

# EDCTP Update

December 2021



## Highlights

- **2021 End of Year Message from Dr Michael Makanga**
- **World AIDS Day 2021: tackling inequalities**

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**2021 End of Year Message from Dr Michael Makanga**

*“Despite the protracted COVID-19 pandemic, the second EDCTP programme (EDCTP2) has demonstrated laudable resilience and is yielding very tangible results on various fronts. After eight years of implementing the EDCTP2 programme with the cooperation of the many EDCTP partners and constituencies, as well as the fully committed and reliable High Representatives and EDCTP staff, we are enthused to share our progress in the journey so far.”*



— Dr Michael Makanga, EDCTP Executive Director

[Read the full message »](#)

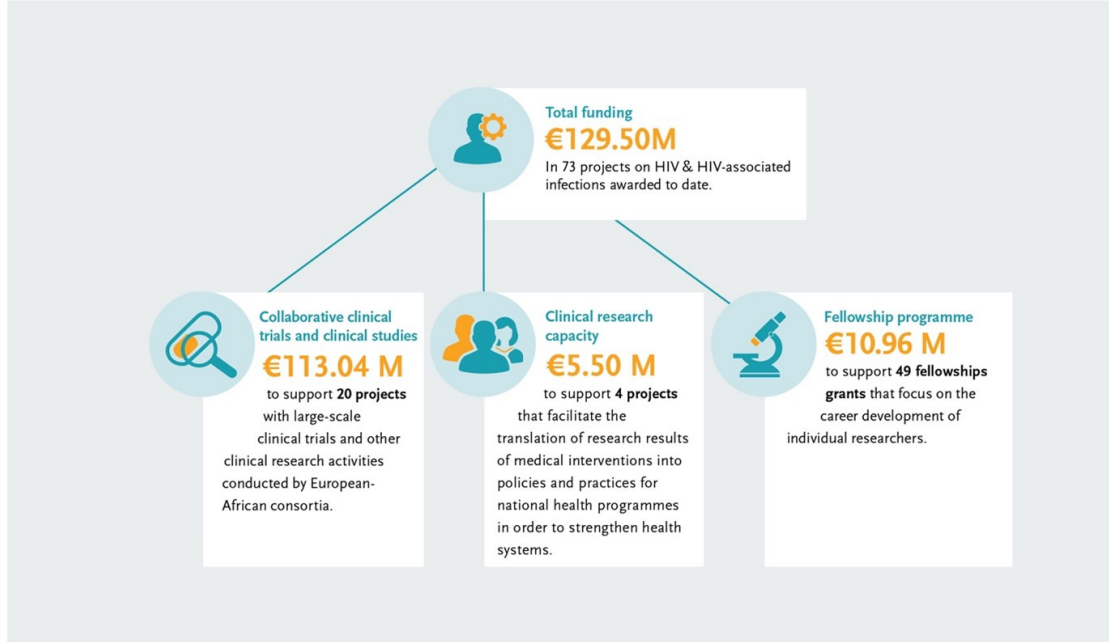
**See the facts & figures in our Summary of achievements 2014–2021**



[Download brochure \(PDF\)](#)

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**World AIDS Day 2021: tackling inequalities**



The COVID-19 pandemic is exposing inequalities ever more clearly. The burden of these inequalities is culminating in an increasing magnitude of vulnerable populations, undermining the wellbeing of our societies. EDCTP therefore is fully committed to this year's World AIDS Day's theme **END INEQUALITIES. END AIDS. END PANDEMICS.** and continues to support research that reduces the burden of disease as well as inequalities. EDCTP believes that integration of activities in different domains is key to achieve this.

[Read the full message »](#)

## Project news

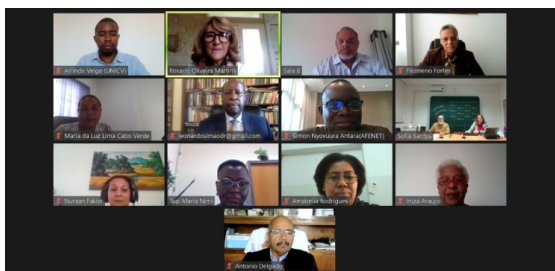
### AfriKADIA Phase II trial in Nature Medicine's '11 clinical trials that will shape medicine in 2022'



The [AfriKADIA consortium](#) Phase III trial on a short regimen to treat the neglected tropical disease visceral leishmaniasis is highlighted in Nature Medicine as one of [11 clinical trials that will shape medicine in 2022](#).

[Read more »](#)

### Master in Field Epidemiology training for Portuguese-speaking West African countries



The inaugural meeting of the first edition of the "[Master in Field Epidemiology Training for Portuguese-speaking West African Countries](#)" (2022-2024) took place in virtual format from 9 to 13 December 2021. The virtual meeting was attended by the EDCTP High Representative Africa, Dr Leonardo Simão and EDCTP Project Officer Nuraan Fakier.

The Master's programme will start in April 2022 and will last for 24 months. The first edition is intended to train 15 staff from the National Health Services (NHS) from three countries: Cape Verde, Guinea-Bissau and São Tomé and Príncipe. The training is funded by EDCTP and the Africa CDC as part of a scheme aiming to [support a total of 150 "EPI-Biostat Fellows" through ten grants awarded to institutions in sub-Saharan Africa and Europe](#). [Read more »](#)

## CAPRISA 012 Phase I trial completed



The CAPRISA 012 SAMBA trial is a Phase I/II trial of subcutaneous administration of monoclonal broadly neutralising antibodies as an immunisation strategy for HIV prevention. The overall goal is to develop a combination of two anti-HIV monoclonal antibodies and a new, safe and effective long-acting HIV prevention technology, principally for women, in order to alter the course of the HIV epidemic in Africa.

The 012A trial (Phase I) that assessed the monoclonal antibodies VRC07-523LS and PGT121 has been completed. All 45 participants have successfully exited the study. There were no safety concerns. All safety data are finalised, and the manuscript is under review for publication. The 012B trial (Phase I) is evaluating the monoclonal antibodies CAP256V2LS and VRC07-523LS and has enrolled to date 42 HIV-negative participants. These participants have been followed up and have all successfully exited the study. There have been no safety concerns. Interim pharmacokinetics analysis demonstrated favourable antibody concentrations. Screening and enrolment into the HIV positive groups is ongoing. [Read more »](#)

## UPTAKE study updates on activities



The UPTAKE study launched its [official website](#) at the start of October. UPTAKE represents a unique multidisciplinary collaboration of five leading research institutions in both Africa and Europe who have come together with the mission to empower choice in HIV prevention technologies for African girls, young women, and female sex workers through behavioural science.

Following completion of community engagement and site identification activities earlier this year, in-depth interviews for Stage 1 of the study are now underway in Kenya and Uganda with adolescent girls and young women, female sex workers, health care providers, and policymakers. The project is also hosting four postgraduate students (two PhD and two MSc candidates) at [KAVI-ICR](#) and [MRC/UVRI & LSHTM Uganda Research Unit](#) under the academic leadership of [LSHTM](#). You can read blog posts from the students on the [UPTAKE study blog](#).

## HIV-CORE 006 Phase I HIV vaccine trial completes volunteer recruitment in time for World AIDS Day

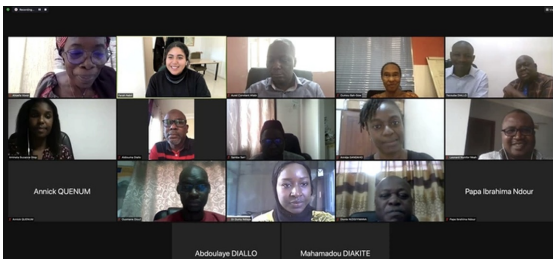
The [Globally Relevant AIDS Vaccine Europe-Africa Trials Partnership \(GREAT\)](#)



announced the [successful completion of recruitment of all volunteers](#) for the Phase I HIV-CORE 006 HIV vaccine clinical trial at four vaccine trials sites in Kenya, Uganda, and Zambia on 1 December 2021, in time for World AIDS Day. This trial aims to evaluate the safety, tolerability, and immunogenicity of the HIV vaccine candidate HIVconsvX, which has been designed to target vulnerabilities common across many HIV-1 variants.

The GREAT project also contributes to infrastructure upgrades and capacity strengthening at the partnering African clinical research centres. Since the [first vaccinations were administered](#) at the Center for Family Health Research in Lusaka, Zambia (CFHRZ) in August 2021, a total of 88 participants have been enrolled and vaccinated within a four-month period. The final enrolments took place at the KEMRI-Wellcome Trust Research Programme in Kilifi, Kenya. As of 1 December 2021, the participant retention rate is 100% and adherence to vaccination and follow-up visits exceeds 95%. The investigators extend their gratitude to all participants for their huge commitment to the success of this trial.

## **BCA-WA ethics II first webinar of the "Biostatistics for ethicists" series – recording and presentation available**



On 30 November 2021, the BCA-WA-ETHICS II project launched its first webinar series entitled "Biostatistics for ethicists" with the objective of strengthening the capacities of ethicists and research evaluators in biostatistics and research methodology.

The webinar was attended by 32 participants from 6 African countries (Benin, Burundi, Cameroon, Guinea-Conakry, Senegal, and Mali). To access the recording and presentation, please visit the [BCA-WA ethics II website](#).

## **IMPALA project first annual meeting**



From 23 to 25 November 2021, the first annual meeting for the IMPALA project (An Innovative Monitoring system for PAediatrics in Low-resource settings: an Aid to save lives) took place in Zomba and Blantyre, Malawi. The consortium discussed the progress that has been made in developing an affordable, durable and user-friendly monitoring system for hospitalised children in low-resource settings. [Read more »](#)

## **ETEC ETVAX project: first ETEC vaccine administered**

The ETEC ETVAX project focuses on developing an inexpensive all-in-one paediatric formulation of ETVAX® and evaluating the new formulation in a Phase



III field efficacy trial against enterotoxigenic *E.coli* (ETEC)-associated diarrhoea in Zambia. Before starting with the Phase III trial, the new formulation is evaluated for immunogenicity and safety in a non-inferiority study comparing the new all in one formulation to the older admix formulation in healthy adult volunteers in Sweden.

This two-armed, non-inferiority study officially started on 15 November 2021, when the First Subject First Dose in the Bridging study (OEV-125) was administered.

## HAT-r-ACC study for sleeping sickness completes recruitment



The HAT-r-ACC consortium is pleased to share that patient recruitment for this study has now been completed in Malawi and Uganda. The main objective of the [HAT-r-ACC project](#), funded by EDCTP and Portuguese Fundação para a Ciência e a Tecnologia (FCT), is to provide clinical data to assess the safety and efficacy of [fexinidazole](#) as a treatment for both stages of *T.b. rhodesiense*. The study will be completed before the end of 2022, once the last patients have had their 12-month follow-up visits. [Read more »](#)

## MAMAH and MA-CoV: updates on participants enrolment



The ongoing MAMAH multi-country study evaluates the safety and efficacy of the antimalarial dihydroartemisinin-piperazine (DP) for intermittent preventive and treatment of malaria in pregnant women living with HIV, which recently completed the enrolment of 667 pregnant women (26 November 2021) in Gabon and Mozambique.

Timely, the first participant of the MA-CoV study (Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations) was enrolled on 25 November 2021 in Lambaréné, Gabon. MA-CoV is a clinical study that will run for 21 months and aims to recruit around 1000 women, leveraging on the MAMAH trial's participants. This trial aims at understanding the COVID-19 burden and natural history among pregnant women living in malaria-endemic areas and areas with high prevalence of HIV infection in sub-Saharan Africa. Other objectives of the study are to characterise clinical presentation of COVID-19 in pregnancy, to evaluate the incidence of infection during pregnancy, and to identify risk factors of maternal and neonatal morbidity and mortality associated with COVID-19 infection, as well as the risk of mother-to-child transmission of SARS-CoV-2.

Visit the [MA-CoV newly launched website](#).

# INTEGRATION kick-off meeting



The INTEGRATION consortium held its kick-off meeting on 22 and 23 November 2021 both in person at Hôtel l'Amitié, Bamako, Mali, and virtually. The INTEGRATION study has the potential to produce a direct benefit in public health impact at both regional and global level, improving the health of expecting mothers as one of the populations most in need by providing evidence-based information. [Read more »](#)

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## Recent events

### **Seventh Annual Science Forum South Africa (SFS21) | 1-3 December 2021**

The Forum was organised by the South African Department of Science and Innovation (DSI) and was also a preparatory event for South Africa's hosting of the World Science Forum in 2022 (WSF 2022) which will take place in Cape Town from 5 to 9 December 2022. EDCTP organised the parallel session *Advancing a collaborative African agenda for global health sciences: Africa – EU global health partnerships*. The session aimed to accelerate the broader discussion on advancing the African agenda for partnerships for global health sciences. [Read more »](#)

### **AERAP Africa-Europe Science Collaboration Platform | 8-9 December 2021**

The AERAP Science organised a series of roundtable discussions to consider the contribution of science to the priorities for the EU-Africa summit, currently scheduled for 17 and 18 February 2022. EDCTP Executive Director Dr Michael Makanga gave a presentation during the Policy Roundtable *How will multi-stakeholder science cooperation support the objectives of the 2022 EU-Africa Summit and ensure a strong policy, legislative and regulatory basis for science in, and cooperation with, Africa*. [Read more »](#)

### **Webinar Pediatric Praziquantel Consortium | 8 December 2021**

EDCTP Executive Director Dr Michael Makanga provided the closing remarks to a webinar of the Pediatric Praziquantel Consortium's which celebrated a major milestone: the completion of the Phase III trial of arpraziquantel – a potential new treatment option for the estimated 50 million preschool-aged children suffering from schistosomiasis. Recordings of the webinar are available via the Consortium's website. [Read more »](#)

### **International Conference on Public Health in Africa (CPHIA 2021) | 14-16 December 2021**

Organised by Africa CDC, the meeting put a spotlight on emergency health response in Africa and allowed participants to share and learn about progress made, best practices in public health interventions and the latest in innovative research. EDCTP was represented in the Conference's Organising Committee. In addition, EDCTP Executive Director Dr Michael Makanga spoke on the response to COVID-19 in Africa to prepare for future health threats, and EDCTP representatives moderated and took part in panels during various tracks of the conference. [Read more »](#)

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## Publications

- *BMJ Open*: [Evaluation of the safety and efficacy of dihydroartemisinin-piperazine for intermittent preventive treatment of malaria in HIV-infected pregnant women: protocol of a multicentre, two-arm, randomised, placebo-](#)

[controlled, superiority clinical trial \(MAMAH\)](#). González R, Nhampossa T, Mombongo G, et al

- *Antibiotics*: [Pharmacovigilance Data as a Trigger to Identify Antimicrobial Resistance and Inappropriate Use of Antibiotics: A Study Using Reports from The Netherlands Pharmacovigilance Centre](#). Jean Marie Vianney Habarugira, Linda Härmark, Albert Figueras
- *Vaccines*: [Using Population-Based Structures to Actively Monitor AEFIs during a Mass Immunization Campaign-A Case of Measles-Rubella and Polio Vaccines](#). Kajungu D, Nambasa V, Muhoozi M, et al.
- *Trials*: [An open-label, randomized, single intravenous dosing study to investigate the effect of fixed-dose combinations of tenofovir/lamivudine or atazanavir/ritonavir on the pharmacokinetics of remdesivir in Ugandan healthy volunteers \(RemTLAR\)](#). Walimbwa SI, Kaboggoza JP, Waitt C, et al.
- *Trials*: [A cluster randomized controlled trial for assessing POC-CCA test based praziquantel treatment for schistosomiasis control in pregnant women and their young children: study protocol of the freeBILy clinical trial in Madagascar](#). Fusco D, Rakotozandrindrainy R, Rakotoarivelo RA, et al.
- *Plos Neglected Tropical Diseases*: [Minimally invasive sampling to identify leprosy patients with a high bacterial burden in the Union of the Comoros](#). Braet SM, van Hooij A, Hasker E, et al.
- *Medicine*: [Predictors of oral pre-exposure prophylaxis \(PrEP\) uptake among individuals in a HIV vaccine preparedness cohort in Masaka, Uganda](#). Kusemererwa S, Kansime S, Mutonyi G, et al.
- *Int J Infect Dis*: [Emergence of new SARS-CoV-2 Variant of Concern Omicron \(B.1.1.529\) - highlights Africa's research capabilities, but exposes major knowledge gaps, inequities of vaccine distribution, inadequacies in global COVID-19 response and control efforts](#). Petersen E, Ntoumi F, Hui DS, et al.
- *Malar J*: [Safety monitoring experience of single-low dose primaquine co-administered with artemether-lumefantrine among providers and patients in routine healthcare practice: a qualitative study in Eastern Tanzania](#). Moshia, D., Kakolwa, M.A., Mahende, M.K. et al.

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## Fellows

Video: 'La statisticienne qui traque le VIH' (Dr Agnes Kiragga)





This video from Leblob features EDCTP Career Development Fellow Dr Agnes Kiragga, who is using machine learning algorithms to identify persons at risk of disengagement from care using routine observational HIV databases in Uganda. Her work has been used to support prevention of mother-to-child transmission of HIV with mothers that disengaged from treatment during and after pregnancy and led to campaigns of male engagement in HIV testing programmes.

## Podcast: From dental surgeon to leader in the field of medical mycology – Dr Beatrice Achan



This video from Leblob features EDCTP Career Development Fellow Dr Agnes Kiragga, who is using machine learning algorithms to identify persons at risk of disengagement from care using routine observational HIV databases in Uganda. Her work has been used to support prevention of mother-to-child transmission of HIV with mothers that disengaged from treatment during and after pregnancy and led to campaigns of male engagement in HIV testing programmes.

## Studentships under EDCTP Career Development Fellow Dr Michael Owusu



Dr Michael Owusu is a Career Development Fellow of EDCTP who got funding to investigate the aetiological agents of respiratory diseases among HIV and non-HIV children in Ghana. Dr Owusu conducted a 4-arm case-control study on HIV and non-HIV children to determine the microbial pathogens that are associated with respiratory infections. His project found that RSV and Influenza A are the main viral pathogens associated with respiratory infections and severe pneumonia among non-HIV infected children. His study also found out that viral-bacterial co-infections could result in severe pneumonia among children.

Additionally, his project supported three students who all worked on various topics highlighted in this project. Two of the students have successfully submitted their thesis and another has passed her dissertation. [Read more »](#)

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## Recently signed grants

### [Career Development Fellowships in poverty-related diseases and child and adolescent health – 2020](#)

- **Maf\_TBprogress** | Dr Baltazar Cá | From latent infection to active disease: understanding the evolution of tuberculosis disease using *Mycobacterium africanum*

infections in Guinea-Bissau

- **PHICAMS** | Dr Gerald Mboowa | Pathogen detection in HIV-infected children and adolescents with non-malarial febrile illnesses using metagenomic next-generation sequencing approach in Uganda
- **HIV-LUNG MICROBIOME** | Dr Alex Kayongo | Microbiome fuels Th17 mediated airway inflammation in COPD among HIV-infected individuals

### Senior Fellowships Plus 2019

- **The RETAIIn study** | Dr Catherine Orrell | Improving RETention and viral load outcomes for people taking Antiretroviral therapy through early Identification of missed doses
- **ESRIFAL** | Prof Samuel Wanji | Exploiting the synergy of registered drugs Rifampicin and Albendazole to shorten the treatment duration of Macrofilaricide for the cure of Onchocerciasis in areas co-endemic with Loiasis: A phase II Clinical Trial study

### Paediatric drug formulations for poverty-related diseases 2019

- **PMC-II** | Prof Kamija Phiri | Combining monthly dihydroartemisinin-piperazine and azithromycin for the post-discharge management of children with severe anaemia in Malawi, Kenya and Uganda; a randomised, double-blind trial

### Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives – 2020

- **GELA** | Dr Tamara Kredo | Global evidence, local adaptation: Enhancing evidence-informed guideline recommendations for newborn and young child health in three countries in sub-Saharan Africa

## Resources



[Collaborative clinical R&D](#)  
online



[Clinical research capacity](#)  
PDF



[Fellowships](#)  
online

- EDCTP | [Knowledge Hub: Tools and guidance for conducting clinical research](#)
- EDCTP | [Guidelines for grantees - Progress report](#)
- EDCTP | [Template for Grant Agreement Annex 5](#)
- ERUDIT | [Planning for Financial Sustainability manual](#)

## Training and funding opportunities

- MAECI and ICGEB: [WE-STAR Fellowships](#)
- BCA-WA-ETHICS II: Conference on research ethics during COVID-19 | 22 – 25 March 2022 in Dakar, Senegal and virtual. [Travel grants are available for African participants from outside Senegal](#) (Deadline: 15 January 2022). [Download the official congress flyer](#).
- BCA-WA-ethics II: [Training research ethics and gender mainstreaming](#) | 17-19, 20 and 26-28, 10:00-12:00 GMT (French) The training is aimed at members of ethics committees and researchers, and is given entirely in French.
- Leprosy Research Initiative (LRI): [call for proposals](#). LRI funds research with a focus on leprosy – including research applications combining leprosy with other neglected tropical diseases (NTDs) or other diseases that share cross-cutting issues with leprosy.

## Mark your calendar

### [1st EU-Africa PerMed Stakeholder Workshop](#) | 9 & 10 February 2022

The EU-PerMed Project, through the Kenya National Commission for Science Technology and Innovation (NACOSTI) is organising its first stakeholder workshop on 9 and 10 February 2022 in Kenya. This workshop, organised as a hybrid event, will bring together a mix of stakeholders to discuss the precision medicine agenda in Africa and ways to strengthen the collaboration with Europe. Prof. Moses Bockaire, EDCTP Director of International Cooperation (Africa) and Head of Africa Office, and Prof. Yazdan Yazdanpanah, Chair of the EDCTP Board will speak at the event.

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*EDCTP Communications thanks the colleagues who provided information for this Update.*

