



## EDCTP Update | November 2022



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### **Strong recommendation for pyronaridine-artesunate in revised WHO malaria treatment guidelines**

Pyramax® (pyronaridine-artesunate), a once-daily, three-day treatment for uncomplicated malaria, has recently been recommended in the World Health Organization's (WHO) guidelines for malaria. Pyramax is a fixed-dose artemisinin-based combination therapy (ACT) and the only one to be specifically indicated for the blood-stage treatment of the two dominant species of malaria parasite: *P. falciparum* and *P. vivax*. The medicine is also

available in a child-friendly granule formulation to ensure palatability and therefore correct dosage in this vulnerable population.

Both Pyramax tablets and Pyramax granules received European Medicines Agency (EMA) positive scientific opinions from the Committee for Medicinal Products for Human Use (CHMP). The studies conducted by the EDCTP-supported West African Network for Clinical Trials of Antimalarial Drugs ([WANECAM](#)) in a [Phase IIIb/IV safety and efficacy study](#) were key in informing EMA's decision to grant a revised product label for Pyramax tablets in 2018. Following the positive scientific opinions for use, a large Cohort Event Monitoring study was implemented in five African countries under the supervision of the EDCTP-supported Central African Network on Tuberculosis, HIV/AIDS and Malaria ([CANTAM](#)) to evaluate the safety and effectiveness of Pyramax under conditions similar to everyday clinical practice. This [study](#), which reported high effectiveness (D28 PCR-adjusted cure rate of 98.6%), included over 8,500 acute malaria episodes in 7,154 patients. Inclusion in the latest version of the WHO guidelines for malaria is a key step towards broader use of the medicine.

[Read more](#)

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## WHO publishes guiding principles for pathogen genome data sharing

When pathogen genome data is shared nationally and internationally, it helps to prevent, detect, and respond to epidemics, pandemics as well as endemic diseases. Inequities in access to new technologies leave blind spots in global surveillance that put us all at risk. The WHO has published [Guiding Principles for Pathogen Genome Data Sharing](#), providing practical assistance to researchers, epidemiologists, and public health officials. It charts a path for timely sharing of pathogen genome data, while acknowledging the legitimate concerns and needs of scientists around the world that are the originators of this data.

[Read more](#)

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## Issues in Product Development survey

The [Stop TB Partnership Working Group on New TB Vaccines](#) (WGNV) is considering providing a platform for the TB vaccine R&D community to share resources and information on TB vaccine product development and to provide opportunities for researchers to connect with each other and with potential partners and collaborators. To make this platform as useful as possible, WGNV is seeking input on what would be most beneficial and helpful to the TB vaccine R&D community. If this is an area of interest to you, please take a few minutes to complete a brief survey and share your views.

[Complete the survey](#)

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## Recent events

### AERAP roundtable on future Africa-Europe collaboration | 16 November 2022

Africa-EU Research Infrastructures (AERAP) organised a [roundtable](#) on the future potential for Africa-Europe collaboration on research infrastructure and related science and

innovation capacity on 16 November 2022. EDCTP Director of International Cooperation Africa & Head of Africa Office Professor Moses Bockarie was one of the speakers of the session "African leadership on research infrastructures".

[Read more](#)

## The Global Health Network Conference | 24–25 November 2022

Under the theme "Enabling Health Research in Every Healthcare Setting", this conference brought together health research teams, organisations, health workers, policy makers and practitioners to explore together how health research can be embedded into every healthcare setting. The conference was hosted by University of Cape Town, South Africa. EDCTP Strategic Partnerships & Capacity Development Manager, Dr Thomas Nyirenda, was a plenary speaker at the conference, presenting on "EDCTP: Connecting and building research excellence across Africa".

[More information](#)

The EDCTP Regional Networks of Excellence together with Developing Excellence in Leadership, Training and Science (DELTA) consortia organised a pre-conference symposium on 23 November 2022 entitled "Enhancing research capacity strengthening: lessons from EDCTP and DELTA consortia". The networks shared their experience of implementing various Theories of Change for research capacity building. Ms Michelle Nderu, EDCTP Project Officer, presented on "Gender and geographical inclusivity in capacity building: Addressing gender and diversity gaps in clinical research capacity".

[More information](#)

## Life Science 2.0 (Stockholm Life Science Conference) | 28 November 2022

On 28 November 2022, the Stockholm Life Science Conference took place under the theme "Life Science in the wake of Covid-19". EDCTP Executive Director Dr Michael Makanga took part in a panel discussion on "Precision medicine & New Generation Clinical trials."

[More information](#)

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## Project news

### AMBITION-cm: Cost and cost effectiveness study



The [AMBITION-cm](#) project published an economic analysis in Lancet Global Health demonstrating the cost and cost-effectiveness of the single, high-dose liposomal amphotericin (L-AmB) regimen for cryptococcal meningitis in five countries in Eastern and Southern Africa. The AMBITION-cm trial results were published earlier this year in New England Journal of Medicine ([NEJM](#)) and found that this new treatment regimen was non-inferior to previous WHO standard of care and associated with fewer adverse events. In this new study, the team developed costing tools for cryptococcal meningitis

management in Botswana, Malawi, South Africa, Uganda and Zimbabwe and presented a cost-effectiveness analysis. The L-AmB was cost-effective and might be even less costly and potentially cost-saving in real-world implementation given the lower drug-related toxicity and the potential for shorter hospital stays. The costing tools are freely available to use or adapt for future research studies and were applied to the resource use of all participants in the trial.

[Read the article](#)

## WANECAM 2: Novel ganaplacide/lumefantrine-SDF combination moves to Phase III



Novartis and Medicines for Malaria Venture (MMV) have announced the decision to progress ganaplacide/lumefantrine-solid dispersion formulation (SDF) into Phase III development for the treatment of patients with acute uncomplicated malaria caused by *P. falciparum* and *P. vivax*. Ganaplacide (previously known as KAF156) is a novel antimalarial compound with a new mechanism of action, and is the partner drug with a new formulation of lumefantrine optimised for once-daily dosing. The Phase III study will be conducted by the West African Network for Clinical Trials of Antimalarial Drugs ([WANECAM 2](#)) consortium. EDCTP is investing EUR 10 million with an additional EUR 1 million from the German Federal Ministry for Education and Research (BMBF) in support of developing this promising novel antimalarial treatment.

[Read more](#)

## LeishAccess: Project launch in Eastern Africa



The Drugs for Neglected Diseases initiative (DNDi) and its partners have launched a three-year project known as LeishAccess that seeks to promote access to treatments for leishmaniasis patients. The project will contribute towards the World Health Organization Neglected Tropical Diseases roadmap targets for the control and elimination of visceral leishmaniasis. The project was launched at a community clinical trial results dissemination meeting in Kacheliba, West Pokot, Northwestern Kenya.

[Read more](#)

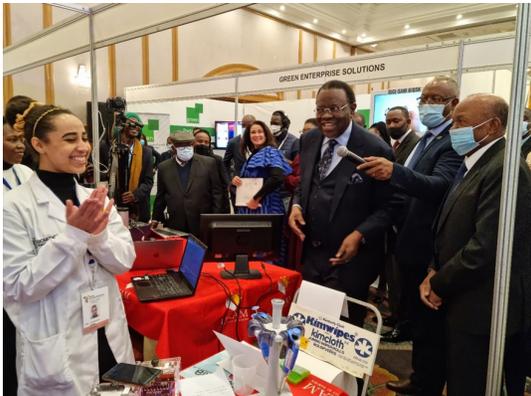
## DIAGMAL investigator meeting



The [DIAGMAL](#) consortium held its first face-to-face investigators' meeting in Mombasa, Kenya on 24 and 25 October 2022. The main objective of the DIAGMAL project is to assess the diagnostic performance of a simplified molecular diagnostic platform for malaria. This diagnostic test circumvents the need for complex DNA extractions, is performed with simple solar-powered equipment and has a dipstick read-out system. Its performance is evaluated in five different malaria-endemic settings across Africa, namely Burkina Faso, Ethiopia, Kenya, Namibia and Sudan. The project also includes research on the cost-effectiveness of the implementation of the platform, works towards registration and pre-qualification of the diagnostic device and includes a strong capacity-building component.

[Read the full article](#)

## DIAGMAL platform introduced at Namibia Fourth Industrial Revolution (4IR) conference



The [DIAGMAL](#) diagnostic platform, a simplified molecular diagnostic platform for malaria, was recently presented at the Namibia Fourth Industrial Revolution Conference ([4IR](#)). This conference aimed to showcase and raise awareness of emerging technologies, and to encourage all sectors to embrace technological solutions. The presentation was delivered by Lydia Eloff and Dr Davis Mumbengegwi of the University of Namibia (a DIAGMAL project partner). The DIAGMAL test attracted much attention, including that of His Excellency Dr Hage G. Geingob, the President of Namibia, who applauded the development of this platform and asked for further development of these type of diagnostics in the field of human and veterinary infectious diseases.

## COVAB study provides vital information to guide Covid-19 vaccine development

As Covid-19 infections spread globally, it was unclear what the effect of a prior coronavirus infection might have on boosting or weakening protection against subsequent infections and disease severity. The [COVAB](#) study set out to collect and



disseminate information on Covid-19 infection in three ways. Firstly, the project compared antibody responses between people in the United Kingdom and Uganda. Secondly, in South Africa, the investigators developed an *ex vivo* challenge model in which nasal and oral tissue that were being removed as part of a routinely indicated operation were experimented on. The researchers attempted to infect these tissues with coronavirus. Thirdly, in South Africa and Uganda, COVAB provided guidance on how to communicate public health messages around Covid-19 research and vaccines for hard-hit communities.

[Read the full article](#)

## POR TB annual meeting



The Prevention of Tuberculosis Recurrence Consortium ([POR TB](#)) held its annual meeting virtually on 15 November 2022. The meeting included presentations from work package leaders and clinical trial sites in South Africa and Tanzania, where the study is conducted. After delays related to the SARS-CoV-2 pandemics, the POR TB Phase II trial to determine efficacy of the multistage vaccine H56:IC31 for prevention of recurrent TB disease is fully enrolled with 831 randomised trial participants. A protocol amendment to extend the project for 21 months was approved by EDCTP. The presentations from clinical trial sites focused on participants' retention, reduction of losses-to-follow-up and ascertainment of clinical trial endpoints. EDCTP Senior Project Officer Dr Michelle Helinski attended the meeting virtually. The POR TB trial results are expected on the first quarter of 2024.

[Read the full article](#)

## PERFECT: Next Generation Sequencing equipment donation by Italian Agency for Development Cooperation



Within the frame of the PERformance Evaluation of Covid-19 Tests ([PERFECT](#))-study, an in-kind contribution of a Next Generation Sequencing equipment was offered by the Italian Agency for Development Cooperation (AICS) to the Chantal BIYA International Reference Centre (CIRCB) in Yaoundé-Cameroon. The PERFECT study evaluates diagnostic performance of molecular and serological tests of SARS-CoV-2 on well-characterised

specimens from Covid-19 infected individuals in West and Central Africa and is coordinated by former EDCTP Career Development Fellow Dr Joseph Fokam. A ceremony for the equipment donation and visit to the PERFECT study project laboratory facility was conducted by the Minister of Public Health of Cameroon, the Italian Ambassador to Cameroon, the AICS Regional Director, the Director General of CIRCB and members of the community. A training workshop was organised in the same month for capacity building of laboratory staff on full-length next generation sequencing and interpretation of whole genome sequencing data.

## TESA III annual meeting



The Trials of Excellence in Southern Africa ([TESA III](#)) Regional Network of Excellence hosted its first General Assembly in Luanda, Angola on 17 and 18 November 2022. The meeting was facilitated by the TESA coordinator, Fundação Manhiça (FM-CISM) in collaboration with Angola Health Research Center (CISA) and National Health Researcher Institute from Angola (INIS).

[Read more](#)

## Core-NB project meeting



The [Core-NB](#) consortium had its second project meeting in Windhoek, Namibia, on 2 November 2022. The consortium aims to answer critical questions concerning Covid-19 disease epidemiology in the context of low-resource countries with a high burden of poverty and high rates of TB and HIV, namely, Namibia and Botswana. Core-NB brings together researchers from the Research Center Borstel (RCB), and the University of Namibia (UNAM) with health experts from Victus Global Botswana Organisation (VGBO) and Health Poverty Actions (HPA). Both VGB and HPA are non-profit organisations (NGOs) working to improve lives through health promotion and economic empowerment. The project, which is in enrolment phase, is highly collaborative and interdisciplinary, with investigators from Namibia and Botswana working closely with colleagues in Europe.

## BCA-WA-ETHICS II: Trainees-led training successfully concluded

Scientists from Benin and Senegal who had



participated in the [gender mainstreaming and research ethics internship](#) at the University of Zaragoza and Aragon research ethics committee have successfully led a refresher version of the 'Research ethics and gender mainstreaming' training programme. The online training took place between 24-28 October 2022, and was attended by 30 participants from eight different countries (Angola, Benin, Central African Republic, Guinea-Bissau, Guinea-Conakry, Mali, Mozambique, and Senegal). The training materials will be published soon.

[Read the full article](#)

## BCA-WA-ETHICS II: Guidelines for ethical review of mental health research protocols



### Guidelines for the ethical review of mental health research protocols from a culturally-sensitive perspective

Mercury Shitindo<sup>1,2\*</sup>, Farah Nabil<sup>3</sup>

The BCA-WA-ETHICS II project has published '[Guidelines for the ethical review of mental health research protocols from a culturally-sensitive perspective](#)' in the African Journal of Bioethics. In most of Africa, mental illness is considered a silent epidemic due to structural and systemic barriers such as inadequate healthcare infrastructure, insufficient numbers of mental health specialists, stigma and discrimination related to mental illness, and lack of access to all levels of care. There is an urgent need to have guidelines that give guidance to research ethics involving mental health participants. The BCA-WA-ETHICS II project created a 54-item assessment tool to guide the process of mental health research protocol evaluation taking into account ethical, gender, and sociocultural factors in Africa.

[Read the guidelines](#)

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## EDCTP Fellows

### Strengthening scientific excellence at Mount Kenya University

There remains a huge human resource deficit in Africa, with many young African scientists moving to high-income countries for cutting-edge education, and remaining there after their training, leading to the so-called "brain drain". The Mount Kenya University (MKU) Directorate of Research and Innovation set out to reverse this and achieve "brain gain" with establishment of



the MKU post-doctoral research programme in 2016. With a strong belief that post-docs are the engine of research, the MKU post-doctoral programme now supports a total of eight post-docs with funding from different bodies. In this guest contribution from former EDCTP Fellow Dr Jesse Gitaka you will read about the efforts undertaken by MKU to retain diverse local scientific talent with support from EDCTP.

[Read more](#)

## MTI-plus project develops Microbial Variance Tracker



Dr David Kateete, a molecular biologist and EDCTP Career Development fellow from Uganda, has developed clinical metagenomic tools with Dr Adrian Muwonge, a collaborator in the United Kingdom. These tools will be used to analyse the bioinformatics data generated by the MTI-plus project: [Microbial variance tracker](#) which allows rapid examination and comparison of samples by their structural variability as well as a [tool](#) that would allow quick viewing of shotgun sequencing data.

[Read more](#)

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## Publications

EDCTP is a member of [Europe PMC](#). This enables EDCTP-funded researchers to share their publications via one central location. Sharing publications by EuropePMC also ensures that they will satisfy the requirements for EDCTP-funded research projects: making publications openly accessible as soon as possible.

[Submit your manuscript through Europe PMC Plus](#)

- *BMJ Open*: [Strengthening ethics committees for health-related research in sub-Saharan Africa: a scoping review](#). Chaudhry I *et al.* (21 November 2022)
- *EBioMedicine*: [Trypanosome spliced leader RNA for diagnosis of acoziborole treatment outcome in gambiense human African trypanosomiasis: A longitudinal follow-up study](#). Ipos Ngay Lukusa *et al.* (December 2022)
- *PLOS One*: [Optimization and validation of an ELISA assay for the determination of antibody responses to CN54gp140 and AIDS-VAX BE for use in the Phase IIb PrEPVacc vaccine trial](#). Gombe B *et al.* (3 November 2022)
- *J Antimicrob Chemother*: [High concordance in plasma and CSF HIV-1 drug resistance mutations despite high cases of CSF viral escape in individuals with HIV-associated cryptococcal meningitis in Botswana](#). Kelentse N *et al.* (2 November 2022)
- *PLOS Negl Trop Dis*: [The acceptability of the AMBITION-cm treatment regimen for HIV-associated cryptococcal meningitis: Findings from a qualitative methods study of participants and researchers in Botswana and Uganda](#). Lawrence DS *et al.* (24 October 2022)
- *AIDS Res Ther*: [Predicting viral load suppression by self-reported adherence, pharmacy refill counts and real time medication monitoring among people living with HIV in Tanzania](#). Ngowi KM *et al.* (15 November 2022)
- *BMC Infect Dis*: [Seroprevalence of SARS-CoV-2 antibodies among children and adolescents recruited in a malariometric survey in north-eastern Tanzania July 2021](#). Lyimo E *et al.* (12 November 2022)

- *Malar J*: [Malaria attributable fractions with changing transmission intensity: Bayesian latent class vs logistic models](#). Mwai K *et al.* (11 November 2022)
- *Trials*: [Intensified tuberculosis treatment to reduce the mortality of HIV-infected and uninfected patients with tuberculosis meningitis \(INTENSE-TBM\): study protocol for a phase III randomized controlled trial](#). Maitre T *et al.* (8 November 2022)
- *Infection*: [Creatine kinase-\(MB\) and hepcidin as candidate biomarkers for early diagnosis of pulmonary tuberculosis: a proof-of-concept study in Lambaréné, Gabon](#). Essone PN *et al.* (8 February 2022)

## Resources

 <p>EDCTP 2014-2020</p>	 <p>EDCTP 2014-2020</p>	 <p>EDCTP 2014-2020</p>
<p><a href="#">Collaborative clinical R&amp;D</a> online</p>	<p><a href="#">Clinical research capacity</a> PDF</p>	<p><a href="#">Fellowships</a> online</p>

- 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](#)
- Europe PMC webinar | [Watch the recording](#) and [download the slides](#)
- TRUST project | [Video introducing the Global Code of Conduct](#)

## Training and funding opportunities

### NIH/NIAID Funding opportunity Announcement (FOA) for the International Centers of Excellence for Malaria Research (ICEMR) programme

National Institutes of Health (NIH)/ National Institute of Allergy and Infectious Diseases (NIAID) have published a Funding Opportunity Announcement (FOA) for the International Centers of Excellence for Malaria Research (ICEMR) programme. The ICEMR is intended to support research that is conducted primarily in countries in which malaria is endemic, and must provide for significant involvement of local/regional researchers in study design, development, and execution.

[More information and deadlines](#)

### AVAREF webinar on conducting multi-country clinical trials in Africa | 15 December 2022

The African Vaccine Regulatory Forum (AVAREF) is organising a webinar for developers

and manufacturers with an interest in conducting multi-country clinical trials in Africa. The webinar will be held through Zoom on 15 December 2022 from 13:00-14:30 UTC/14:00-5:30 WAT & CET. Please note that there is a limit to number of participants.  
[Register in advance](#)

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## Mark your calendar

### **Global Health EDCTP3 exchange meeting for Belgian and sub-Saharan African stakeholders | 5 December 2022 (online)**

The Institute of Tropical Medicine (ITM) Antwerp, Belgium, and the Flemish Ministry of Research, Innovation and Economy are hosting an online exchange meeting on the Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU). The Global Health EDCTP3 partnership will be introduced and perspectives will be shared by participating states. The meeting will be concluded by a discussion and Q&A session.

[More information](#)

### **World Science Forum 2022 | Cape Town, South Africa | 6-9 December 2022**

From 6-9 December 2022, the 2022 World Science Forum (WSF) will be held at the Cape Town International Convention Centre. Under the theme "Science for social justice", participants will be interrogating the role of science in society. Over 1000 people are expected to attend the Forum, which will be held in Africa for the first time. EDCTP Executive Director Dr Michael Makanga, Director of International Cooperation Africa & Head of Africa Office Prof. Moses Bockarie, and Strategic Partnerships & Capacity Development Manager Dr Thomas Nyirenda will attend the meeting.

[More information](#)

### **Conference on Public Health in Africa (CPHIA 2022) | 13-15 December 2022**

The second Annual Conference on Public Health in Africa (CPHIA 2022) will take place in-person from 13-15 December 2022. The conference provides a unique platform for African researchers, policymakers and stakeholders to come together and share perspectives and research findings in public health. On 12 December 2022, a media briefing will take place on [Africa CDC & EDCTP's joint Fellowship programme on epidemiology and biostatistics](#). On 14 December 2022, EDCTP Strategic Partnerships & Capacity Development Manager Dr Thomas Nyirenda and Prof. Rose Leke, Emeritus Professor of Immunology and Parasitology and founder of HIGHER Women Consortium Cameroon, will lead Track 8: "A renewed focus on Africa's major infectious diseases: HIV, TB, Malaria and NTD's". On 15 December, EDCTP Executive Director Dr Michael Makanga will be a speaker at the plenary session on "Increasing Local Production in Africa: Advocacy, Research and Development Capacity in Diagnostics, Therapeutics and Vaccine Manufacturing".

[More information](#)

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*EDCTP Communications thanks everyone who provided information for this Update.*



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