of clinical trial capacity requires investment in multiple areas. **Laboratory infrastructure** may need to be upgraded to support the analyses integral to clinical studies. In particular, **diagnostic capabilities** may need to be strengthened. **Clinical trial sites** may need further development so patients can be recruited, cared for, and studied in safe settings.

Above all, **human capacity** needs to be developed to ensure that trials are performed safely, efficiently and rigorously. The Africa Centres for Disease Control and Prevention (Africa CDC) public health workforce strategy has identified serious staffing shortages and outlined priority development needs to enable the region to contribute its fair share to trials.

For the past 15 years, the **East African Consortium for Clinical Research (EACCR)** has built subregional capacity for clinical research thanks to funding through successive EDCTP programmes. It has provided a framework for collaborative studies and baseline data collection, as well as a high-quality network that supports the training and career development of early-career researchers.

The project

The EACCR4 project is building on this foundation, with the **network expanding** to include 23 partner institutions from 13 countries, including seven from sub-Saharan Africa. Three countries with less well-developed health research systems – the Democratic Republic of the Congo (DRC), Somalia and Zambia – have joined the network, alongside additional European institutions.

The network is also strengthening its connections with **national public health institutes** in participating countries and placing greater emphasis on clinical research during epidemics.

The EACCR4 project incorporates a broad spectrum of **capacity-building activities**, with a focus on less well-developed institutions. At least two clinical research sites will be upgraded, and integrated support will be provided to strengthen laboratory capacities. Site capacities will be audited to inform site-specific development plans. Weaker sites will be paired with stronger sites and supported through training and mentorship, with the aim of certifying four additional laboratories during the project. The network's statistics and data management platform will be strengthened and expanded to new sites.

Through the project, nine PhD students and 18 master's students will be supported. Training will also be provided to clinical and laboratory personnel, and 28 new clinical research associates

will be trained in clinical trial monitoring. Five emerging leaders will benefit from research leadership training, with priority being given to promising researchers from the three new countries with less well-developed clinical research systems.

The network's HIV/AIDS and TB research will focus on surveillance for drug resistance and application of digital, machine learning and models for predicting HIV and TB drug resistance. The malaria programme will address parasite drug resistance and insecticide resistance in mosquito vectors. Neglected tropical disease research will focus on epidemiology and diagnostics.

Epidemics are a new priority area for the network. Key activities will include strengthening genomics surveillance, preparation for clinical trials in outbreak situations, and training for research during outbreaks. There will be a focus on strengthening laboratory diagnostic capacity, as well as introducing mobile laboratories in the DRC and Zambia and linking existing labs to national public health institutes in other countries.

The impact

The EACCR4 project will further strengthen clinical research capacity in East Africa. It will:

- Provide a high-quality environment for training early-career researchers.
- Support the accelerated development of some of the most promising future research leaders.
- Equip more sites to carry out high-quality research, including during outbreaks.
- Generate new knowledge to support more effective treatment and control of priority infectious diseases.

Project at a glance	
Project duration	1 Jun 2026 - 31 May 2030
Total project cost	€13 923 277,54
Global Health EDCTP3 funding	€12 751 648,96
Disease area	Emerging or re-emerging infectious diseases, HIV/AIDS, Tuberculosis
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	UGANDA NATIONAL HEALTH RESEARCH ORGANISATION
Participating countries	Netherlands, Uganda, Somalia, Tanzania, Zambia, Rwanda, Kenya, Denmark, United Kingdom, Germany, Norway, Sweden, Democratic Republic of the Congo





SINCEP-Africa

Strengthening Institutional Networks and Building Capacity for Epidemiological Preparedness in Africa (SINCEP–Africa)

The SINCEP–Africa project is building on an existing global network of community-based research sites to strengthen epidemic and clinical research capacity in sub-Saharan Africa.

The challenge

Although Africa has traditionally conducted only a small proportion of the world’s clinical trials, recent years have seen a significant uptick in clinical research activity in the region. Nevertheless, there remain areas for further improvement. Furthermore, as experienced during the COVID-19 pandemic, it is challenging for clinical trial sites in sub-Saharan Africa to rapidly launch trials when outbreaks are detected.

To react quickly, clinical trial sites need to be well-prepared in terms of infrastructure and human capacity. Successful and rapid clinical studies require the right infrastructure, trained staff, baseline data, and pre-approved research protocols. However, as outbreaks are difficult to predict, trial sites may also need to remain active to ensure they are always ready to respond.

Networking among clinical trial sites is important to ensure activities are harmonised and to enable data pooling to generate evidence more promptly. Moreover, because outbreaks may be restricted to particular geographic areas, sites in multiple locations need to be ‘research-ready’. The INDEPTH Network is a well-established consortium of 16 sites in Africa that conduct ongoing health and demographic surveillance and regular systematic data collection from local populations. An opportunity exists to build on this foundation to create additional trial-ready sites.

The project

The SINCEP–Africa project is working with INDEPTH Network partners in sub-Saharan Africa to strengthen their capacity to carry out clinical research during disease outbreaks. The project will include 14 existing INDEPTH sites in the region plus two new sites in Côte d’Ivoire and the Democratic Republic of the Congo (DRC).

The project will first audit the sites’ ongoing **surveillance activities** to identify any gaps that need to be addressed to enable clinical research studies to be carried out. Surveillance activities in routine healthcare will be strengthened, and sites’ capacity for clinical research will be reinforced through **training and infrastructure upgrades** as required. Around 500 academics and trial support staff will benefit from a mix of short-term and long-term training opportunities, including 40 graduate students, 15 PhD students and 10 postdoctoral fellows.

Laboratory capacity for diagnostics and other key technologies will be strengthened where necessary in collaboration with international partners. Laboratory quality management systems will be introduced where needed, and accreditation plans will be developed, with at least five laboratories due to be accredited through the project. In collaboration with national regulatory authorities, the project will also strengthen intervention **safety-monitoring systems** at the sites.

In addition, the project will introduce an **AI-driven electronic surveillance system** across participating sites. This will automatically share data with a central database for analysis. This system will be

used to develop predictive models that generate insights to guide local decision-making and disease-control activities.

To launch research studies rapidly during outbreaks, clinical trial protocols need to be approved in advance. The project is therefore engaging with national and regional bodies, including ministries of health, national regulatory authorities and research ethics committees, to build support for research and gain pre-approval of master protocols for outbreak-linked clinical studies. This work is being organised in partnership with the African Vaccine Regulatory Forum (AVAREF) and the EDCTP-funded LusoAfro–BioEthics project.

To ensure that trial sites remain ‘warm’ between outbreaks, the project will seek opportunities to host clinical studies of interventions for malaria, TB, HIV/AIDS, and diarrhoeal diseases. The project team is engaging with potential trial sponsors to highlight opportunities the network offers for multicentre trials.

The impact

The SINCEP–Africa project will make a significant contribution to clinical research capacity building in sub-Saharan Africa. It will:

- Extend the work of existing high-quality health surveillance and research sites so that they can take part in clinical trials.
- Create a network of sites able to rapidly initiate clinical research when disease outbreaks occur.
- Provide an integrated data management and analysis infrastructure for generating actionable insights from site surveillance data.
- Extend the range of sites capable of carrying out research on interventions for the key poverty-related infectious diseases affecting sub-Saharan Africa.

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2031
Total project cost	€25 600 413,30
Global Health EDCTP3 funding	€13 366 351,00
Disease area	Emerging or re-emerging infectious diseases, Cross-disease or disease unspecific
Intervention type	Surveillance tools, Therapies, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies, Environment and biodiversity, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	INDEPTH NETWORK PRIVATE COMPANY LIMITED BY GUARANTEE
Participating countries	Netherlands, Ghana, United Kingdom, France, Côte d’Ivoire, Burkina Faso, Democratic Republic of the Congo, Mali, Mozambique, Tanzania, Kenya, Uganda, Spain, United States, Ethiopia, Nigeria, Senegal



WANETAM-4

West African Network of Excellence for TB, AIDS and Malaria

The WANETAM–4 project is strengthening a key West African research network to support further capacity building, development of the next generation of African Clinical research leaders and building of closer relations with national public health institutions.

The challenge

Over the past two decades, clinical research capacity in sub-Saharan Africa has begun to grow significantly. Research networks, including the **regional networks of excellence** funded through successive EDCTP programmes, have made major contributions to this capacity building. However, the region still faces multiple infectious disease challenges and frequent outbreaks, emphasising the continuing need to strengthen the clinical research ecosystem.

The **West Africa Network of Excellence for Clinical Trials in TB, AIDS and Malaria (WANETAM)** has previously received three tranches of EDCTP funding. These enabled the WANETAM team to establish a highly effective network of clinical research sites, supporting multi-centre clinical studies, providing training and career development opportunities for young African scientists, and developing their research leadership skills.

Among its many achievements, WANETAM has established genome surveillance networks for multiple infections, created a network of data managers, and developed quality assurance systems for clinical trial laboratories within the network.

The project

In the WANETAM–4 project, the network will continue to conduct a range of research studies in its core areas of interest, while also strengthening its contributions to capacity building, leveraging its platform for cross-disciplinary research, and building closer ties with national public health institutes. The network has expanded to include institutions in 12 sub-Saharan African countries, including anglophone, francophone and lusophone countries, to overcome linguistic barriers to collaboration.

- **Tuberculosis:** The network’s TB research will focus on characterising **TB-associated multimorbidity** across the life course, risk factors and links to drug resistance. It will also provide a platform for TB vaccine and other trials.
- **Malaria:** The malaria workstream will work with national malaria control programmes on the **implementation of new interventions** to control malaria and advance malaria elimination. It will also provide a platform in four settings for adaptive trials of interventions, and also undertake surveillance activities to track drug and insecticide resistance.
- **HIV/AIDS:** Research is focusing on enhancing **early infant diagnosis and viral load monitoring**, collecting data on **drug resistance** mutations, and delivering training on **vaccine R&D**. Studies will also test long-acting antiretroviral interventions, effects of treatment on the microbiome, and characteristics of the HIV reservoir in the long-term virally suppressed individuals.
- **Pandemic preparedness:** The network is hosting **Special Collaborative Training on Epidemic Preparedness and Surveillance (SCTEPS)**, a capacity-building programme on pandemic preparedness for 30 researchers and public health officials from 13 national public health institutes.

- **Neglected tropical diseases (NTDs):** Activities are focusing on integrated surveillance of NTDs, improving capacity for diagnosis based on skin lesion characteristics, and strengthening genomic surveillance of cholera and environmental surveillance of Lassa fever.

Cross-cutting capacity-building activities have a particular focus on building **scientific leadership skills**. The network will also support **infrastructure upgrades** at less well-developed research sites, provide courses on **institutional strengthening**, and deliver training in key areas of **clinical trial development and management**, including trial oversight and pharmacovigilance.

The impact

WANETAM–4 will continue the scientific research programmes and capacity building begun in previous incarnations of the network. It will:

- Provide a platform for high-quality, multi-centre studies in key areas of infectious disease.
- Strengthen research capacity at sites with less experience in hosting clinical research.
- Build research expertise and the research leadership skills of promising early-career researchers.
- Facilitate enriched collaborations across countries, often siloed because of linguistic barriers.

Through its activities, WANETAM–4 will generate important new knowledge on poverty-related infectious diseases, while also creating opportunities for more ambitious clinical studies and providing training for the next generation of African research leaders.

Project at a glance	
Project duration	1 Jul 2026 – 30 Jun 2031
Total project cost	€15 276 514,80
Global Health EDCTP3 funding	€12 751 884,95
Disease area	Emerging or re-emerging infectious diseases, Neglected infectious diseases, Tuberculosis
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	WEST AFRICAN RESEARCH AND INNOVATION MANAGEMENT ASSOCIATION WARIMALTD
Participating countries	Netherlands, Nigeria, Ghana, Guinea-Bissau, Burkina Faso, Senegal, Benin, Mali, Guinea, Portugal, United Kingdom, Germany, France, Belgium





Training networks

SUPPORT

Supporting the next generation of African experts on preventing mortality among children living with HIV through a translational training

The SUPPORT project is leveraging two EDCTP2-funded HIV projects to provide a career development platform for African researchers.

The challenge

Despite some progress, sub-Saharan Africa still has relatively few health researchers, and it is often difficult for researchers to advance their careers within the region.

International research partnerships, such as those supported by EDCTP, create additional opportunities for capacity building. Each programme typically includes projects for master's and PhD students, but there is also potential to embed studies for additional early- and mid-career researchers.

The project

The SUPPORT project is leveraging the infrastructure created by the EDCTP2-funded **UNIVERSAL** and **EMPIRICAL** programmes by embedding training opportunities for an additional eight early-career researchers and five mid-career postdoctoral researchers.

The UNIVERSAL and EMPIRICAL programmes are both focused on the **management of HIV infections in children**. An estimated 1.7 million children in sub-Saharan Africa are living with HIV and, despite successful efforts to reduce mother-to-child transmission, around 160,000 new infections occur each year. Although HIV infections in children can be controlled, children are at increased risk of both opportunistic and endemic infections and of acquiring multidrug-resistant infections.

The UNIVERSAL study is evaluating first and second-line fixed-dose combinations for use in children. The EMPIRICAL study is assessing empirical treatment of pneumonia, to which children living with HIV appear particularly susceptible.

For the SUPPORT project, Makerere University in Uganda is acting as the scientific leadership hub. Fellows will be integrated into sites within the UNIVERSAL and EMPIRICAL networks in Mozambique, Senegal, Uganda, Zambia, and Zimbabwe. They will conduct their own research projects on HIV management in children and benefit from an integrated mix of face-to-face and online research training activities, including internships at European institutions.

Each fellow will have two mentors – one local and one from elsewhere within the SUPPORT network. Fellows and mentors will jointly develop and follow up on personal career development plans. The project has a strong emphasis on equity: it will ensure balanced gender representation, involve collaborations across English-, French-, and Portuguese-speaking countries, and recruit fellows from countries with less well-developed health research systems.

The impact

The SUPPORT project will have both scientific and capacity-building impact. It will:

- Generate additional evidence on treatment and care of children living with HIV in sub-Saharan Africa.
- Enable 8 early- and 5 mid-career scientists from Africa to carry out research within international networks, providing an outstanding learning environment with guidance and support from mentors

The SUPPORT project is strengthening health research capacity in sub-Saharan Africa in a key field of medicine, pediatric HIV care, which is presenting multiple new challenges to health systems across Africa.

Project at a glance	
Project duration	1 Jun 2024 – 30 Nov 2028
Total project cost	€5 081 593,75
Global Health EDCTP3 funding	€5 081 593,75
Disease area	HIV/AIDS, Lower respiratory tract infections, Other childhood infectious diseases
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Co-morbidities and non-communicable diseases, Health security
Project coordinator	UNIVERSIDAD COMPLUTENSE DE MADRID
Scientific project leader	MAKERERE UNIVERSITY
Participating countries	Spain, Uganda, France, Italy, Zimbabwe, Netherlands, Mozambique, Zambia, Senegal





SOFAR

SOuthern aFrica research cApacity netwoRk

The SOFAR project is establishing a training programme to advance the careers of promising students and early-career researchers in Southern Africa.

The challenge

Despite accounting for more than 20% of the global disease burden, sub-Saharan Africa accounts for only around an estimated 2% of global clinical trial activity. This leads to limited representation of African scientists in international research projects and a lack of focus on African health challenges.

A key challenge is the limited health research workforce in sub-Saharan Africa. The region has around 19 health researchers per million population, compared with 304 per million population in Europe.

The project

Focusing on a set of countries in Southern Africa, the SOFAR project is addressing this issue by creating a training programme for promising individuals at different stages of their research career, drawing on the resources available at three centres of excellence in Africa and two European higher education institutions. It will provide a supportive environment for the training of 15 individuals – four master’s students, six PhD students and five postdoctoral scientists.

The project is also partnering with key organisations within the region, including ministries of health, WHO and the Africa Centres for Disease Control and Prevention (Africa CDC), which will offer placements to students recruited to the programme.

The SOFAR project brings together institutions in Zambia and Zimbabwe with a strong programme of health research and a long track record in research training. It is also taking advantage of opportunities offered by the Wellcome-funded CREATE programme, which is supporting the training of 25 early-career researchers in Africa and includes SOFAR’s Zambian and Zimbabwean institutions.

The SOFAR programme is providing a mix of face-to-face and digital training opportunities, with the creation of a Digital Global Health Academy. An online network is being established to provide programme participants with peer support, while each fellow also benefits from both a supervisor and a mentor.

In addition, the project will work to strengthen all aspects of fellows’ recruitment, training, mentoring, and counselling, ensuring that application processes are transparent and equitable, and that mentoring meets the needs of fellows. Training is being provided to academic supervisors in sub-Saharan Africa, building the capacity of institutions to nurture the next generation of researchers.

As well as key technical skills and practices associated with scientific research, such as grant writing, project management and scientific paper development, training will also cover areas such as open access and knowledge exchange, including working with policymakers.

The impact

The SOFAR project will significantly increase research capacity in Southern Africa. It will:

- Provide comprehensive and high-quality research training to 15 promising scientists at different stages of their research careers.
- Ensure that programme participants gain experience within public health environments.
- Enable postdoctoral scientists to establish themselves as independent researchers.
- Provide opportunities to researchers from Portuguese-speaking as well as English-speaking countries in Southern Africa.
- Strengthen supervisory and mentoring capacity within the region.

Strengthening research capacity in sub-Saharan Africa will ensure that research focuses on the region’s priority health challenges and generates evidence to inform regional policymaking, thereby reducing the disease burden in the region.

Project at a glance	
Project duration	1 Oct 2024 - 31 Mar 2029
Total project cost	€4 370 387,88
Global Health EDCTP3 funding	€4 370 387,50
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies
Project coordinator	LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN
Scientific project leader	BIOMEDICAL RESEARCH AND TRAINING INSTITUTE LBG
Participating countries	Germany, Zimbabwe, Zambia, Mozambique



BRIDGE NETWORK

Scaling Up Research in SSA Countries in Infectious Diseases: African-European Training Network in Integrated Health Informatics and Data Sciences

The BRIDGE NETWORK project is establishing five centres of excellence to build skills in the use of health data to address key health challenges in sub-Saharan Africa.

The challenge

There is growing interest in using routinely collected health data to gain a better understanding of patterns of disease, assess the effectiveness of drugs in real-world settings, and monitor the safety of medical interventions.

However, these data are typically distributed across a wide range of data sources, including electronic health records, disease registries, research study databases and other repositories. It is technically challenging to link these data sources, particularly when different types of data are collected or when data are held in different formats.

In addition, sub-Saharan Africa has a shortage of both healthcare workers and clinical researchers, including those with skills in health informatics. There are few training opportunities in sub-Saharan Africa for clinicians or early-career researchers with an interest in applying informatics to improve health.

The project

The BRIDGE Network project is establishing a training programme to strengthen human capacity in health informatics research in sub-Saharan Africa.

Building on a long-standing European-African collaboration, five centres of excellence are being established in Benin, Ethiopia, Kenya, Rwanda, South Africa and Uganda. These centres will provide training on the use of health data to individuals at different levels, including four postdoctoral fellows and up to 20 PhD students, with a further 20 being trained to postgraduate certification level.

The centres will provide a high-quality environment in which PhD and postdoctoral researchers can develop research projects based on local health needs and data sources. The centres will also develop data standards and a technical infrastructure to ensure the compatibility of data and facilitate data sharing. This will be based on a federated approach, where data remains in a secure environment during analysis.

Certification-level training will draw upon an existing European programme. It will include mentoring by staff in both Europe and Africa, as well as a placement at an academic or industry site in Europe.

The impact

The BRIDGE Network project will strengthen health informatics research capacity in sub-Saharan Africa. It will:

- Create a cohort of researchers, at different career stages, with the ability to apply health informatics methodologies to address locally relevant health questions.
- Provide additional opportunities for postgraduate students to develop their careers within Africa further.
- Build leadership skills so that responses to emerging health challenges can be led by researchers from sub-Saharan Africa.

Ultimately, the BRIDGE Network project will strengthen human research capacity to leverage the growing opportunities offered by health data to improve healthcare and reduce the burden of disease in sub-Saharan Africa.

Project at a glance	
Project duration	1 Oct 2024 - 31 Mar 2029
Total project cost	€4 999 200,00
Global Health EDCTP3 funding	€4 999 200,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies
Project coordinator	UNIVERSITEIT GENT
Scientific project leader	RWANDA BIOMEDICAL CENTER
Participating countries	Belgium, Rwanda, Norway, Ethiopia, South Africa, Uganda, Benin, Kenya





CATCR

Central Africa Training Platform for Clinical Research on infectious diseases

The CATCR project is training a new generation of researchers in the increasingly critical field of antimicrobial resistance.

The challenge

Antibiotics have been the mainstay of treatment of bacterial infections for nearly a century, but their use inevitably selects for drug-resistant strains of bacteria. For many pathogens, **antimicrobial resistance (AMR)** has become widespread, making it increasingly difficult and expensive to treat certain infections. Sub-Saharan Africa, and Central Africa in particular, are badly affected by AMR. It is estimated that more than 4 million lives could be lost to drug-resistant infections in sub-Saharan Africa over the next 30 years.

AMR is a complex issue affected by multiple factors. These include the **overuse and misuse of antibiotics**, which creates selection pressures favouring the survival and spread of drug-resistant strains, and the potential spread of AMR genes through **environmental routes** and via livestock. A **One Health approach** is therefore often adopted, which covers issues such as antimicrobial use in veterinary medicine and animal husbandry, as well as environmental factors affecting transmission of AMR genes.

AMR is a particular challenge for tuberculosis, with **multidrug-resistant TB infections** being very hard to treat and of growing concern. A salient issue in TB is **detecting cases** (of both drug-sensitive and drug-resistant forms) to limit the spread of infection. An estimated 70% of drug-resistant TB cases in Africa are currently not being diagnosed.

With AMR a growing challenge in sub-Saharan Africa, it is important that the region has sufficient researchers to understand local challenges better and to design and evaluate appropriate solutions. However, the region has relatively few researchers with expertise in this area.

The project

The CATCR project is helping to address this shortfall through a new **research training programme** focused on developing research capacity in **antimicrobial resistance (AMR) in Central Africa**.

It is focused on three key areas:

- **Antimicrobial usage in patients with parasite infections** (including malaria), including understanding prescribing, dispensing and utilisation, and ways to promote good practice.
- The prevalence and spread of **carbapenemase-producing Enterobacterales**, a key class of drug-resistant gut bacteria, in humans and livestock, with a One Health focus.
- The epidemiology of **drug-resistant tuberculosis**, characterising drug-resistance genes, and determining their implications for treatment.

The project is delivering **technical training in these areas to up to 5,000 researchers and health workers from Cameroon, the Republic of Congo, the Democratic Republic of the Congo (DRC) and Gabon, drawing on existing South-North and South-South networks, training opportunities and resources. Other training activities will include laboratory attachments and seminars/workshops.**

In addition, a fellowship programme is being organised that will provide research training opportunities for seven PhD students and three mid-career (postdoctoral) researchers. This will leverage the existing EDCTP-funding Central African Network of Excellence (CANTAM) and link trainees with expert mentors from across the region. GSK will also provide input to increase fellows' understanding of translation and commercialisation of health research.

The impact

The CATCR project is building capacity in an area of growing public health importance in sub-Saharan Africa. It will:

- Advance scientific understanding in several key areas of AMR relevant to Central Africa.
- Build a cohort of researchers with a wide-ranging understanding of AMR and local challenges.
- Strengthen the research and leadership skills of African-based researchers.

Through these routes, the project will strengthen AMR research capacity in Central Africa, creating research leaders able to lead the battle against multiple key AMR challenges.

Project at a glance	
Project duration	1 Nov 2024 - 30 Apr 2029
Total project cost	€4 846 237,68
Global Health EDCTP3 funding	€4 846 237,68
Disease area	Cross-disease or disease unspecific, Tuberculosis, Neglected infectious diseases
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	EBERHARD KARLS UNIVERSITAET TUEBINGEN
Scientific project leader	FONDATION CONGOLAISE POUR LA RECHERCHE MEDICALE
Participating countries	Germany, Congo, Cameroon, Democratic Republic of the Congo, Netherlands, France, Gabon, United Kingdom



SAHRI-Fellowship

Sub-Saharan Africa Health Research and Innovation Fellowship Programme (SAHRI Fellowship Programme)

The SAHRI Fellowship project provides promising researchers from sub-Saharan Africa with a structured three-year training programme that includes a 6-month internship at a biotech company.

The challenge

Sub-Saharan Africa has fewer health researchers than other regions. Multiple training programmes, including several supported by the Global Health EDCTP3 programme, are working to close this capacity gap.

The project

The SAHRI Fellowship project aims to address this gap by supporting researchers through a **research-training programme** that covers all aspects of biomedical innovation and entrepreneurship and includes hands-on experience in a biotech research environment.

A partnership between institutions in Burkina Faso, Ethiopia, Kenya, Rwanda, Tanzania and Uganda, as well as two European centres, the Institute of Tropical Medicine Antwerp and KU Leuven, the SAHRI Fellowship project will select 12 promising mid-career researchers from across Africa. Each fellow will complete a two-year **Master of Science programme in Tropical Medicine** as well as a module in systems thinking in biotech development, both at leading institutions in Europe.

Furthermore, each fellow will undertake a **6-month internship at BioNTech**, gaining hands-on industry training in vaccine development and manufacturing under the mentorship and supervision of subject matter experts.

Each fellow will complete a **12-month project in sub-Saharan Africa**, applying what they have learned with seed funding for their research. They will be hosted during this period by a high-quality research centre, including institutions in the EDCTP regional Network of Excellence and the East African Consortium for Clinical Research (EACCR).

Once selected, each fellow will develop a **personalised development plan** outlining their learning journey. They will also benefit from a **structured mentorship programme**, with input from multiple mentors across the consortium.

The impact

The SAHRI Fellowship project will strengthen research capacity in a key area of the health sciences. It will:

- Provide a highly structured and personalised training programme for 12 promising mid-career researchers from multiple sub-Saharan African countries.
- Enable fellows to gain experience in the day-to-day realities of a cutting-edge biotech company.
- Support application of new skills and knowledge in R&D in a practically focused project in an outstanding learning environment within sub-Saharan Africa.

The SAHRI Fellowship project will make an important contribution to strengthening capacity in new product development in sub-Saharan Africa, boosting the regional workforce's ability to translate scientific advances into new products to improve health.

Project at a glance	
Project duration	1 Aug 2025 - 31 Jul 2030
Total project cost	€4 471 197,45
Global Health EDCTP3 funding	€3 499 947,45
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Health security
Project coordinator	INSTITUUT VOORTROPISCHE GENEESKUNDE
Scientific project leader	THE GOOD SAMARITAN FOUNDATION
Participating countries	Belgium, Tanzania, Ethiopia, Germany, Burkina Faso, Rwanda, Uganda, Kenya





CREATIVE

Clinical ResEArch Training fellowship with Industry involEement

The CREATIVE project is developing a cohort of early-career researchers with theoretical and hands-on experience in clinical trials across academic and industry settings.

The challenge

Despite its high disease burden, less than 2% of clinical trials are carried out in sub-Saharan Africa. This leads to a relative neglect of African-specific challenges and a lack of data on interventions in African populations. These factors contribute to delays in access to medical innovations tailored to the needs of African countries.

One of the critical factors limiting clinical trial activity in sub-Saharan Africa is a **lack of suitably trained researchers**. High-quality research training is essential to ensure that researchers from the region can design, lead, and contribute to studies addressing the priority health challenges facing their countries.

The project

The CREATIVE project is addressing this key skills gap, providing a clinical trials training programme for 12 early-career researchers from six countries: Ethiopia, The Gambia, Ghana, Uganda, Zambia and Zimbabwe.

Through the programme, fellows will complete a three-year distance-learning **master's degree in epidemiology or clinical trials** with the London School of Hygiene & Tropical Medicine. Fellows will remain embedded in their host institutions throughout their fellowships, spending time in the UK to complete specific modules in years 2 or 3.

In their first year, fellows will be **embedded in a clinical trial or clinical research study** hosted by a CREATIVE consortium partner in their home country, enabling them to gain firsthand experience of clinical studies.

In addition, each fellow will have an opportunity for industry exposure through an **internship, work placement or work shadowing** during their fellowship. This will provide fellows with unique insights into clinical research from an industry perspective.

Alongside this hands-on learning, fellows will also benefit from a **digital clinical training academy** through which online seminars will be offered every three to four months, specifically designed to meet their needs. Other benefits include intensive mentoring

support, co-design of personal development plans, and career-planning discussions towards the end of the fellowship.

Fellows will also be supported and encouraged to engage with existing clinical research networks in sub-Saharan Africa. In addition, as they progress as a single cohort, this will provide opportunities for relationship-building and peer support that last beyond the fellowship.

The impact

The CREATIVE project will provide a significant boost to clinical research capacity in sub-Saharan Africa. It will:

- Create a new cohort of researchers with an understanding of both academic and industry clinical research.
- Increase the number of skilled clinical researchers and research leaders in the region.
- Generate new career development opportunities and promote retention within sub-Saharan Africa.
- Help to foster a culture of innovation and entrepreneurship.

The CREATIVE project will strengthen the clinical research base in sub-Saharan Africa, supporting innovation and clinical research that accelerates the development and implementation of novel interventions addressing the region's key health challenges.

Project at a glance	
Project duration	1 Feb 2026 - 31 Jul 2030
Total project cost	€3 491 817,05
Global Health EDCTP3 funding	€3 491 817,05
Disease area	Cross-disease or disease unspecific
Project coordinator	LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER
Scientific project leader	UGANDA NATIONAL HEALTH RESEARCH ORGANISATION
Participating countries	United Kingdom, Uganda, Zambia, Ghana, Ethiopia, Zimbabwe



MAGNETS

Malaria Genomic Epidemiology and Biostatistics Network for Enhancing Talent in Sub-Saharan Africa

The MAGNETS project is promoting the integration of genomic epidemiology into malaria surveillance to strengthen evidence-based decision-making for malaria control and elimination in Africa.

The challenge

After many years of progress, the battle against malaria has stalled in recent years. More than 250 million people are affected each year, with 600,000 deaths due to malaria, most of them in sub-Saharan Africa.

Advances in malaria **genomics and data science** are creating **unprecedented opportunities** to improve surveillance, monitor parasite evolution, detect drug and insecticide resistance, assess diagnostic performance, and better understand malaria transmission dynamics. These advances are generating increasingly complex datasets that demand specialised analytical skills to translate them into evidence.

Across sub-Saharan Africa, there remains a critical shortage of professionals trained at the interface of genomics, epidemiology and biostatistics. **Building long-lasting local expertise** is essential to ensure that genomic data can effectively strengthen malaria control strategies.

The project

The MAGNETS project is building additional expertise to apply genomic intelligence to **malaria surveillance**, strengthening regional capacity to utilise genomic data to enhance malaria control. The project brings together six partner institutions: Centro de Investigação em Saúde de Manhiça (Mozambique), the Armauer Hansen Research Institute (Ethiopia), the Infectious Disease Research Collaboration (Uganda), the Wits Health Consortium (South Africa), ISGlobal (Spain), and the University of California San Francisco (USA).

It will support 10 early-to-mid-career researchers to complete a **master's programme in epidemiology or biostatistics**, alongside a dedicated MAGNETS training in malaria genomics. This training will focus on translating genomic and epidemiological information into **actionable strategies** for enhancing disease control and reducing the malaria burden in communities. Fellows will be able to conduct their master's research projects in Ethiopia, Mozambique, South Africa or Uganda.

Fellows will undertake a project on a topic **relevant to the activities of national malaria control programmes**. These projects will be based on ongoing research studies or public health activities, with fellows analysing rich real-world datasets during training.

MAGNETS training will incorporate **cohort activities and structured mentorship** to complement fellows' master's studies. The curriculum will be designed based on the competencies required of fellows, combining these activities, guided work on individual research projects and development of oral and written communication skills. Group activities will include workshops, online seminars and a data analysis 'bootcamp'. Fellows will receive structured, personalised training and mentorship, based on an individual development plan.

The impact

The MAGNETS project will play a major part in building sustainable genomic surveillance capacity for malaria. It will:

- Equip a new generation of scientists to translate genomic data into malaria policy and control decisions.
- Build a network of research institutions and national health authorities working together to advance genomic epidemiology for malaria control.
- Generate new insights into malaria transmission and resistance, enhancing regional understanding of the disease and strengthening the evidence base for control efforts.

By strengthening local expertise rather than relying solely on external technical support, MAGNETS will help ensure that advances in malaria genomics are translated into sustainable public health capacity across sub-Saharan Africa.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2029
Total project cost	€1 359 532,87
Global Health EDCTP3 funding	€1 299 902,77
Disease area	Malaria
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	FUNDACAO MANHICA
Participating countries	Netherlands, Mozambique, South Africa, Spain, Ethiopia, Uganda, United States





STEAM-3D

Sustainable Training in Epidemiological Analysis and Modelling for Data-Driven Decision-making in Africa (STEAM-3D)

The STEAM-3D project is creating an infrastructure to expand the range of training opportunities in epidemiology and data science in Sub-Saharan Africa.

The challenge

Most countries in sub-Saharan Africa face the recurring challenge of controlling infectious diseases, with each successive outbreak threatening population health, disrupting livelihoods, and impeding economic development.

Effective monitoring and control programmes depend on surveillance data to provide information on the presence and spread of key pathogens. Once detected, evidence-based approaches can reduce the risk of new outbreaks and rapidly bring outbreaks under control.

Infectious disease modelling can be pivotal to these activities, especially for the design and implementation of disease control programmes. Modelling can identify areas where outbreak risk is highest, enabling targeted prevention activities, providing insights into likely outbreak dynamics, guiding response planning and demonstrating the likely impact of different intervention strategies.

A key barrier to the use of infectious disease modelling is the limited expertise and experience of modelling techniques in many sub-Saharan African countries. Surveillance and modelling played crucial roles during the COVID-19 pandemic, most notably in helping to identify emerging viral variants. There are now opportunities to leverage this expertise to advance epidemiology and infectious disease modelling in a wider range of countries.

The project

The STEAM-3D project is drawing on the expertise and experience gained during the COVID-19 pandemic to establish a regional training platform for building sub-Saharan African capacity in epidemiology and data science.

Hosted by the South African Medical Research Council (SAMRC), which played a key role during the pandemic, the project is organising two intensive training workshops (one introductory, one advanced), each of which includes several training courses. These will cover key areas of epidemiology and data science, including:

- Infectious disease modelling techniques.
- Routine Health Data for Disease Monitoring and Excess Mortality Estimation.
- Application of AI/machine learning technologies.
- Evidence-to-policy methodologies.
- Knowledge translation.

In years one and two, each workshop will be offered to 10 participants from each partner country – Cameroon, Malawi, Mozambique and South Africa. Year two will also include a virtual workshop, building on previous workshops and a focus on advanced statistical modelling approaches. In year three, participation will be opened to all countries, with each partner

site acting as host – enabling the workshops to be held in English (Malawi), French (in Cameroon) and Portuguese (in Mozambique).

Workshops will be one week in duration and will build technical skills, with a strong focus on use of evidence and scientific communication. Workshops will incorporate a course on dashboard development and how to create an e-platform for ongoing education and communication. Practical applications will also be promoted by use of real-world datasets during training exercises.

In addition, two outstanding trainees will be identified in each country and provided with additional training and mentoring, including multiple international mentors. They will participate in a summer school in Europe and will be trained to deliver the devolved learning activities.

Sustainability will be further promoted by the involvement of multiple regional networks, and the creation of an infectious disease modelling working group, hosted by the SAMRC, to support networking, knowledge exchange and further ongoing professional development.

The impact

The STEAM-3D project will strengthen infectious disease modelling capacity in sub-Saharan Africa. It will:

- Facilitate the sharing of knowledge and experience held within a centre of excellence in South Africa.
- Establish additional training hubs catering to researchers and public health professionals from anglophone, francophone and lusophone countries.
- Create a community of practice to support ongoing development of the field and adoption within disease control programmes.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2029
Total project cost	€1 846 556,28
Global Health EDCTP3 funding	€1 299 701,92
Disease area	Emerging or re-emerging infectious diseases, HIV/AIDS, Cross-disease or disease unspecific
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
Participating countries	Netherlands, South Africa, Belgium, Cameroon, Malawi, Mozambique



ICI3D

Strengthening epidemic modelling capacity in ssa through the international clinics on infectious disease dynamics and data (ICI3D) programme

The ICI3D project is creating a regional training hub to expand expertise in infectious disease modelling and promote its use to inform policymaking.

The challenge

Mathematical modelling has become a valuable tool for those planning health services, particularly programmes relating to infectious diseases. Modelling has multiple uses, for example, to forecast likely future trends in infectious diseases and to evaluate the potential impact of interventions – analyses that can inform prioritisation, resource allocation, and other aspects of programmatic decision-making.

Realising the potential of infectious disease modelling requires both skilled researchers able to span the fields of mathematical modelling and infectious diseases, as well as policymakers with a solid grasp of the potential application of modelling techniques in their areas of responsibility. Currently, there is limited experience of infectious disease modelling within sub-Saharan Africa and limited practical application to enhance public health.

The project

The training programme of ICI3D is strengthening regional capacity for infectious disease modelling by building on the foundation laid by the existing **International Clinics on Infectious Disease Dynamics and Data**. Since their launch in 2009, these clinics have trained more than 750 professionals and researchers.

The training model will be adapted to support the development of a regional training hub in infectious disease modelling. This project will deliver two updated annual clinics, strengthen the alumni network, and launch a Modelling Clinic Accelerator to replicate the ICI3D model across the region. Two annual clinics will be offered:

- **Meaningful Modelling of Epidemiological Data (MMED):**
A two-week in-person training course in Cape Town, South Africa, tailored to quantitative researchers and focusing on data-driven infectious disease modelling.
- **Dynamical Approaches to Infectious Disease Data (DAIDD):**
A one-week in-person training course in Nairobi, Kenya, tailored to public health professionals and researchers with limited prior mathematical expertise, to introduce dynamic modelling approaches.

The team is working with European partners to embed **health economic methodologies** into each course. Courses will include modular lectures, interactive coding demonstrations, and computer practices, with materials developed under FAIR and open-source principles and continuously refined to align with current public health priorities across the region. The objective is to train at least 50 participants a year, with around 10 coming from ministries of health or national public health institutes.

The project also aims to build a **peer network** of modelling experts. In the ICI3D model, alumni contribute to future teaching – half of the ICI3D faculty are alumni who have taken on mentoring, teaching and leadership roles. Members of this network will also be able to continue developing their professional skills through an online alumni forum offering continuing education webinars, career development opportunities, and collaborative research initiatives.

A third objective is to spin out **new training sites** that replicate the ICI3D training model. A ‘modelling clinic accelerator’ programme will use a train-the-trainer model and leverage ICI3D faculty expertise in developing online, open-source curricula to establish two additional clinics in the region.

The impact

The ICI3D project will significantly expand infectious disease modelling capacity in sub-Saharan Africa and promote its application to address public health challenges. It will:

- Increase the number of researchers with up-to-date skills in infectious disease modelling.
- Provide continuing professional development opportunities for modelling specialists.
- Create a self-sustaining ecosystem to maintain the supply of infectious disease modelling experts.
- Encourage greater use of modelling and health economic analyses within national health systems.

Collectively, these activities will boost the use of infectious disease modelling in sub-Saharan Africa, enhancing countries’ ability to respond to and prevent key infectious disease threats.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2029
Total project cost	€1 424 097,60
Global Health EDCTP3 funding	€1 297 468,50
Disease area	Emerging or re-emerging infectious diseases, HIV/AIDS, Tuberculosis
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	Netherlands, Kenya, South Africa, Belgium





AFRITRAC

African training network for biostatistics, epidemiology and infectious disease modelling

The AFRITRAC project is strengthening epidemiological expertise in Sub-Saharan Africa, particularly the ability to apply mathematical modelling approaches to infectious diseases and to integrate key sociocultural factors affecting disease transmission.

The challenge

As noted by the Africa Centres for Disease Control and Prevention (Africa CDC), Africa has a severe shortage of trained epidemiologists. It has an estimated 1,900 field epidemiologists, compared with a need for 6,000, and 5,000 frontline epidemiologists compared with a target of 25,000.

In addition, relatively few epidemiologists in Africa have expertise or experience in **biostatistics and infectious disease modelling**. The capacity to establish **predictive modelling** to guide disease control activities is therefore limited. Where capacity does exist, experts tend to be isolated, with limited opportunities to network, gain new expertise and experience, and advance their careers.

The project

The AFRITRAC project is working with Africa CDC to create a **regional hub** to support the training and networking of epidemiologists with skills in data analysis and modelling.

The project will create training opportunities for 35 early-career professionals (13 from Central Africa and 11 each from East and West Africa) to gain additional skills in biostatistics, data analysis and mathematical modelling. Training will have a strong emphasis on both theoretical understanding and practical application to address priority public health questions.

Fellows will complete a **master's programme**, which will draw on materials and course content already developed by project partners. Curricula will be harmonised across the six training institutions to ensure quality and coherence.

As part of their training, fellows will undertake two specially designed short courses on **infectious disease modelling** and **human/behavioural aspects** of infectious disease control. The latter is designed to strengthen fellows' language skills and their appreciation of the impact of social and cultural factors on disease epidemiology. Through a visiting fellowship component of the programme, fellows will be able to spend 3 months experiencing the language and culture of another country, broadening their horizons and cross-cultural sensitivity.

In addition, 15 members of the programme's cohort will be supported to undertake a more in-depth **research fellowship** in a European or sub-Saharan African country.

The programme will also serve as a regional hub for **networking**. An annual networking forum will be organised, and the project team is engaging with national public health partners to ensure that fellows can gain hands-on experience through placements. Course content will focus strongly on Africa's public health priorities, including outbreak responses, vulnerable populations, surveillance, the impacts of climate change, and emerging and re-emerging pathogens.

The impact

The AFRITRAC project will make a major contribution to developing the expertise of Africa's public health workforce. It will:

- Build the skills of epidemiologists in Africa so they are better able to analyse as well as collect data.
- Develop well-rounded professionals with a broad range of technical skills as well as interpersonal skills that will enable them to function in a variety of settings within the region.
- Harmonise curricula across teaching institutions, ensuring consistency and coverage of key emerging approaches.
- Have a multiplier effect as trainees pass on their skills and experiences to others.

The AFRITRAC project will build skills in key areas of biostatistics and infectious disease modelling, ensuring that countries are better able to detect, prevent and respond to infectious disease outbreaks.

Project at a glance	
Project duration	1 May 2026 - 30 Apr 2030
Total project cost	€1 362 074,55
Global Health EDCTP3 funding	€1 302 444,45
Disease area	Emerging or re-emerging infectious diseases, Neglected infectious diseases, Cross-disease or disease unspecific
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	MINISTRY OF HEALTH
Participating countries	Netherlands, Uganda, Cameroon, Tanzania, Mali, United Kingdom, Kenya, Ghana, Gabon, Burundi, Democratic Republic of the Congo, Ethiopia



ANTENNA

Training Hubs for Statisticians, Epidemiologists in Eastern, Central and Western Africa

The ANTENNA project is creating new training hubs for epidemiologists and statisticians in Eastern, Central and West Africa.

The challenge

Infectious diseases are a moving target, with disease burdens constantly changing due to a wide range of social, environmental and other influences. Understanding current disease patterns and projecting how they might change in the future is critical to effective disease control and the optimal use of limited resources.

Unfortunately, many sub-Saharan African countries have limited capacity to **track and respond to changing patterns of infectious disease and, consequently, public health concerns**. This is particularly true of countries in Central and West Africa. However, several countries in East Africa have developed considerable expertise in epidemiology and biostatistics, providing an opportunity for South-South networking to contribute to wider capacity building.

The project

The ANTENNA project is establishing a training hub for epidemiologists and statisticians spanning English-, French-, and Portuguese-speaking countries in East, Central and West Africa. The project will establish and train a cohort of 10 epidemiology and biostatistics fellows, three from Cameroon, three from Senegal, and four from Guinea-Bissau. Within each country, cross-disciplinary hubs are being set up comprising academic institutions, clinical/research centres, and ministries of health/national public health institutes.

Using a mix of master's-level and short-term technical training, the project integrates theory with practical application by strengthening links between academic institutions, clinical sites, national public health research institutes and ministries of health. Trainees will work with real-world African data sets and focus on developing policy-relevant analyses to inform decision-making.

ANTENNA builds on prior work by Data Science Without Borders, which identified 42 research-ready datasets to support trainees' learning. It is also taking advantage of an existing mentorship scheme/framework developed by an EU partner and the London School of Hygiene and Tropical Medicine, as well as the African Population and Health Research Centre's (APHRC) Virtual Learning Academy, an online learning platform that supports training, mentorship, and knowledge exchange.

Trainees will benefit from field placements and internships at partner organisations. Students will develop a comprehensive learning plan and have regular progress meetings with supervisors. In addition to technical training, they will learn additional skills such as science writing for publications and grant applications, and developing outputs for policymakers. At annual datathons, fellows will work collaboratively on previously unseen or unshared datasets to address a practical challenge, with an award for the best team effort.

Drawing on existing course materials and integrating new content in areas such as AI, the project will create a standardised curriculum in epidemiology and biostatistics for universities in the three countries.

The ANTENNA project also aims to create a sustainable career ecosystem, helping fellows integrate and continue their professional development after their fellowship. They will be connected to an alumni network for peer support and to existing communities of practice, and will be supported in participating in formal professional networks. A career progression tracker will be created to monitor their professional journeys.

The impact

The ANTENNA project will have a significant impact on the skills base in East, Central and West Africa. It will:

- Create a cohort of new epidemiology and biostatistics specialists in countries with limited capacity in this area.
- Ensure fellows have a solid grounding in both theoretical methods and practical application to support policymaking in their home countries.
- Provide opportunities for fellows to become embedded within wider professional networks to support their continuing professional development.
- Fellows will have the capacity to analyse local datasets that speak to local health concerns and, consequently, inform health decision-making.

Ultimately, the project will strengthen the capacity of Cameroon, Guinea-Bissau, and Senegal to analyse health and other data to inform disease control and programme management, thereby improving the management of infectious diseases and population health.

Project at a glance	
Project duration	1 Jun 2026 - 31 May 2029
Total project cost	€1 413 133,55
Global Health EDCTP3 funding	€1 299 996,37
Disease area	Cross-disease or disease unspecific
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	AFRICAN POPULATION & HEALTH RESEARCH CENTRE KENYA
Participating countries	Netherlands, Kenya, Cameroon, Guinea-Bissau, Senegal, Portugal, United Kingdom, Uganda, Cabo Verde





FORTRESS-SSA

Fostering outbreak resilience through training, research, epidemiology, and statistical science to strengthen the sub-Saharan Africa public health workforce

The FORTRESS-SSA project is strengthening data-use capabilities within the public health workforce in sub-Saharan Africa, to promote the use of evidence-based approaches to pandemic preparation and outbreak control.

The challenge

Emerging and re-emerging infections pose a constant threat to countries in sub-Saharan Africa. Small clusters of cases can rapidly escalate into national-level outbreaks, spread to new countries, and trigger global public health emergencies and pandemics.

The **public health workforce** is central to pandemic preparedness and outbreak control. However, many countries in the region have insufficient numbers of epidemiologists and other public health specialists. Furthermore, many public health professionals have not been trained in the latest data analytics techniques, such as infectious disease modelling and the use of AI/machine learning, which are playing an increasingly important role in infectious disease control.

Nevertheless, some centres of excellence and specialist networks exist, which can provide a foundation to build the skills of the public health workforce in sub-Saharan Africa.

The project

The FORTRESS-SSA project is extending the existing capacity-building work being carried out by the **Sub-Saharan Africa Consortium of Advanced Biostatistics (SSACAB)**, a multi-institutional network that develops cutting-edge statistical and data science methods, trains the next generation of African biostatisticians, and strengthens evidence-based health policy across the continent. SSACAB already provides master's, PhD and postdoctoral-level training and has strong partnerships with national, regional and international partners. The FORTRESS project will support additional partnerships with national public health institutes in Mozambique, South Africa and Zambia, as well as with research centres in Mozambique and Zambia.

To support English-, French- and Portuguese-speaking trainees, the project will provide full-time **master's training** at three hubs in anglophone South Africa, francophone Benin and lusophone Mozambique. Trainees will have the opportunity to specialise in epidemiology and biostatistics, infectious disease epidemiology, or field epidemiology. The programme will support the training of 15 early to mid-career health professionals, five at each hub, with trainees selected in collaboration with national institutions.

The first year of the programme will be classroom-based. The second year will include a six-month **research internship** at a national public health institute, research centre or NGO, providing opportunities for trainees to apply their theoretical knowledge to practical public health challenges. In addition, training will cover areas such as leadership and policy engagement. The project is establishing a structured supervision and mentorship framework to support trainees, who will also be attached to technical working groups to gain further experience.

In addition, the project will provide **short-term training courses** for 90 members of staff from national public health institutes and ministries of health. These will cover areas such as infectious disease modelling, surveillance and outbreak response. Courses will be co-designed in collaboration with country health policymakers, and a train-the-trainer model will be used to promote knowledge transfer within public health bodies.

The impact

The FORTRESS-SSA project will strengthen epidemiology and biostatistics capacity in sub-Saharan Africa. It will:

- Provide intensive master's training to 15 health professionals/researchers.
- Ensure that training provides a rigorous theoretical grounding in epidemiology and biostatistics as well as practical application to address public health challenges.
- Build institutional capacity by delivering technical training to significant numbers of staff members from national public health institutes and ministries of health.
- Promote workforce retention and integration of trainees into national and regional systems after graduation.
- Strengthen relationships between academic and public health institutes to facilitate further collaboration and application of modelling to public health challenges.

The FORTRESS-SSA project will increase the pool of African experts to support efforts to detect, prevent and respond to pandemic threats, and enhance capacity for data-driven decision-making to strengthen outbreak detection and health system preparedness.

Project at a glance	
Project duration	1 Jun 2026 – 31 May 2029
Total project cost	€1 866 753.53
Global Health EDCTP3 funding	€1 301 075,80
Disease area	Emerging or re-emerging infectious diseases, Neglected infectious diseases, HIV/AIDS
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG
Participating countries	Netherlands, South Africa, Benin, Mozambique, United Kingdom, Zambia, Kenya



EpiScientia Network

African National Public Health Institutes (NPHIs) Network of Training In Integrated Health Informatics And Data Sciences, Scaling Up Infectious Disease Modelling

The EpiScientia project is strengthening national pandemic preparedness and infectious disease control capabilities in sub-Saharan Africa through a practically focused capacity-building programme.

The challenge

Infectious diseases remain a key challenge in sub-Saharan Africa. Controlling such diseases is complicated by their dynamic nature and sensitivity to factors such as climate change, population movements and environmental disruption.

National public health institutes have a key role to play in tracking infectious diseases and developing projections of disease patterns over time to guide disease control initiatives. Although there has been much recent investment in such institutes in sub-Saharan Africa, their impact is held back by a **skills gap** in key areas, such as data science, epidemiology and health informatics. This is a major missed opportunity, as increasing amounts of health data are being generated in the region that could provide valuable insights into the current and potential future burden of different infectious diseases.

One specific challenge is that frontline staff at national public health institutes frequently miss out on training opportunities. They may be too busy working on day-to-day activities or ineligible for capacity-building programmes that focus more on academics. This limits the potential of national public health institutes to deliver high-quality, evidence-informed and policy-relevant input to health policymakers.

The project

The EpiScientia project is addressing this skills gap by creating a new capacity-building programme with a strong focus on **work-based learning** and **practical application of knowledge** in data science, epidemiology and health informatics.

It is centred on a Master's course run by the African Centre of Excellence in Data Sciences at the University of Rwanda. In collaboration with five national public health institutes (in Benin, Ethiopia, Mozambique, Rwanda and Senegal), the project will build the competencies of frontline staff in health informatics, data science and infectious disease modelling.

Ten fellows will be supported through a **Master's programme in biostatistics**, with additional modules in data mining and machine learning. A further 27 **trainees** will receive certificate-level training in **health-oriented big data analysis and data science**. Training will be a mix of face-to-face modules, online learning, and supervised workplace-based projects, focusing on topics directly relevant to national public health institutes' ongoing activities and priorities.

In addition, the project is creating a harmonised **federated data platform** to support trainees' learning. This will facilitate the analysis of multiple data sources based on a federated approach to data management, which enables remote and

integrated analysis of data that remains held within local secure data environments. This platform will bring data together from multiple sources, such as electronic health record systems, electronic disease and other registries, and community health data, using internationally recognised health data categorisation frameworks to ensure consistency.

As well as serving as a learning environment for trainees, this platform will also be a valuable long-term national asset supporting health data analysis in national public health institutes to underpin data-driven decision-making.

The impact

The EpiScientia project is addressing a key skills gap in infectious disease control. It will:

- Create a cohort of specialists with skills in analysing and interpreting health data and in generating timely evidence-based outputs that address local health priorities.
- Improve technical capacities, career development and retention within national public health institutes, strengthening institutional capacity.
- Ensure that the growing tide of health data in the region is utilised to generate actionable insights to improve infectious disease control.
- Create a network of specialists and foster knowledge exchange, amplified by partnerships with Africa CDC to ensure alignment with regional frameworks.

Project at a glance	
Project duration	1 May 2026 – 30 Apr 2031
Total project cost	€1 661 260,49
Global Health EDCTP3 funding	€1 299 115,39
Disease area	Emerging or re-emerging infectious diseases, Cross-disease or disease unspecific
Intervention type	Surveillance tools, Other prevention tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Digital technologies, (Other) emerging technologies, Co-morbidities and non-communicable diseases, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	UNIVERSITY OF RWANDA – African Center of Excellence in Data Sciences (ACE-DS)
Participating countries	Netherlands, Rwanda, Senegal, Ethiopia, Belgium, Spain, Mozambique, United Kingdom, Benin





The PHM Hub

A Public Health Modelling & Data Science Fellowship Centre of Excellence in West and Central Africa

The PHM Hub project is strengthening epidemiology and disease-modelling capacity in West and Central Africa, with a particular focus on the human-animal interface.

The challenge

Infectious diseases continue to pose a major challenge in sub-Saharan Africa. Issues of growing importance include outbreaks triggered by the transmission of pathogens from wild animals or livestock, as well as the impact of climate change and the disruption of ecosystems due to changing land use, which are profoundly affecting the risk of infection.

Surveillance is essential for tracking changing patterns of disease, providing data to support early and effective responses to emerging challenges. However, this requires a skilled workforce able to convert data into action. Sub-Saharan Africa currently faces a severe shortage of researchers with skills in biostatistics, epidemiology and infectious disease modelling.

The project

To address this critical skills gap, the PHM Hub project is establishing a **fellowship hub** in West and Central Africa, building on strong existing centres in Gabon and Senegal and links to European institutions.

Through the programme, fellows will undertake a **Master's degree in biostatistics** with specialisation in epidemiology, as a specialised track within an existing Master's programme. The project will also offer a **university diploma** in infectious disease dynamics and modelling.

Of 35 trainees, 20 will be postgraduate fellows undertaking the Master's degree, with a further 15 individuals from a wide range of professions and backgrounds selected for the university diploma course.

Each participant on the programme will benefit from a comprehensive **support package**, including mentoring, a personal development plan and a three-month research project. The PHM Hub will partner with training labs, National Public Health Institutes and the West African Health Organisation (WAHO), encouraging cross-disciplinary research and innovative problem-solving.

To develop their wider research skills, participants will also receive training in areas such as science communications, ethics of data management and scientific leadership. Teaching will be delivered through a digital platform developed in sub-Saharan Africa.

The programme is adopting a '**One Health**' perspective, recognising the importance of a complex range of drivers of disease linked to the human-animal interface, the environment, and the impact of a changing climate.

The impact

The PHM Hub project will address a critical capacity gap in West and Central Africa. It will:

- Create a skilled regional workforce of public health modellers, data scientists and epidemiologists, providing national policymakers with access to modelling and scenario planning expertise for epidemic response.
- Help to generate regionally relevant knowledge, ensuring that responses reflect the specific nature of regional health challenges.
- Increase the use of locally generated data and analyses in policy processes, with African governments able to rely on their own experts for forecasting, risk assessment and health planning.
- Establish a network of scientific leaders and institutions that work collaboratively across borders.
- Strengthen the academic ecosystem, with curricula, digital learning platforms, and mentoring structures integrated into partner universities.

The PHM Hub project will create a cohort of experts equipped to lead modelling efforts at national and regional levels, enhancing national and regional capacities in the surveillance, prevention and management of infectious diseases, and ensuring more effective responses to outbreaks.

Project at a glance	
Project duration	1 Jun 2026 – 30 Nov 2030
Total project cost	€1 449 170.05
Global Health EDCTP3 funding	€1 300 054.95
Disease area	Emerging or re-emerging infectious diseases, Cross-disease or disease unspecific
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Antimicrobial resistance (AMR) or drug resistance
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	RESEAU AFRICA IN DE RECHERCHE EN SANTE
Participating countries	Netherlands, Senegal, Austria, Belgium, United Kingdom, Germany, Gabon



TIMERA

Training Initiative for Modelling Epidemic Response in Africa

The TIMERA project is strengthening national capacities to use modelling to address the challenges posed by emerging and re-emerging infections.

The challenge

Sub-Saharan Africa faces a high and growing burden of infectious diseases, yet its capacity to anticipate and respond to outbreaks remains uneven. A **key challenge** is the limited local expertise in infectious disease modelling, with most capacity concentrated in the Global North. Weak surveillance systems, shortages of skilled professionals, and limited data infrastructure further restrict the use of modelling for timely, evidence-based decision-making. As a result, responses to outbreaks often rely on external support that may not fully reflect local contexts. **Strengthening Africa-led modelling capacity** is therefore essential to enable faster, more accurate, and context-specific responses to future epidemics and pandemics.

Mathematical modelling is a tool of growing importance in infectious disease control. When it comes to outbreaks, it can be used to enhance preparedness by identifying high risk areas where surveillance and prevention efforts need to be focused. It can also be used to provide insights into the likely **evolution of outbreaks** and **potential impacts of interventions**, to guide public health response strategies.

The project

The TIMERA project is **strengthening mathematical and statistical modelling capacity** in sub-Saharan Africa to improve the detection of infectious disease threats, generate insights into potential outbreak dynamics, and underpin evidence-based decision-making. It aims to strengthen national and continental modelling capacity by working in collaboration with national public health institutes, ministries of health, and leading academic institutions.

The project is organising **short-term, combined training programmes** for early- to mid-career researchers and public health professionals with a strong commitment to apply modelling approaches in infectious disease control. In total, it will train 50 African fellows, adding significantly to the regional epidemiological workforce.

Training will be delivered through a combination of in-person and online learning. Trainees will participate in two intensive, two-week face-to-face blocks, complemented by online modules, thematic workshops, and supervised internships, and will benefit from continuous specialised mentoring. Trainees will be paired with experienced experts, receiving personalised guidance throughout the course, with separate mentors for modelling and infectious disease components of the training. In addition, fellows will undertake applied projects, ensuring that they acquire both core technical competencies in infectious disease modelling, including exposure to AI-supported approaches, as well as the ability to apply their expertise to real-world challenges.

Where feasible, fellows will also undertake short **internships** at their home institution, a national public health institute, or a

ministry of health, anchoring their learning in real-world contexts. The project places a strong **emphasis on policy translation**, equipping participants not only with technical modelling skills but also with the ability to communicate findings effectively to policymakers.

The programme also has a strong focus on **group work**, with fellows working together for three months after their final face-to-face training module to develop outputs in formats suitable for communication to policymakers.

In addition, the Field Epidemiology and Laboratory Training Programme (FELTP), run by the project scientific leader at Addis Ababa University, will serve as a platform for **mentoring and supporting the fellows' post-graduation**. This will help to establish a regional, Africa-led alumni network in epidemiological modelling that will sustain and amplify the programme's long-term impact.

The impact

The TIMERA project will build capacity in Africa for outbreak preparedness and response. It will:

- Train 50 public health professionals from sub-Saharan Africa in the latest infectious disease modelling techniques, including the use of AI/machine learning tools.
- Ensure that training is both theoretically rigorous and rooted in the need to address real-world public health challenges.
- Provide opportunities for continuing professional development and peer exchange to maintain and strengthen regional technical capabilities.

The TIMERA project will significantly strengthen regional capabilities to use infectious disease modelling to anticipate and respond to outbreaks, enhancing preparedness and response and ultimately reducing the impact of emerging and re-emerging infections.

Project at a glance	
Project duration	1 Jul 2026 – 30 Jun 2029
Total project cost	€1 886 429.60
Global Health EDCTP3 funding	€1 299 009.50
Disease area	Emerging or re-emerging infectious diseases, Lower respiratory tract infections, Diarrhoeal diseases
Intervention type	Surveillance tools
Overarching topic	Digital technologies, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	ADDIS ABABA UNIVERSITY
Participating countries	Netherlands, Ethiopia, Senegal, Mozambique





PACoPPDeT

Pan-Africa Consortium on Pharmaceutical Product Development Training (PACoPPDeT)

The PACoPPDeT project is developing a cohort of researchers with a deep understanding of all aspects of pharmaceutical product development.

The challenge

The momentum behind Africa's local pharmaceutical manufacturing agenda is positioning the continent as a **frontier for product development**, driven by its growing population and disease burden. Realising this potential, not just in drug development, but also in drug discovery, requires investment in R&D, cost-competitive technologies, and workforce development through sustained collaboration. Despite accounting for a substantial proportion of the world's disease burden, sub-Saharan Africa hosts only a small proportion of clinical trials. Furthermore, expertise is concentrated at the phase II and phase III stages of product development, and African-based researchers rarely take the lead in key areas such as protocol development or data analysis.

Sub-Saharan Africa is therefore not well placed to discover and develop new interventions or usher them through the clinical evaluation and regulatory pathway to implementation. It is encouraging that attention is being given to manufacturing capacity in the region; however, a broader perspective is needed so that the interventions manufactured also **originate in Africa** and are **designed to address African health priorities**.

Pharmaceutical discovery and development is a long and complex process with a number of well-established steps from early pre-clinical discovery stages through clinical evaluation in progressively larger trials, regulatory approvals and high-quality manufacturing. Many African countries currently have few researchers with a comprehensive end-to-end overview of this pathway.

Central to pharmaceutical development is '**pharmacometrics**' – use of statistical and modelling techniques to optimise drug dose regimen design. The Pharmacometrics Africa NPC organisation has been established to build capacity in this area.

The project

The PACoPPDeT project is developing a **master's training programme** to further strengthen pharmacometrics capacity in sub-Saharan Africa, building on the model established by the Pharmacometrics Africa initiative.

Targeted at mid-career researchers, the programme will offer a **two-year master's course** covering areas such as drug discovery, pharmacokinetics and pharmacodynamics, pharmacogenomics, biostatistics, preclinical and clinical drug development, regulatory science, and scientific leadership. Two cohorts of 15 students will be selected from across the breadth of sub-Saharan Africa. A further 100 individuals will be able to gain certificate-level qualifications by undertaking specific modules.

The course will be a mix of face-to-face and virtual learning, as well as a **hands-on placement** in a partner organisation, and will draw on existing modules that project partners have successfully used in experiential training programmes. It will be delivered by **subject matter experts** from a range of sectors, including academia, industry and medicines regulation.

All materials will be made **freely available**, so other institutions can develop similar courses. In addition, the project will translate its materials into **French** to support uptake in francophone countries in sub-Saharan Africa. After completing the course, graduates will be expected to contribute to teaching, **diffusing the knowledge** learned and expanding the programme's reach.

Students will also benefit from a **structured mentoring scheme** and will have extensive networking opportunities. The aim is to develop students' peer networks so they have access to a pool of expertise spanning all stages of pharmaceutical development that they can call upon when needed.

The impact

The PACoPPDeT project will add significantly to pharmacometrics capacity in sub-Saharan Africa. It will:

- Provide mid-career professionals (30 MSc and 100 certificate-level degrees) with the knowledge and skills to play a lead role in the development and clinical evaluation of new pharmaceutical products.
- Create a regional network of well-connected and mutually supportive experts in pharmaceutical product development.
- Build leadership and entrepreneurial skills to encourage Africa-led drug discovery and development.

Ultimately, the project will help to create a stronger R&D ecosystem in Africa that is better able to support the discovery, clinical evaluation and licensing of new pharmaceutical products tailored to the needs of African populations, delivering both health and economic benefits to the region.

Project at a glance	
Project duration	1 Jul 2026 - 30 Jun 2030
Total project cost	€3 495 000,00
Global Health EDCTP3 funding	€3 495 000,00
Disease area	Cross-disease or disease unspecific
Project coordinator	THE UNIVERSITY OF MANCHESTER
Scientific project leader	STRATHMORE UNIVERSITY
Participating countries	United Kingdom, Kenya, South Africa, Switzerland



SCEAM-CA

Strengthening capacity in epidemic analytics and modelling in Central Africa

The SCEAM-CA project is expanding a training programme to build capacity to monitor and respond to emerging infections in francophone Central Africa.

The challenge

Central Africa is a global recognised **biodiversity hotspot**. The drawback of this ecological diversity is an increased risk of **zoonotic infection** – the spread of infections from animals to humans. Multiple outbreaks of Ebola virus and other highly dangerous pathogens have occurred in recent decades.

Furthermore, Central Africa is experiencing other profound changes that affect the risk of zoonotic infections and influence their rapid spread within human populations. These include the impact of conflict, displacement and large-scale population movements, deforestation and land use changes, and climate change, all of which affect the risk of exposure to zoonotic pathogens and the dynamics of outbreaks in human populations.

Central Africa is therefore an **interconnected ecosystem**. Wherever they originate, pathogens can rapidly disseminate through multiple countries. A subregional approach to outbreak control and response is therefore essential.

The project

The SCEAM-CA project is extending a recently launched master's programme in **infectious disease modelling and outbreak analytics** at the One Health Institute for Africa (Institut One Health pour l'Afrique, **INOHA**) in the Democratic Republic of the Congo (DRC) and organising other activities to enhance modelling capacity to address outbreaks in francophone countries in sub-Saharan Africa.

The project is developing a two-year regional master's programme. Year 1 will include a one-month immersion period in a national public health institute, ministry of health or research institution, while in year 2 trainees will undertake a 3–6-month research internship at a partner laboratory. The programme will support 20 trainees from five francophone countries – Burundi, Cameroon, the Republic of Congo, DRC and Gabon.

In addition, targeted training will be offered to mid-career public health professionals. Two specialist technical workshops will be organised, as well as an annual meeting, for 10 staff from ministries or health or national public health institutes from participating countries.

To support these training activities, the project is introducing **high-performance computing infrastructure** at INOHA. This will support its role as a regional training hub, with the new infrastructure hosting an e-learning platform and data management systems to enable training in data analytics within a secure environment. A range of real-world datasets will be used to support training and development of outputs with real public health relevance.

The project will foster regional collaborations and stronger linkages between academia and public health bodies, ministries of health and national public health institutes. It will also provide trainees with intensive mentoring support and facilitate regional and international networking.

The impact

The SCEAM-CA project will significantly boost epidemiology and data science skills in French-speaking countries in sub-Saharan Africa. It will:

- Provide 20 early-career researchers with intensive training in the latest modelling and other analytical techniques.
- Ensure skills are developed in the context of real-world datasets and address priority public health challenges.
- Build awareness and expertise within ministries of health and national public health institutes to strengthen a culture of data-driven decision-making.
- Create new networks to support continuing professional development and career progression.

The SCEAM-CA project will create a cohort of epidemiology and modelling specialists in francophone countries with the potential to lead efforts to apply data science techniques to identify areas at high risk of outbreaks, predict likely outbreak dynamics, and assess the potential impact of interventions, strengthening outbreak capabilities.

Project at a glance	
Project duration	1 Jul 2026 - 30 Jun 2029
Total project cost	€1 669 029,10
Global Health EDCTP3 funding	€1 290 126,00
Disease area	Emerging or re-emerging infectious diseases, Diarrhoeal diseases, Malaria
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Digital technologies, Environment and biodiversity
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	UNIVERSITE DE KINSHASA
Participating countries	Netherlands, Democratic Republic of the Congo, Burundi, South Africa, France, United Kingdom





IDM-Africa

Strategic Training Hub for Infectious Disease Modelling in sub-Saharan Africa

The IDM-AFRICA project is creating a training programme to strengthen capacity for infectious disease modelling in sub-Saharan Africa.

The challenge

Mathematical modelling is an increasingly important aspect of infectious disease control. Models have a wide range of uses, providing a way to anticipate likely future disease trends and to assess the potential impact of different intervention strategies. Modelling can therefore inform decision-making, helping to identify where activities should be focused and which disease control strategies are likely to be most effective and cost-effective.

Unfortunately, the capacity for infectious disease modelling is limited in most sub-Saharan African countries. Without modelling specialists, countries are limited in their ability to generate accurate forecasts, assess the potential impacts of interventions or disease control strategies, and implement evidence-based public health policies.

The project

The IDM-AFRICA project is addressing these key skills gaps by creating a **new training programme for modellers**, in partnership with the Africa Centre for Disease Control and Prevention (Africa CDC) and EU institutions with long-standing expertise in this area.

The project plans to train **47 early- to mid-career researchers** through workshop training and a structured **one-year fellowship programme** that combines a strong theoretical foundation with practical application. At least five training sites will be established to support the initial training of 35 researchers at intensive workshops, with a further 12 more advanced researchers completing a fellowship programme.

Five regional workshops will be organised, with pre-workshop preparatory sessions and pre- and post-workshop assessments to track learning outcomes. The workshops will be rooted in the analysis of real-world datasets to emphasise application to practical challenges.

The advanced fellows will also work with **genuine datasets** related to local public health priorities as part of more intensive modelling projects embedded within their fellowships. They will be expected to generate policy outputs and academic papers, and will undertake a one-month placement during which they will receive intensive mentoring. The project will ensure good gender balance among fellows and recruit at least five students from French-speaking countries.

Five **annual policy workshops** will be organised in partnership with the Africa CDC and the ministries of health. Fellows will be expected to generate at least 12 policy briefs, which will be disseminated in at least five countries, helping to build policy literacy among fellows.

The impact

The IDM-AFRICA project is making a major contribution to the strengthening of infectious disease modelling capacity in sub-Saharan Africa. It will:

- Provide initial training to a group of early-career researchers, providing an entry point into more extensive use of modelling techniques.
- Train a cohort of researchers in advanced modelling with a focus on practical application to address public health priorities.
- Generate analyses of direct relevance to regional health challenges.

Strengthening modelling capacity will ensure that more researchers have the skills required to analyse health and other data and to generate outputs that enable policymakers to optimise programme design and implementation.

Project at a glance	
Project duration	1 Aug 2026 - 31 Jul 2031
Total project cost	€1 574 197,90
Global Health EDCTP3 funding	€1 300 370,90
Disease area	HIV/AIDS, Tuberculosis, Malaria
Intervention type	Surveillance tools
Overarching topic	Digital technologies
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	THE INFECTIOUS DISEASES INSTITUTE LIMITED
Participating countries	Netherlands, Uganda, Mali



OCTOPUS

One Collaborative Training Programme for Outbreak Preparedness and Universal Surveillance

The OCTOPUS project is using a cascading training model to enhance data science capacity in East Africa.

The challenge

Constant vigilance is essential in East Africa to detect and respond to **emerging infections**. Multiple outbreaks of Ebola virus, for example, have been detected over the past decade, alongside other haemorrhagic fever viruses and emerging infections. Due to factors such as population movements, land-use changes and climate change, there is a growing risk of zoonotic infections. In addition, the subregion is badly affected by **antimicrobial resistance**, which is undermining the ability of health systems to treat many infectious diseases. Importantly, infections can readily spread between countries, emphasising the need for a coordinated cross-country approach.

These issues highlight the critical need for strong **surveillance systems** to detect clusters of cases with the potential to develop into epidemics, as well as rapid and efficient **response mechanisms** to nip nascent outbreaks in the bud. In addition, with resources inevitably limited, evidence-based approaches need to be adopted to optimise the impact of control activities.

As well as comprehensive systems for data collection, countries also need the capacity to analyse these data, to understand likely hotspots, outbreak dynamics and the potential impact of control measures, informing prevention and response strategies. However, capacity to analyse data, particularly to apply mathematical modelling techniques, is limited in many countries.

The project

The OCTOPUS project is addressing this skills gap through a **training programme** designed to have a **catalytic effect** by enabling trainees to become additional trainers and pass on their expertise to others. The project is **establishing a two-year Master's programme** for participants from six countries in the **greater East African subregion** – Burundi, the Democratic Republic of the Congo (DRC), Kenya, Rwanda, Tanzania and Uganda. OCTOPUS will also provide short-term technical training opportunities for Africa. These countries vary significantly in their infectious disease modelling and outbreak response capabilities, providing opportunities for South-South exchange of knowledge and experience.

The Master's programme will be a **hybrid two-year programme**, targeting early to mid-career researchers. The first year will be spent on **academic coursework** at a globally recognised training site in Denmark. The second year will be dedicated to **practical research** within a ministry of health, a national public health institute, a research institute, or a university in sub-Saharan Africa. Ten fellows will be enrolled, two each from Burundi, DRC, Kenya and Uganda and one each from Rwanda and Tanzania (based on capacity-building needs and recent history of zoonotic outbreaks). In addition, a range of **workshops, short courses and seminars** will be organised to enhance the awareness and knowledge of public health professionals from participating countries. Five participants will attend from each country.

Both forms of training will have a strong focus on **practical application** of data science tools and modelling. Trainees will work with real-world datasets and tools shared by project

partners. They will develop actionable knowledge products, such as data dashboards, geospatial maps and outbreak prediction models.

The impact of these activities will be amplified by the subsequent **training activities undertaken by participants**. Country staff participating in short-term training events will share their new knowledge with colleagues in their home countries. Once a quarter, Master's graduates will each host a week-long workshop for 25 participants. This will extend the project's reach from 45 direct trainees to an estimated 4,500 beneficiaries. In addition, the project is also creating a **data catalogue** and a cross-border data-sharing and public health **data analytics platform**. This will integrate surveillance data from multiple countries, enabling subregional analyses, including AI-enabled predictive models.

The project will also implement a comprehensive **mentorship scheme** and work with ministries of health and national public health institutes on a career development framework and progression pathways. Consultations will be undertaken to identify key barriers and career roadblocks, which will inform the design of a continuing professional development programme.

The impact

The OCTOPUS project will make a major contribution to public health workforce skills development in East Africa. It will:

- Train a new cohort of early to mid-career researchers in the latest data science and machine learning/AI technologies.
- Ensure that theoretical learning is backed up by experience of practical application to address public health challenges.
- Amplify impact by ensuring that each trainee passes on knowledge to colleagues through a structured secondary training programme.
- Create a cross-border data analytics platform that will enable countries to share data and collaborate on subregional analyses.

Project at a glance	
Project duration	1 Aug 2026 - 31 Jul 2030
Total project cost	€1 359 556,00
Global Health EDCTP3 funding	€1 299 926,00
Disease area	Diarrhoeal diseases, Malaria, Tuberculosis
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Co-morbidities and non-communicable diseases, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	CHUKA UNIVERSITY
Participating countries	Netherlands, Kenya, Democratic Republic of the Congo, Rwanda, Tanzania, Denmark, Uganda, Burundi





KWTRP

Empowering researchers and policymakers in sub-Saharan Africa through infectious disease modelling training

The KWTRP project is strengthening capacity for infectious disease modelling to enhance disease control in sub-Saharan Africa.

The challenge

Countries in sub-Saharan Africa face the ongoing challenge of minimising the impact of infectious diseases, using a range of tools at their disposal. With resources limited, it is vital that they focus on priority areas and optimise responses to ensure the greatest impact on disease control.

Infectious disease modelling is becoming central to disease control and decision-making. Modelling can provide policymakers with tools for exploring a wide range of potential scenarios, including how infectious diseases might spread, what impacts they might have, and how different interventions could reduce these impacts. This can enable policymakers to focus efforts on the strategies most likely to be effective.

The use of infectious disease modelling in sub-Saharan Africa is currently held back by a lack of technical expertise. It is also important to raise awareness among policymakers on the potential power of modelling and to strengthen links between researchers and policymakers so that modelling efforts are directed at priority public health challenges and deliver policy-relevant analyses.

The project

The project is strengthening capacity for infectious disease modelling among researchers and policymakers by providing training for English-, French-, and Portuguese-speaking participants.

The programme includes short courses for researchers, focusing on epidemiology, statistical modelling, and advanced mathematical modelling, applied to the dynamics of infectious disease outbreaks and evaluation of intervention strategies. Five intensive two-week courses will be offered, two each in English and French and one in Portuguese, focusing on foundational epidemiology, statistical modelling, and mathematical modelling techniques, which will provide training for 125 researchers during the course of the project.

For policymakers, three one-week courses are being organised, focusing on practical modelling applications and case studies. Up to 15 participants will take part in each course.

Researchers will also have the opportunity to apply for research fellow placements. These will be embedded in projects addressing priority infectious disease challenges, enabling fellows to learn by doing. Ten such fellowships will be awarded following a competitive process, with projects due to last nine months.

In addition, the project is organising a quarterly seminar series to promote continuous learning and exchange. Seminars will cover practical uses of modelling in areas such as vaccine assessment and control of antimicrobial resistance (AMR). Targeted regional workshops will also be arranged to demonstrate the impact of modelling activities.

The project consortium has a strong background in capacity building and training. To facilitate the use of real-world data in training exercises, the project will utilise Epiverse, a trustworthy data analysis software suite and platform established by European partners.

The impact

The project will significantly expand the pool of infectious disease modellers in sub-Saharan Africa. It will:

- Provide high-quality technical training in infectious disease modelling to a new cohort of researchers.
- Ensure that training is closely integrated with public health needs and policymaker decision-making.
- Raise awareness of modelling among policymakers and strengthen links with academic experts with modelling experience.

Ultimately, greater modelling expertise will enable policymakers to draw on local specialists and make more use of local data to enhance disease control efforts and the use of resources.

Project at a glance	
Project duration	1 Sep 2026 - 31 Aug 2029
Total project cost	€1 572 283,18
Global Health EDCTP3 funding	€1 278 338,08
Disease area	Cross-disease or disease unspecific
Intervention type	Surveillance tools, Cross-intervention or intervention unspecific
Overarching topic	Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	HEALTH RESEARCH OPERATIONS KENYA LIMITED
Participating countries	Netherlands, Kenya, Mozambique, United Kingdom, France



SPHERE-Africa

Strengthening public health education in research & epidemiology in Africa (SPHERE-Africa)

The SPHERE-AFRICA project is developing a training programme to build capacity for data use to enhance epidemic preparedness and response activities in sub-Saharan Africa.

The challenge

Over recent decades, sub-Saharan Africa has experienced many infectious disease outbreaks. Multiple pathogens have the potential to cause new outbreaks that could grow into national, regional, or even global public health emergencies.

Key to outbreak control is **early detection**, so that control measures can be put in place before an infection has a chance to take root in human populations. This depends on strong surveillance systems to detect emerging pathogens and clusters of cases that have the potential to grow into a full outbreak. However, surveillance systems are patchy in many sub-Saharan African countries, which also typically have limited numbers of epidemiologists – particularly those with skills in modelling to maximise the use of surveillance and other data.

The project

The SPHERE-AFRICA project is establishing a new **Master's and short-course training programme** to build capacity in epidemiology, data use, and modelling to enhance outbreak detection, prevention, and response.

Master's training will be provided for at least **15 fellows**, with priority given to researchers from ministries of health or affiliated institutions. Trainees will register for a Master's course in Mali (epidemiology) or South Africa (biostatistics), undertaking a mix of coursework, a placement, and a research project. Fellows will also take part in training offered at other consortium sites. This combination will ensure a strong focus on 'learning by doing'.

During year one, trainees will complete **foundational modules** in South Africa or Mali and rotate through various **field placements** to gain practical experience in different settings. During year two, they will take part in **virtual learning activities** and complete a **longer-term placement**. Placements will be organised in partnership with national public health institutes in participating countries, with each trainee having an appointed supervisor to oversee their work.

The programme also incorporates a strong commitment to **mentoring**. Each trainee will have a primary mentor, who will help to create a personalised development programme, as well as additional secondary mentors, one from Europe and one from sub-Saharan Africa. Trainees will also complete modules on general research skills and research writing.

In addition, the programme will support the assimilation of trainees into academic and public health networks. Within the programme, **trainees will work collaboratively** on projects and make use of a shared data platform. Annual dissemination events will be held with regional stakeholders, including representatives from ministries of health and national public health institutes. Efforts will also be made to promote trainees' contact and

collaboration with other networks and organisations. Trainees will also be integrated into the Africa Centre for Disease Control and Prevention (Africa CDC) rapid responder network.

Training for up to 50 early- to mid-career researchers will be provided in a range of key areas, including the development of systematic reviews and meta-analyses, outbreak response mechanisms, genomic surveillance of pathogens, mathematical modelling, and bioinformatics/data science, including the use of AI/machine learning technologies. Training will be offered at sites in multiple countries, including Ethiopia, Mali, Mozambique, Senegal and South Africa, as well as at Africa CDC and in the UK.

The impact

The SPHERE-AFRICA project will strengthen epidemiological and data-use capacity in sub-Saharan Africa. It will:

- Train a cohort of promising researchers in key skills required to make use of surveillance and other data
- Provide opportunities for the practical application of data science skills to address public health challenges
- Strengthen connections between trainees, public health organisations and key professional networks.

Through these activities, the SPHERE-AFRICA project will expand and strengthen work force expertise, ensuring that surveillance and other data are used to identify areas at high risk of outbreaks, to rapidly detect emerging outbreaks, and to ensure that responses are based on the best available evidence.

Project at a glance	
Project duration	1 Sep 2026 - 31 Aug 2030
Total project cost	€1 713 646,18
Global Health EDCTP3 funding	€1 240 334,18
Disease area	Emerging or re-emerging infectious diseases, HIV/AIDS, Tuberculosis
Intervention type	Surveillance tools
Overarching topic	Antimicrobial resistance (AMR) or drug resistance, Climate crisis or climate adaptation, Environment and biodiversity, Co-morbidities and non-communicable diseases, Women's health, Health security
Project coordinator	EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP
Scientific project leader	STELLENBOSCH UNIVERSITY
Participating countries	Netherlands, South Africa, Italy, Senegal, Ethiopia, Mali, Mozambique, United Kingdom





Ethics and regulatory capacities



BREEDIME

Building resilient research ethics, Diagnostics and medicines regulatory capacity during routine and public health emergency periods

The BREEDIME is building on previous EDCTP efforts to strengthen regulatory capacity in Tanzania, enabling the country to support regulatory development in Rwanda.

The challenge

Multiple countries in sub-Saharan Africa have made significant upgrades to their regulatory systems over the past two decades. However, the capabilities of regulatory systems vary markedly between countries, and remain underdeveloped in many. This is a significant barrier to hosting additional clinical studies.

Multiple EDCTP2-funded projects, including ASCEND, PAVIA, PROFORMA, and SMERT, have helped build regulatory, pharmacovigilance, and research ethics capacity in Tanzania. These projects have made an important contribution to the progression of the Tanzanian national regulatory authority to the WHO maturity level 3. It is also recognised as a Regional Centre of Regulatory Excellence (RCORE).

However, the COVID-19 pandemic revealed significant capacity gaps, particularly in the approval and oversight of clinical research during health emergencies. In addition, medical interventions are becoming increasingly complex, specialist knowledge is needed to assess *in vitro* diagnostics, and clinical trial design is constantly evolving. Such developments present new challenges to those involved in oversight of clinical research.

The project

The BREEDIME project focuses on regulatory capacity development in key areas of clinical research in Tanzania and on leveraging these efforts to strengthen regulatory systems in Rwanda, which only established a national medicines regulatory authority in 2018.

Training courses are being organised on key aspects of clinical research during health emergencies. The project will also focus on building national expertise in areas such as post-market evaluation, enabling regulatory staff to conduct product information reviews and ensure that manufacturers' descriptions of medical products are accurate.

The project will also develop an ethics framework for the sharing of materials and health data during health emergencies, drawing on established European standards.

This additional expertise in Tanzania will provide a basis for stronger South-South capacity building, with Tanzania providing support to Rwanda's newly established national regulatory authority.

The impact

The BREEDIME project will further enhance regulatory capacity in Tanzania. It will:

- Help to close key gaps in expertise, particularly relating to regulatory oversight of clinical research during health emergencies.
- Enable Tanzania to support regulatory capacity development in neighbouring countries, particularly Rwanda.
- Create new partnerships to support ongoing sharing of expertise and experience.

These project activities will further consolidate Tanzania's status as a favoured site for clinical research in sub-Saharan Africa and enable it to better fulfil its role as a regional centre of regulatory excellence.

Project at a glance	
Project duration	1 Jun 2023 - 31 May 2026
Total project cost	€599 637,50
Global Health EDCTP3 funding	€599 637,50
Disease area	Cross-disease or disease unspecific, Emerging or re-emerging infectious diseases
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	KAROLINSKA INSTITUTET
Scientific project leader	TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY
Participating countries	Sweden, Tanzania, Rwanda, United Kingdom





ECOWAS-RegECs

Practical strengthening of regulatory and ethics oversight on clinical trials in West Africa using Lassa Fever vaccine development projects and increase regulatory maturity level in targeted countries

The ECOWAS-RegECs project is helping to build regulatory and ethics capacity by simulating scientific advice and review of Lassa fever vaccine clinical trial applications. It uses multi-country review procedures to increase the regulatory maturity level in targeted countries.

The challenge

Lassa fever is an epidemic-prone zoonotic disease endemic in parts of West Africa, including Benin, Ghana, Guinea, Liberia, Mali, Nigeria and Sierra Leone. Clinical development of Lassa fever vaccines raises **complex regulatory and ethical questions**, particularly during outbreaks when trial designs may need to be adapted and reviewed under urgent timelines.

National regulatory authorities (NRAs) and ethics committees therefore need practical experience with vaccine development pathways, joint review procedures, and emergency-use considerations to protect participants while enabling timely clinical trial review.

The project

ECOWAS-RegECs **strengthens regulatory and ethics oversight** of clinical trials in **West Africa** by using Lassa fever vaccine development as a practical learning platform. The project is coordinated by CEPI and implemented with Ghana FDA, WAHO and the Paul-Ehrlich-Institut, with collaboration from AVAREF, vaccine developers, AMRH, WHO, the Gates Foundation, and regulatory and ethics partners in the region.

The project activities included:

- Hands-on simulations and observation opportunities to expose ECOWAS regulators and ethics committee members to scientific advice and clinical trial review through the AVAREF platform of previous submissions from developers of Lassa fever vaccines.
- Joint review processes to support more coordinated, consistent and rapid decision-making across countries, including approaches relevant to public health emergencies.
- Targeted benchmarking and institutional development support for selected NRAs, including Liberia and Senegal, to help strengthen clinical trial oversight and progress towards higher WHO GBT maturity levels.

The impact

ECOWAS-RegECs has strengthened regulatory and ethics readiness for Lassa fever vaccine trials and other outbreak-related studies. It has built practical expertise, improved familiarity with AVAREF procedures and supported more predictable, harmonised review pathways across West Africa.

- Regulators and ethics reviewers gained direct experience of scientific advice and clinical trial review under emergency-relevant timelines.

- Selected NRAs received support to address oversight gaps and advance institutional development plans.
- The project created a practical model for regional cooperation that can be applied to other epidemic-prone pathogens and future vaccine development programmes.

The project has led to the further fine-tuning of the AVAREF procedures, improving transparency, harmonisation, and reliability of the multi-country procedures for clinical trial application review in West Africa. From a European perspective, these advancements are particularly advantageous for European vaccine developers, as standardised review timelines and parallel regulatory and ethics processes minimise uncertainty and administrative hurdles for sponsors. The improved predictability encourages greater investment and collaboration in the region.

With higher regulatory maturity and the use of the AVAREF platform for joint reviews, European developers can expect clearer, faster pathways for vaccine approval and market access. This facilitates earlier entry into African markets and promotes stronger partnerships between European and African regulatory bodies.

Overall, this project has resulted in **improving the experience of the regulators and ethicists** with issuance of **scientific advice and review of clinical trial applications**, which provides mutual benefits: European pharmaceutical and vaccine companies gain a more predictable environment for research, while the region is better equipped to evaluate and deploy vaccines for emerging diseases. The project's achievements contribute directly to global health security by supporting timely and effective responses to epidemics and will provide a blueprint for coordinated work on other vaccine development projects against epidemic-prone pathogens, such as Rift Valley fever.

Project at a glance	
Project duration	1 Jun 2023 – 31 Jul 2025
Total project cost	€514 961,25
Global Health EDCTP3 funding	€514 961,25
Disease area	Emerging or re-emerging infectious diseases, Cross-disease or disease unspecific
Intervention type	Vaccines, Cross-intervention or intervention unspecific
Overarching topic	Health security
Project coordinator	COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS
Participating countries	Norway, Germany, Burkina Faso, Ghana



SCALE-IT

Scaling up capacity to support conduct of clinical trials in the East African community

The SCALE-IT project is using a coordinated approach to strengthen ethics review and regulatory capacity across multiple East African countries.

The challenge

East African countries are hosting an increasing number of clinical trials, many of which are adopting innovative designs such as adaptive platform-based trials. At the same time, there are increasing pressures to increase the speed of review of clinical trial applications.

These trends are posing a growing challenge to national regulatory authorities and ethics review committees, including an increasing workload. It is critical that there is a sufficiently large pool of trained scientists in the region who can review clinical trial applications, including complex study designs. There is also a need to enhance oversight to ensure the safety of trial participants.

The project

Uganda has hosted multiple EDCTP capacity-building projects. One such project helped to develop a national accreditation system for research ethics committees in Uganda, which was used to accredit all 29 such committees in the country. The EDCTP-funded CREU project developed the capacity of Uganda's national regulatory authority through Ethics and regulatory capacities training, mentorships and placements of staff in more mature regulatory bodies.

However, there remains a need to strengthen trial monitoring further and to extend good practices to additional countries, guaranteeing international standards and attainment of Sustainable Development Goal 3. As well as Uganda, the SCALE-IT project connects Burundi, Kenya, Rwanda, South Sudan and Tanzania.

To achieve these goals, the SCALE-IT project is undertaking a range of activities, including:

- Training of regulatory authority staff, ethics review committee members, researchers and clinicians on **scientific and ethics review**, with a particular focus on **adaptive platform-based trials**. The project will make use of a training curriculum developed through a project funded by the US National Institutes of Health (NIH).
- Training of regulatory authority staff, ethics review committee members, and clinical trials monitors on **oversight, monitoring and pharmacovigilance of clinical trials**. To improve accessibility, training will be delivered through a more convenient blended learning approach.

- Training of regulatory authority staff, ethics review committee members and research administrators on **personal effectiveness and leadership skills**, again based on blended learning.

The **East African Health Research Commission (EAHRC)** is acting as the focal point of the project. The EAHRC was established by the heads of state of East African Community (EAC) countries, with the main objective to promote, facilitate and coordinate the conduct and application of health research in the EAC.

The impact

The SCALE-IT project will continue past work to strengthen regulatory and ethics review capacity in Uganda, and connect multiple countries in East Africa. It will:

- Improve the performance of regulatory and ethics review bodies, particularly their handling of trial applications for adaptive platform-based trials.
- Lead to more rapid assessment of clinical trial applications.
- Ensure high-quality feedback is provided to clinical trial applicants.
- Facilitate enhanced monitoring of approved clinical trials.

Collectively, the project activities will make the region a more attractive location for clinical trials to accelerate the development, delivery and uptake of new and improved safe health technologies and rapid response to emerging epidemics for people of all ages living in East African Community countries.

Project at a glance	
Project duration	1 Jun 2023 – 31 May 2026
Total project cost	€600 312,50
Global Health EDCTP3 funding	€600 000,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Health security
Project coordinator	EPICENTRE
Participating countries	France, Uganda, Kenya





ACCESSAFRICA2

Strengthening Clinical Trial Regulatory and Ethical review Oversight in East Africa

The ACCESSAFRICA2 project is strengthening ethics review and regulatory capacity in Ethiopia and Uganda.

The challenge

Although still relatively low, an increasing number of clinical trials are being conducted in sub-Saharan African countries. There are still several barriers that limit further expansion, including the typically lengthy time taken for regulatory review and limited infrastructure for monitoring safety during clinical trials.

The first ACCESSAFRICA project, funded by the EDCTP2 programme, sought to build ethics review and regulatory capacity in Ethiopia and Uganda, with a particular focus on ensuring that participants in clinical research gained access to new interventions at the end of trials. The project was undertaken within the framework of the EDCTP regional Network of Excellence, the **East African Consortium for Clinical Research (EACCR)**.

The project

Building on the partnerships established in the first project, the EDCTP3 Global Health-funded ACCESSAFRICA2 project is working to further develop ethics review and regulatory capacity in Ethiopia and Uganda. The project has a particular focus on pharmacovigilance for clinical trials, improving operational efficiency and coordination, and research during outbreaks and epidemics.

Needs assessments are being carried out in each country to identify capacity gaps and to inform national capacity-development plans. For pharmacovigilance, the project is developing updated guidelines and providing training, drawing on the resources of the **African Vaccine Regulatory Forum (AVAREF)**. This will support coordinated reporting of adverse events to both ethics review and regulatory bodies. The project will also draw on the expertise of the **Kenyan Pharmacy and Poisons Board**, a regional centre of regulatory excellence (RCORE).

Efforts are also being made to **strengthen collaborations** between national regulatory agencies, national ethics committees and institutional review boards. This will create opportunities for coordinated activities, such as joint reviews of applications and site visits, reducing duplication of efforts.

In addition, short-course training will also be provided to at least 30 early- and mid-career researchers to build **research leadership capacity**. Training will also be provided to institutional review board members, leveraging the EACCR network. The project will also provide an opportunity to roll out the guidance on **post-trial access** that was developed during the first ACCESSAFRICA project.

The impact

The ACCESSAFRICA2 project will further strengthen ethics review and regulatory capacity in Ethiopia and Uganda. It will:

- Build capacity in pharmacovigilance, providing a stronger foundation for safety monitoring during clinical studies.
- Strengthen collaborations between ethics review and regulatory bodies, improving efficiencies and reducing application assessment times.
- Enable national regulatory authorities to enhance their maturity level.

Over the longer term, the project will create a sustainable subregional network through which further capacity building can be embedded, enabling more clinical studies to be conducted safely and efficiently in the two countries and elsewhere in East Africa.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2026
Total project cost	€600 000,00
Global Health EDCTP3 funding	€600 000,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	UNIVERSITETET I OSLO
Participating countries	Norway, Ethiopia, Uganda, Thailand



SERCEA

Strengthening Ethics and Responsible conduct of Clinical Trials in East and Sub-Saharan Africa

The SERCEA project aims to strengthen mechanisms that promote and ensure the integrity of scientific research in East Africa.

The challenge

An increasing number of clinical trials are being carried out in sub-Saharan Africa, and in East Africa in particular. The complexity of these trials is also increasing, with new and innovative trial designs being adopted.

Governance of clinical studies is the shared responsibility of ethics review committees and regulatory authorities. Many efforts are being made, including through Global Health EDCTP3-funded projects, to build the capacity of these bodies to address new challenges.

However, it is also important that clinical researchers and members of ethics review committees and regulatory authorities have a shared understanding of what constitutes ethical and appropriate practice in clinical research, and of the general principles that should underpin the design of clinical studies and researcher practice. Currently, there is a lack of national and regional guidelines and codes of conduct covering **scientific integrity**.

The project

The SERCEA project is addressing this gap and also carrying out a range of activities to strengthen the infrastructure for ensuring commitment to and compliance with such codes of conduct and ethical frameworks.

It has a specific focus on:

- Developing a regional **research ethics and integrity framework**, based on a landscaping exercise and consultation. Key sites will be supported to develop **research integrity liaison offices**.
- Establishing an **open data access framework** and trial data platform, to encourage and facilitate the sharing of data from clinical trials.
- Creating an **e-learning platform** focused on good research regulatory practice, based on a course developed by the EDCTP2-funded CREDU project, which is being used in multiple countries in the region.
- Establishing research ethics committees at regional hospitals, to strengthen ethics review capacity across the country, ensure alignment with the national research ethics committee, and, in particular, to enhance safety monitoring of clinical trials.

To promote consistency in approach, the project team will liaise with key regional bodies, including the African Regulatory Forum (AVAREF) and the East African Health Research Commission (EAHRC), a coordinating structure for health-related research issues across multiple East African countries.

The impact

The SERCEA project is creating a foundation for further strengthening of ethics review and regulatory practice in East Africa. It will:

- Raise awareness of the importance of scientific integrity and create a shared understanding of the obligations of clinical researchers.
- Strengthen mechanisms for monitoring adherence to core principles of scientific integrity and ethical conduct of research.
- Ensure consistent standards are applied across multiple East African countries.
- Promote and facilitate open data practices and transparency.

Through these efforts, the project will help to embed a culture of commitment to scientific integrity, enhance ethics review and regulatory capacity, and strengthen safeguards protecting research participants, all of which will act to sustain public trust in clinical research.

Project at a glance	
Project duration	1 Jul 2023 - 30 Jun 2026
Total project cost	€599 000,00
Global Health EDCTP3 funding	€599 000,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Project coordinator	UNIVERSITEIT MAASTRICHT
Participating countries	Netherlands, Tanzania, Malawi, Uganda, Kenya





SEARCH II

Strengthening Regulatory Capacities for Clinical Trials Oversight in Southern Africa: South–South and South–North Collaboration Initiative for Regulatory Bodies

The SEARCH II project is strengthening and harmonising regulatory structures in Southern and Eastern African countries.

The challenge

Effective regulatory systems are essential to protect participants taking part in clinical studies and to safeguard the quality of licensed medical products. The efficiency of such systems is also important to avoid delays in the introduction of new interventions and to ensure that countries are an attractive location for clinical research.

The EDCTP2–funded SEARCH project brought together ministries of health from Botswana, Eswatini, Lesotho, and Mozambique and a European institution to strengthen the capacity of national regulatory authorities and national ethics committees, to promote South–South networking, and to harmonise processes across countries.

The project

In the follow-up SEARCH II project, activities are being extended to new countries, Namibia and Zambia, and an additional European institution has joined the SEARCH consortium.

The aim is to build the capacity of national clinical trial oversight systems, national pharmacovigilance capabilities, and quality assurance processes for licensed products. Existing systems in participating countries will be rigorously assessed and tailored development plans will be put in place for each country.

Although based on individual countries’ needs, these development plans will include a focus on harmonising, streamlining approaches, and introducing new processes and technologies to improve efficiency. This will make use of the guidance and materials developed by the African Vaccine Regulatory Forum (AVAREF) on harmonisation of regulatory procedures.

An extensive training programme will be organised to build human capacity, including at least 10 short courses. At least five regulatory professionals will have the opportunity to undertake placements within more advanced regulatory systems in Botswana and South Africa.

The project has a strong focus on networking, facilitating the diffusion of expertise, new ideas and technologies through the network. As well as AVAREF, links will be built with the Southern

African EDCTP regional Network of Excellence, Trials of Excellence in Southern Africa (TESA), and with the Southern Africa Development Community, both of which have key centres in Botswana.

The impact

The SEARCH II project will support further strengthening of regulatory systems in countries in Southern and Eastern Africa. It will:

- Promote harmonised approaches across different countries, reducing the administrative burden on sponsors organising multicentre trials.
- Encourage sharing of experience, expertise and tools, helping countries to learn from each other.
- Improve efficiencies and reduce turnaround times for clinical trial applications.
- Lead to improvements in the maturity level of national regulatory authorities.

These impacts will help to protect the safety and interests of research participants during trials, better ensure the safety of medical products, and make the countries more attractive sites in which to carry out clinical research.

Project at a glance	
Project duration	1 Jul 2023 - 31 Dec 2026
Total project cost	€599 947,50
Global Health EDCTP3 funding	€599 947,50
Disease area	Cross–disease or disease unspecific
Intervention type	Cross–intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	KEY IMPACTE - CONSULTANTS FOR DEV, SOCIEDADE UNIPESSOAL LIMITADA
Scientific project leader	FUNDACAO MANHICA
Participating countries	Portugal, Mozambique, Botswana, Zambia, Lesotho, Namibia, United Kingdom, Eswatini



CAPACITY 2023

Consortium for developing regulatory capacity for clinical trials using gene therapy products and strengthening pharmacovigilance in the conduct of clinical trials in East Africa

The CAPACITY 2023 project is strengthening capacity for ethics review and regulatory oversight of clinical research projects involving gene therapy and other new molecular and cellular technologies.

The challenge

Globally, rapid progress is being made in the development of molecular and cellular treatments, including for infectious diseases. Conventional pharmaceutical development focuses on small chemicals, but newer generation treatments aim to manipulate gene activity or are based on the use of cells as therapeutic agents.

Although often expensive to develop, molecular and cellular treatments have advantages, in some cases including the potential to be curative, avoiding the need for long-term treatment. In the long run, they could therefore be cost-saving.

Despite their potential, molecular and cellular approaches have made little inroads into sub-Saharan Africa. Increasing clinical research activity in this area will require a range of actions, including raising awareness, developing safety-monitoring systems appropriate for these new technologies, and building knowledge and capacity within the African research community. They also raise specific ethical issues, which will require capacity building in regulatory and ethical review capacity.

The project

Researchers in Uganda and Tanzania are beginning to explore the potential application of molecular and cellular therapies to diseases that have a significant regional impact. Focusing on Uganda, the CAPACITY 2023 project is carrying out a range of activities to create an environment where clinical studies involving these new technologies can be safely and ethically carried out. The lessons learned will be transferable to other sub-Saharan countries.

Key activities include:

- Working with a range of stakeholders to develop **regulatory frameworks** for clinical studies involving gene therapy or other molecular and cellular technologies.
- Strengthening the capacity of **regulatory agencies** to oversee such studies, for example, through short-term training of regulatory staff and placements in bodies with experience in these areas.

- Building the capacity of **researchers and clinicians** in the use of gene therapies and other molecular and cellular technologies, leveraging the experience already gained in pioneer countries.
- Developing guidance and organising training to strengthen **pharmacovigilance systems** specific to these new technologies.

The impact

The CAPACITY 2023 project is helping to establish a foundation for an increased focus on gene therapy and other molecular and cellular medical technologies in sub-Saharan Africa. It will:

- Enhance technical skills in these emerging areas of research.
- Build institutional capacity in gene therapy and other molecular and cellular technologies.
- Provide a robust regulatory framework to ensure effective oversight of clinical studies involving such novel technologies.
- Enable additional countries to learn from Uganda’s experience.

In summary, the project’s work will provide a major impetus to research on molecular and cellular technologies in sub-Saharan Africa, which hold enormous promise but have so far not received the same level of attention as in other parts of the world.

Project at a glance	
Project duration	1 Apr 2024 - 31 Mar 2027
Total project cost	€999 315,35
Global Health EDCTP3 funding	€999 315,35
Disease area	Cross–disease or disease unspecific
Intervention type	Therapies
Project coordinator	UNIVERSIDADE DE COIMBRA
Scientific project leader	THE NATIONAL DRUG AUTHORITY
Participating countries	Portugal, Uganda, Tanzania





CECABI II

Côte d'Ivoire Ethics Capacity Building Initiative (CECaBI II)

The CECABI II project is developing the capacity of research ethics bodies in Côte d'Ivoire and enhancing coordination with its national regulatory authority.

The challenge

Although Côte d'Ivoire has a moderately developed health research system, it has ambitions to increase the number of clinical research projects conducted in the country (Phase II to Phase IV). To achieve this goal, the country needs to strengthen its **research ethics review and regulatory systems** to ensure that studies are conducted to the highest ethical standards.

The CECABI II project, funded through the EDCTP2 programme, helped to build research oversight capacity in Côte d'Ivoire, for example, by supporting the creation of two new institutional review boards, to complement the national research ethics committee, the Comité National d'Éthique des Sciences de la Vie et de la Santé (CNESVS, National Ethics Committee of Life and Health Sciences). However, capacity remains limited, with little follow-up on projects after approval, and the work of CNESVS and Côte d'Ivoire's national regulatory authority, l'Autorité Ivoirienne de Régulation Pharmaceutique (AIRP), is poorly coordinated.

The project

The activities of the CECABI II project, and the relationships developed during the project, have provided a springboard for further strengthening of the Côte d'Ivoire research oversight system through the CECABI II project.

Additional training will be organised to extend and expand the skills base in Côte d'Ivoire. The project is developing a **clinical research management and oversight framework** for Côte d'Ivoire, which will guide the training of research ethics committee members and at least 12% of the 1,000 researchers in the country who conduct clinical research.

To assure high standards in ethical review, Senegal's national research ethics committee (Comité National d'Éthique pour la Recherche en Santé, CNERs) will engage with the CNESVS, rigorously assess its quality assurance and control management systems, and help to develop a pathway towards **ISO certification**.

To support monitoring of approved projects, CECABI II will facilitate the adoption by both the CNESVS and the AIRP of the clinical trials inspection guide and checklist for Good Clinical Practice (GCP) inspections developed by the African Vaccine Regulatory Forum (AVAREF).

Additionally, the project will support at least five more institutions to establish research ethics committees. This will be an opportunity to test a new **registration and accreditation framework** developed in the CECABI I project.

These new committees will be provided with the **RHInnO Ethics digital platform**, ensuring a consistent approach is adopted across all of Côte d'Ivoire's research ethics committees. Furthermore, a new RHInnO Ethics module is being developed that will create a seamless integration between the research Ethics and regulatory capacities approval systems, for example, enabling proposals submitted to research ethics committees to be automatically shared with the national regulatory agency.

The integration of RHInnO Ethics will also enable Côte d'Ivoire to share information with HRWeb Africa, so that it can contribute to an important database on regional clinical research activities.

The impact

The CECABI II project will significantly strengthen the research oversight system in Côte d'Ivoire. It will:

- Expand the number of research ethics committees in the country.
- Ensure that more clinical researchers in Côte d'Ivoire are aware of and trained in the essentials of ethics review.
- Strengthen coordination between the CNESVS and the AIRP, reducing duplication and improving efficiency.
- Improve the quality of clinical trials management and enhance research participants' protection.
- Establish systems for monitoring clinical research projects following approval.

Collectively, these advances will create stronger systems for clinical research governance in Côte d'Ivoire, ensuring better protection for research participants, helping to build trust in clinical research activities, and providing a foundation for expanding its portfolio of clinical research studies.

Project at a glance	
Project duration	1 Jun 2024 – 31 May 2027
Total project cost	€1 000 000,00
Global Health EDCTP3 funding	€1 000 000,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies
Project coordinator	ETHIXPERT NPC
Scientific project leader	MINISTÈRE DE LA SANTÉ DE L'HYGIÈNE PUBLIQUE ET DE LA COUVERTURE MALADIE UNIVERSELLE
Participating countries	South Africa, Côte d'Ivoire, France, Senegal



SECRET

Supporting Research Ethics Committees for efficient functionality and national accreditation to REview clinical Trials in Uganda and Ethiopia

The SECRET project addresses a critical gap in Africa's clinical research ecosystem: the limited capacity of national research ethics review systems to provide quality ethical review and oversight to the ever-growing volume of clinical trials conducted across the region. Working in Uganda and Ethiopia, SECRET brings together a consortium of partners committed to building a robust, efficient, and internationally recognised research ethics infrastructure that will protect trial participants, attract quality research, and strengthen health research systems across East Africa.

The challenge

Clinical trial activity in sub-Saharan Africa has increased substantially in recent years, yet the regulatory and ethical oversight infrastructure has not kept pace. The key gaps in clinical trial review and oversight in the region include:

- **Limited clinical trials ethics review capacity:** Few research ethics committees (RECs) have the capacity to review and provide oversight for clinical trials in the region.
- **Absent accreditation systems:** National accreditation frameworks that guarantee the quality of ethical review are largely absent, raising questions about the protection of research participants.
- **Low trial registration:** Many clinical trials, particularly single-country studies, remain unregistered, undermining transparency and accountability in research.
- **Paper-based protocol submission systems:** Nearly half of RECs across the region still rely on paper-based protocol submission systems, limiting efficiency and data management capacity.
- **Emergency response gaps:** Slow ethical review turnaround during outbreaks and epidemics constrains Africa's ability to generate timely research evidence when it is most needed.

The project

SECRET takes a systems-strengthening approach across four interlinked objectives:

1. **National accreditation systems.** Establishing formal accreditation frameworks for research ethics committees (RECs) in Ethiopia, ensuring that ethical review meets national and international quality standards and is recognised by funders, regulators, and the global research community.
2. **Capacity building for REC review of clinical trials.** Providing targeted training and support to RECs to strengthen their ability to review complex clinical trials, including those conducted during outbreaks and epidemics.

3. **National clinical trial registries.** Establishing a national clinical trial registry in Uganda, linked to the Pan-African Clinical Trials Registry and aligned with the WHO international registration standards, to increase transparency and accountability in research conducted in the region.

4. **Digital protocol submission systems.** Developing and implementing electronic protocol submission systems to modernise REC operations, reduce administrative burden, improve turnaround times, and enable better data management and reporting.

The impact

By the end of the project, SECRET will have created a stronger, more efficient, and internationally recognised research ethics environment in Uganda and Ethiopia. Specifically, the project will:

- Increase participation of Uganda and Ethiopia in high-quality clinical trials by ensuring their ethics review systems meet international standards.
- Improve the protection of research participants through rigorous, well-resourced, and independently accredited ethics review.
- Provide a replicable model for national ethics system strengthening that can be adapted and scaled across East Africa and beyond.
- Strengthen Africa's capacity to conduct timely, well-regulated research during health emergencies and outbreaks.
- Contribute to Sustainable Development Goal 3 on good health and well-being by enabling more and better clinical research on poverty-related and neglected infectious diseases in the region.

Project at a glance	
Project duration	1 Jul 2024 – 30 Jun 2027
Total project cost	€1 148 180,00
Global Health EDCTP3 funding	€1 148 180,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	INSTITUUT VOOR TROPISCHE GENEESKUNDE
Scientific project leader	UGANDA NATIONAL HEALTH RESEARCH ORGANISATION
Participating countries	Belgium, Uganda, South Africa, Ethiopia





STRATEGIC

Sustainable eThics Reviews of digital heAlth Technology dEsiGn In sub saharan afriCa

The STRATEGIC project is developing the capacity of sub-Saharan African countries to regulate the use of digital tools in research and clinical practice.

The challenge

Digital tools are becoming increasingly central to both research and clinical practice. They have a wide range of applications, spanning diagnosis, support for clinical decision-making, storage of health data in electronic patient records, through to data collection, storage and analysis in research. A growing number of these tools now have integrated artificial intelligence (AI) functionalities.

These tools have great potential to enhance the quality and efficiency of care delivery, as well as facilitate the use of clinical data for research purposes. However, they also create or exacerbate existing ethical and regulatory issues. Key issues include privacy and data security, informed consent, safety, equity and accessibility, algorithmic bias and discrimination, accountability and liability, and ethical use of big data.

It is therefore essential that further development and deployment of such tools take place within a robust governance environment tailored to local contextual realities in sub-Saharan Africa.

The project

The STRATEGIC project is bringing together a wide range of stakeholders from across sub-Saharan Africa to support the collaborative development of a robust, evidence-based and contextually appropriate approach to the oversight of research and innovation involving digital health tools.

It will systematically map the existing ethical and legal infrastructure covering digital tools in sub-Saharan Africa, highlighting gaps and needs. It will also identify emerging applications and study five digital technology use cases to explore key issues.

The project team will then collaborate with a broad range of stakeholders from different sectors to co-develop a comprehensive new oversight framework for digital technologies in healthcare. The project will develop training materials, which will be disseminated through existing training infrastructure and networks. It will also develop and pilot culturally sensitive, flexible and adaptive review processes.

Key outputs will include a handbook on stakeholder inclusion and responsible design of digital health technologies. The project's activities will create a sustainable e-community, supporting longer-term sharing of knowledge and best practices.

The STRATEGIC consortium includes the hosting body of a national ethics committee, as well as a European umbrella association (EUREC) that links multiple national research ethics committees, and four universities. The African partners represent English-, French- and Portuguese-speaking countries in sub-Saharan Africa, ensuring that its outputs will have wide applicability.

The impact

The STRATEGIC project will strengthen the capacity of countries in sub-Saharan Africa to oversee the use of digital health technologies in research and clinical practice. It will:

- Strengthen established ethics review processes that do not yet consider the ethical issues raised by digital health technologies.
- Facilitate greater use of digital health technologies in clinical trials in Africa.

The development of a rigorously developed, consistent, and culturally sensitive framework will help ensure that the great potential of digital health technologies can be realised while maintaining respect for key individual rights and garnering public support.

Project at a glance	
Project duration	1 Apr 2024 - 31 Mar 2027
Total project cost	€769 496,25
Global Health EDCTP3 funding	€769 496,25
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies
Project coordinator	RHEINISCHE FRIEDRICH-WILHELMS-UNIVERSITÄT BONN
Scientific project leader	GHANA HEALTH SERVICE
Participating countries	Germany, Ghana, Cameroon, Mozambique, Italy, United Kingdom



RER-CTO

Reinforce the Ethical and Regulatory Ecosystem for the Transformation of Clinical Trials Oversight in Ethiopia, Tanzania and beyond

The RER-CTO project is strengthening clinical trial oversight capacity and harmonising regulatory processes in Ethiopia and Tanzania.

The challenge

It is essential that clinical trials in sub-Saharan Africa are conducted **safely and ethically**. Responsibility for ensuring such conduct generally lies with **national regulatory authorities** and **research ethics committees** (national and institutional). Despite much progress over the past two decades (including multiple capacity-building projects supported by EDCTP programmes), the capacity to oversee clinical trials varies significantly between countries in sub-Saharan Africa.

Although the safe and ethical conduct of clinical trials is a top priority, it is also important that the review of clinical trial applications and the monitoring of ongoing studies are carried out expertly and efficiently to avoid unnecessary delays and to ensure that countries are favoured locations for conducting research. In multiple countries, there remains considerable scope to strengthen the capacity of individual members of research ethics committees and to enhance the efficiency of regulatory and ethics review systems, as well as their coordination.

The project

The RER-CTO project is strengthening capacity, improving efficiency and enhancing coordination across clinical trial oversight structures in Ethiopia and Tanzania, two countries at different levels of maturity but with a shared desire to attract more clinical trial activity.

The project is undertaking a range of activities, including:

- Mapping the **legal and policy frameworks** in the two countries, making comparisons with international standards, and supporting the development of updated legal and policy documents when necessary.
- Supporting the introduction of **digital clinical trial application and monitoring systems** in Ethiopia, which currently relies on manual submissions, and the enhancement of existing electronic systems in Tanzania.
- Mapping **training needs** in the two countries for research ethics committee members and national regulatory authority staff, followed by the development of short courses in clinical trial monitoring and research ethics; one to three courses will be delivered to around 100 individuals.

- Developing **joint clinical trial review guidelines** for national regulatory authority and national ethics committees to ensure coordinated post-approval monitoring, drawing on guidance developed by the African Vaccine Regulatory Forum (AVAREF).

In addition, the project is working to strengthen collaboration and mutual support across the two countries.

The impact

The RER-CTO project will help to significantly strengthen and harmonise regulatory and ethics review capacity in Ethiopia and Tanzania: It will:

- Facilitate the introduction and optimisation of new digital systems to accelerate regulatory and review processes.
- Support harmonised approaches across regulatory and ethics review bodies to improve the efficiency of clinical trial application assessment and monitoring.
- Build expertise in key issues in research ethics and clinical trial oversight in the two countries.
- Generate comprehensive training materials that will be made available to other countries.

Collectively, these activities will make both Ethiopia and Tanzania more attractive places in which to conduct clinical research, increasing clinical trial activity and accelerating the evaluation of new medical interventions.

Project at a glance	
Project duration	1 Jul 2024 - 30 Jun 2027
Total project cost	€926 152,50
Global Health EDCTP3 funding	€926 152,50
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies
Project coordinator	UNIVERSITETET I OSLO
Scientific project leader	ARMAUER HANSEN RESEARCH INSTITUTE
Participating countries	Norway, Ethiopia, Tanzania, Sweden





CT-Luso

Ethics and regulatory capacities Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries

The CT-Luso project is developing ethical review and regulatory capacity specifically in Portuguese-speaking countries in sub-Saharan Africa.

The challenge

Strengthening **ethical review and regulatory capacity** has been a priority for multiple countries in sub-Saharan Africa. As well as protecting the interests of research participants, capacity building will also ensure that countries can offer an attractive environment for conducting clinical research.

Portuguese-speaking countries in sub-Saharan Africa, however, have long been at a disadvantage, because most training materials have been developed in English (or occasionally French). Only limited resources have been produced in or translated into Portuguese. Although stakeholders from these countries have been part of multiple EDCTP capacity-building projects, language barriers prevent them from fully benefiting from such activities.

The EDCTP2-funded **BERC-Luso** project made a significant contribution to developing the capacity of Portuguese-speaking countries in sub-Saharan Africa. All five such countries now have national research ethics committees and national regulatory agencies, although their maturity varies significantly.

The project

The CT-Luso project is correcting this imbalance, working with all five Portuguese-speaking countries in sub-Saharan Africa – Angola, Cabo Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe – to strengthen ethical review and regulatory capacity, and to create opportunities for networking for mutual benefit.

Bringing together 16 institutions across the five countries (plus partners from Europe), the project is undertaking a landscaping analysis to assess deviations from gold-standard practices and the functional maturity of national regulatory agencies (NRAs) and national research ethics committees. Based on these assessments, advanced training will be provided to close knowledge gaps and promote best practices.

National development roadmaps will be developed for each country, focusing on areas such as strengthening national legislation when necessary, and building the capacity of national regulatory agencies, research ethics committees and individual researchers.

The project is working with stakeholders in each country to co-develop the required legislation, development plans and training opportunities. A total of 28 representatives from the five countries, appointed by each country according to their professional specialities, will receive certified post-graduate education and training. A further 100 researchers will receive less intensive training.

Over the medium term, the project team aims to establish the foundation for a cross-country community of practice, connected to regional and global networks. Online discussion forums will support interactions between stakeholders in different countries.

In the long term, the project aims to establish a cluster of countries adopting common practices to attract additional clinical research projects. The project has been engaging political leaders, including ambassadors, from the outset to promote collaboration and capacity-building.

The impact

The CT-Luso project will provide a major boost to clinical research in Portuguese-speaking countries in sub-Saharan Africa. It will:

- Strengthen the legislative basis for clinical research governance in each country.
- Create a cadre of highly trained professionals with expertise in clinical research governance.
- Establish a wider pool of professionals and researchers with knowledge of research oversight and ethical good practice.
- Strengthen and harmonise processes across all five countries.

Collectively, these activities will make Portuguese-speaking countries in sub-Saharan Africa a more attractive location for clinical studies, ultimately increasing the number of studies conducted in these countries.

Project at a glance	
Project duration	1 Sep 2024 - 31 Dec 2027
Total project cost	€997 513,75
Global Health EDCTP3 funding	€997 513,75
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Project coordinator	ORDEM DOS FARMACEUTICOS
Scientific project leader	MINISTERIO DA SAUDE
Participating countries	Portugal, Mozambique, Guinea-Bissau, Cabo Verde, Angola, São Tomé and Príncipe



Other coordination and support actions



NGS4PublicHealth

Leveraging African genomic sequencing platforms for public health impact

The NGS4PublicHealth project is helping to coordinate and provide additional support to a group of projects funded through the Global Health EDCTP3 programme's genomic surveillance initiative.

The challenge

During the COVID-19 pandemic, genome sequencing provided a key tool for understanding the epidemiology of COVID-19 and tracking the evolution of SARS-CoV-2, including the emergence and spread of new variants.

The pandemic led to a significant investment in sequencing capacity in sub-Saharan Africa. However, there are significant opportunities to extend the use of genome sequencing to other pathogens and to strengthen the linkage between genomic surveillance activities and disease control, so that data analysis informs policy and practical action.

The Global Health EDCTP3 programme and the Bill and Melinda Gates Foundation collaborated on a joint call for proposals to strengthen the use of pathogen genomic surveillance in sub-Saharan Africa. This initiative is providing funding to five projects – **EpiGen Ethiopia**, **GenPath Africa**, **GREAT LIFE**, **ODIN** and **PANGenS** – which are applying genomic surveillance approaches to a range of pathogens across different geographic areas.

The project

The NGS4PublicHealth project is carrying out a coordinating role for the other genomic surveillance projects and providing them with access to additional expertise and resources.

It brings together two key bodies:

- The **African Pathogen Genomics Initiative (Africa PGI)**, established by the Africa Centres for Disease Control and Protection (Africa CDC), to promote the use of genomics technologies in disease control in sub-Saharan Africa.
- The **Global Health Network (TGHN)**, an open-access portal providing access to capacity-development resources and a virtual space for collaboration.

Project funding will primarily support a **project coordinator**, based in South Africa, who will liaise with the Africa CDC, coordinate support to the other projects, and promote cross-project collaborations.

Africa PGI and TGHN have been working together to strengthen capacity in genomics and bioinformatics in sub-Saharan Africa, and to promote their use in public health, mostly working through National Public Health Institutes. Key aims include sustaining and growing sequencing capacity in Africa and promoting linkage to clinical and epidemiological data to address key public health questions.

Africa PGI will provide projects with access to additional expertise in pathogen sequencing, the experience of its laboratory network, encompassing 20 African National Public Health Institutes, its existing digital architecture, and technical training opportunities (for example, through its Next Generation Sequencing Academy).

A coordinated approach across projects will help to establish consensus standards, enable projects to document and share best practices, and support the development of communities of practice linked to pathogens or applications of sequencing.

The impact

The NGS4PublicHealth project will ensure that the other genomic surveillance projects are better able to meet their objectives and achieve greater public health impact. It will:

- Increase the literacy of genomics experts in the principles and methods of epidemiology, and of epidemiologists in the use of genomic data.
- Establish communities of practice linked to particular pathogens or applications of sequencing.
- Facilitate sharing of expertise and experience between projects.
- Ensure alignment in data standards and adoption of standardised methodologies.

By linking and coordinating other projects and providing access to additional expertise and resources, the project will magnify the impact of the individual projects, maximising impacts on public health and providing examples of how genomic surveillance can be applied within national public health systems.

Project at a glance	
Project duration	8 Sep 2022 – 7 Jul 2026
Total project cost	€19 507 092,65
Global Health EDCTP3 funding	€50 000,00
Disease area	Emerging or re-emerging infectious diseases
Intervention type	Surveillance tools
Overarching topic	Health security, Digital technologies
Project coordinator	UNIVERSITY OF THE WESTERN CAPE
Participating countries	South Africa, United Kingdom, Ethiopia



EDCTP Africa Office

Strengthening global cooperation and institutional capacities in sub-Saharan Africa to facilitate implementation of the GH EDCTP3 programme

Additional support for the EDCTP Africa Office is ensuring that the programme has a strong presence in sub-Saharan Africa, helping to strengthen regional partnerships and support local capacity building.

The challenge

EDCTP programmes have always operated as 'partnerships of equals' between European and African member states. EDCTP programmes have long had an **Africa Office**, located in Cape Town, South Africa, hosted by the South African Medical Research Council, which together with a European Office is part of the virtual secretariat of the EDCTP Association and acts as a focal point for EDCTP activities in the African region.

The Global Health EDCTP3 is a partnership between the **European Union** (represented by the European Commission) and the **EDCTP Association**, which represents the interests of African and European member states participating in the initiative. The Africa Office is a key component of the activities of the EDCTP Association.

With an increasing number of African countries joining the EDCTP Association, participating in the Global Health EDCTP3 programme, and the scale of funding continuing to grow, it is essential that the Africa Office has the capacity to strengthen and expand its activities in the region for effective impact of the programme.

The project

Additional funding to the EDCTP Association will enable it to maintain a strengthened Africa Office and increase the profile of the Global Health EDCTP3 programme within the African region.

The funding will support a range of activities, including:

- **Strengthening collaborations with key stakeholders** in the African region, including like-minded organisations, other funders, industry and other bodies working in the field with similar aims.
- Facilitating the renewal or development of new **memoranda of understanding with key regional partners**, including the Africa Centres for Disease Control (Africa CDC), Africa Union Development Agency/New Partnership for Africa Development (AUDA-NEPAD), and the WHO African Regional Office.
- Facilitating greater exchange and collaboration across the five **Regional Networks of Excellence and Pandemic Preparedness**.

- Supporting design and implementation of Global Health EDCTP3 funded **capacity-building activities**.
- Organising workshops on **proposal development and grants management**.
- Organising **annual scientific meetings of EDCTP Fellows** from African region.
- Maintaining and promoting use of the **EDCTP Alumni Platform**.
- Contributing to Global Health EDCTP3 **communication and outreach** activities.
- Contributing to the organisation of **EDCTP Forums**.
- Promoting **open science practices** to ensure that new knowledge generated through Global Health EDCTP3 funding delivers the most public benefit globally.

The impact

Funding to the Africa Office will ensure that the Global Health EDCTP3 programme has a strong, visible presence in sub-Saharan Africa. It will:

- Build EDCTP visibility in sub-Saharan Africa and strengthen relationships with key regional stakeholders.
- Support multiple aspects of capacity building in the region.
- Promote linkages and building of South-South, South-North collaborations as well as public-private partnerships.
- Improve the quality of grant applications and efficiency of grants management within African institutions.

Through these activities, the Africa Office will play a key role in ensuring that sub-Saharan African countries continue to be equal partners in the EDCTP partnership and in strengthening the region's research and innovation ecosystem.

Project at a glance	
Project duration	1 Jan 2023 – 31 Dec 2025
Total project cost	€2.953.000,00
Global Health EDCTP3 funding	€2 953 000,00
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Health security, Digital technologies
Project coordinator	EDCTP ASSOCIATION
Participating countries	Netherlands



CTCAN

Clinical Trials Community Africa Network

The CTCAN project is creating an umbrella network connecting existing clinical trial networks in sub-Saharan Africa to provide a comprehensive entry point into the African clinical trial ecosystem.

The challenge

Although the number of **clinical trials** being conducted in sub-Saharan Africa is increasing, it remains low given the size of the region's population and its burden of disease. Multiple barriers exist, including the low visibility of clinical research sites, the fragmented clinical trial landscape, and the limited capacity of many sites. Slow and disjointed regulatory processes may also deter clinical trial sponsors, as may the lack of epidemiological data on target diseases at trial sites.

Several clinical trial networks have been established in sub-Saharan Africa, but none provides a holistic and comprehensive view of clinical trial capacity in the region.

The project

The CTCAN project is creating an overarching umbrella clinical trial network that will link together and extend existing trial networks, providing a single point of entry to a wealth of information about clinical trial sites and laboratories, clinical research expertise, and local epidemiological data on infectious diseases.

It will be founded on the Clinical Trials Community platform, an African-led initiative launched in 2020 to provide an accessible web portal to clinical trial sites in sub-Saharan Africa. This portal provides access to more than 2,000 clinical trial sites and laboratories, plus regulatory information for more than 40 African countries. It provides linkage to clinical trial registries and incorporates epidemiological data from the Global Burden of Disease project.

The CTCAN project is building additional functionalities and integrating information from multiple other clinical trial networks. It will incorporate additional data on trial sites, laboratories and researchers, local disease epidemiology, and materials relevant to local regulatory processes.

It is also creating a **standardised preparedness framework that will allow sites to undertake self-assessments and establish capacity-development plans, drawing on CTCAN's guidance materials, training resources, templates and standard operating procedures (SOPs) relating to quality management systems.**

The project will also provide access to training on regulatory processes, make available clinical trial application software, and explore the potential to provide detailed site reports.

In addition, the project is working with multiple partner networks to develop a region-wide pandemic response plan to expedite clinical research during an emerging outbreak. It will also develop a roadmap outlining the steps required to create a region-wide data-sharing network.

The CTCAN project encompasses a cross-sectoral team, including product development partnerships and major pharmaceutical companies, which are providing tools and resources to support the development of sites' clinical trial capacity.

The impact

The CTCAN project will link together and extend existing clinical trial networks in sub-Saharan Africa. It will:

- Raise the profile of clinical research in sub-Saharan Africa and provide clinical trial sponsors with a single point of entry into the region's clinical trial ecosystem.
- Enable trial sites to benchmark their capacity, generate capacity-development plans, and strengthen capacity through the use of guidance and tools available through CTCAN.
- Create a network for sharing expertise and experience across trial sites.
- Facilitate major multicentre studies, including in response to pandemics.

In a world where countries are competing to host clinical trials, CTCAN will help to make sub-Saharan Africa a more attractive location for clinical research, increase the number of trials conducted in the region, and thereby ensure that African populations gain more rapid access to new medical interventions.

Project at a glance	
Project duration	1 May 2023 - 31 Oct 2025
Total project cost	€2 544 887,38
Global Health EDCTP3 funding	€1 155 462,50
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Overarching topic	Digital technologies, Health security
Project coordinator	NUVOTEQ (PTY) LTD
Participating countries	South Africa, France, United States, Belgium, Spain, United Kingdom



EDCTP Association AO

Strengthening global cooperation and institutional capacities in sub-Saharan Africa to facilitate implementation of the GH EDCTP3 programme

A two-year renewal of funding to the EDCTP Africa Office is enabling it to support and coordinate Global Health EDCTP3-funded capacity-building initiatives, promote partnerships and collaborations, and further raise the profile of the Global Health EDCTP3 programme in sub-Saharan Africa.

The challenge

As of mid-2026, 34 countries in Africa are part of the **EDCTP Association**, the structure that represents the interests of the member states participating in the Joint Undertaking (JU) initiative. The EDCTP Association is managed by a **secretariat** that includes a presence in sub-Saharan Africa – known as the Africa Office.

Hosted by the South African Medical Research Centre (SAMRC) in Cape Town, South Africa, the Africa Office plays a key role in EDCTP operations, liaising with a wide range of regional stakeholders, raising the profile of the Global Health EDCTP3 programme, and strengthening coordination and collaboration across Global Health EDCTP3-funded initiatives.

The operations of the Africa Office are supported through the Global Health EDCTP3 programme through two-year grants, the most recent of which covers the period 2026–2028.

The project

The latest round of funding will enable the Africa Office to continue and extend its work. Priorities include:

- **Proposal development and grants management:** Organising workshops to provide guidance on grant proposal development and grants management. In addition, five **Regional Finance and Operations Contact Points** have been set up at well-established academic centres to support application development and build capacity in grants management.
- **Strengthening regional collaborations:** Engaging with EDCTP Networks of Excellence and Pandemic Preparedness networks to facilitate closer working and promote new collaborations.
- **Regional partnerships:** Contributing to the implementation memorandums of understanding of MoU) with key regional stakeholders, including the Africa Centres for Disease Control and Prevention (Africa CDC) and the WHO Regional Office for Africa including opening discussions for potential MoU with other like-minded organisations working in the sub-Saharan African region.
- **National alignment:** Engaging with member states in Africa to foster closer alignment of national research programmes and facilitating the joining of the EDCTP Association fr countries that are not yet members.
- **Networking and knowledge exchange:** Organising an annual scientific meeting for EDCTP fellows from Africa, EDCTP Networks of Excellence and Pandemic Preparedness and contributing to the development of EDCTP Forums.

- **Linking alumni:** Promoting the EDCTP Alumni Platform and tracking career development, including by enhancing the EDCTP Fellows Alumni Platform and extending linkages to other data sources, such as the Pan-Africa Clinical Trials Registry (PACTR) which is also enhanced and optimised for easy access to its data.
- **Awareness-raising:** Contributing to Global Health EDCTP3 communications activities and raising the profile of its aims, objectives and activities within the African research ecosystem.

The impact

The 2026–2028 Africa Office project will make a major contribution to capacity strengthening in sub-Saharan Africa and to promoting closer alignment of stakeholders active in African health research. It will:

- Strengthen the capacity of institutions and scientists to prepare competitive grant proposals and manage grants effectively in Africa.
- Strengthen EDCTP partnerships with a range of key stakeholders, including national governments, funders, industry and regional public health bodies working in African clinical research ecosystem.
- Raise awareness of EDCTP objectives, activities and impacts in sub-Saharan Africa.
- Strengthen collaborations across EDCTP-funded research programmes and networks in the region.

Collectively, the activities of the Africa Office will help to coordinate and align the activities of multiple bodies, and thereby maximise the impact of the Global Health EDCTP3 programme in Africa.

Project at a glance	
Project duration	1 Feb 2026 - 31 Jan 2028
Total project cost	€2 984 055,73
Global Health EDCTP3 funding	€2 984 055,73
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Project coordinator	EDCTP ASSOCIATION
Participating countries	Netherlands





EDCTP3KHUB

Expansion and consolidation of the EDCTP Knowledge Hub

The KHUB project is expanding and enhancing the EDCTP Knowledge Hub, an online resource offering multiple tools to strengthen capacity-building, improve access to information and facilitate international networking.

The challenge

The ability to conduct high-quality clinical research requires extensive knowledge and expertise. Many researchers and institutions in sub-Saharan African countries without a strong track record in research lack this foundation, which is a major barrier to participation in – and leadership of – clinical research studies.

The [EDCTP Knowledge Hub](#), part of The Global Health Network (TGHN) – an online resource centre focusing on research capacity-building, knowledge exchange and relationship-building in low-resource settings – offers a wide range of training materials and other resources to support capacity-building in sub-Saharan Africa. The TGHN secretariat was recently integrated into the United Nations Office for Project Services (UNOPS).

The Project

The KHUB project is building on the foundation provided by the existing EDCTP Knowledge Hub, extending the range of capacity-building resources available, organising additional activities to strengthen connections between researchers and institutions in sub-Saharan Africa, and creating new ways to promote the diffusion and dissemination of knowledge across regional networks. The project is focusing on five priority areas:

- **Equity, access and inclusion:** Activities are focusing on strengthening research competencies in **marginalised settings** and addressing barriers faced by **women and early-career researchers**. Plans include development of French and Portuguese translation of training materials, mapping of research competency gaps and provision of targeted training, and development of an EDCTP mentorship strategy. The project is engaging with existing training programmes in sub-Saharan Africa focusing on women researchers and will ensure that the perspectives of women and early-career researchers are embedded across all project activities.
- **Research study sponsorship:** Clinical studies require a **sponsor** organisation with legal responsibility for all aspects of a trial. The obligations of trial sponsors are not always well understood, inhibiting the ability of institutions in sub-Saharan Africa to take on this key leadership role. To build awareness and the capacity of institutions to act as sponsors, the KHUB project is developing workshops, guidance and online support, as well as a practical 'how-to' guide to trial sponsorship. A community of practice is being developed, with a forum community platform providing opportunities for peer exchange, while case studies and podcasts will provide institutions with additional materials to draw upon.
- **Community engagement:** Community engagement is increasingly central to clinical research, across the entire study

life cycle from planning and design through to implementation and dissemination of results. The KHUB project is developing a **community engagement resource centre** to showcase good community engagement practice, including guidance materials and case studies. A community engagement toolkit is being developed for EDCTP3 projects. In addition, the project is organising webinars, identifying regional community engagement 'champions', and promoting use of the forum community platform to encourage peer exchange and learning.

- **Good Clinical Practice (GCP):** Conducting international quality trials requires adherence to **International Council for Harmonisation (ICH) GCP standards**. The KHUB project is developing training and implementation support in this area, including workshops, online training modules, case studies and peer learning through the forum community platform. A **'study build' app** is being developed to walk researchers through the steps required to design a high-quality and GCP-compliant clinical study.
- **Knowledge mobilisation:** The KHUB project is organising a range of activities to strengthen collaboration across EDCTP3-supported programmes and networks. **Regional knowledge coordinators** and **digital specialists** are developing a strategy to promote regional networking and information exchange and to enhance the discoverability and accessibility of EDCTP3 project outputs.

The impact

The KHUB project will help to strengthen the capacity of researchers and institutions in sub-Saharan Africa to carry out and lead high-quality clinical research. It will:

- Build capacity of researchers and institutions in countries with under-developed health research systems.
- Enhance the ability of institutions in sub-Saharan Africa to act as clinical trial sponsors.
- Help to embed community engagement within EDCTP3-funded studies.
- Raise awareness of and enhance compliance with the latest ICH GCP standards.
- Strengthen connections between researchers, research programmes and networks in sub-Saharan Africa.

Project at a glance	
Project duration	24 months
Total project cost	€1.000.000
Global Health EDCTP3 funding	€1.000.000
Disease area	Cross-disease or disease unspecific
Intervention type	Cross-intervention or intervention unspecific
Project coordinator	UNITED NATIONS OFFICE FOR PROJECT SERVICES
Participating countries	Switzerland



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