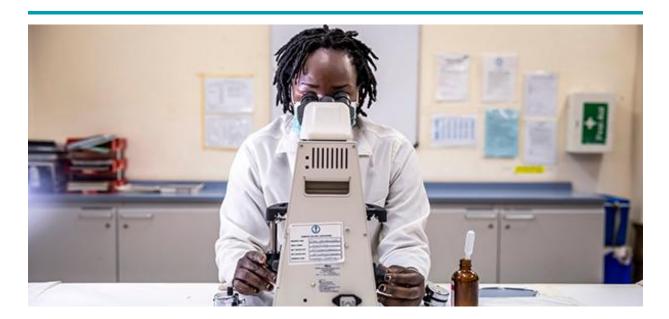


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EDCTP Update | March 2022



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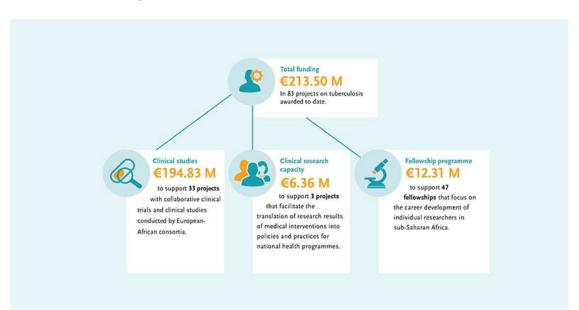
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Single dose of liposomal amphotericin B as effective in treating HIV-associated cryptococcal meningitis as current standard of care



An EDCTP-funded phase III trial of the <u>AMBITION-cm</u> research team confirms that an alternative formulation of amphotericin B, delivered in tiny lipid-based packages (liposomes), would be more suitable for resource-poor settings than the current treatment regimen. The results of the trial, which were published in the New England Journal of Medicine on 23 March 2022, show that a single high-dose liposomal amphotericin B given with 14 days of flucytosine and fluconazole is as good as the current recommended treatment regimen at reducing mortality at 10 weeks and has fewer side effects. These promising results strengthen hope that treatment of one of the most important causes of HIV-associated mortality in Africa can be transformed.

Read more »



World TB Day 2022: EDCTP invests to End TB

On this year's World TB Day, EDCTP joined the global health community in a call to urgently raise investments to achieve the commitments to end TB made by global leaders. Although funding towards TB research and development did not decrease as significantly as expected during the COVID-19 pandemic, it is still below half of the \$2 billion annual financing target committed to by governments at the United Nations General Assembly

High-Level Meeting on TB in 2018. In recognition of this chronic underfunding, EDCTP has made substantial investments in TB research and, together with our partners, recently launched the Global TB vaccine R&D roadmap and published several tools to accelerate TB vaccines R&D.

Read more »

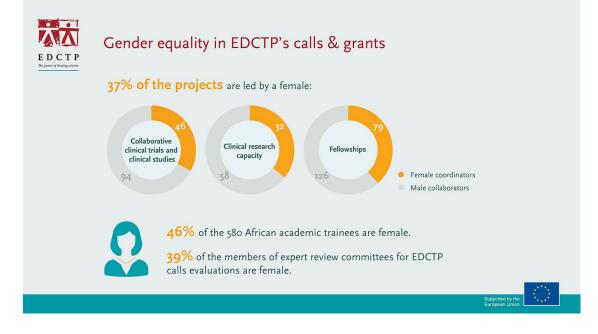
Making EDCTP-funded research open with Europe PMC plus



EDCTP has become a <u>member of Europe PMC</u> (PubMed Central), an open science platform that maintains a worldwide collection of scientific articles and research outputs. Joining Europe PMC enables EDCTP-funded researchers to share their publications via one central location. Sharing publications by Europe PMC ensures that they will also satisfy the requirements for EDCTP-funded research projects: making publications openly accessible as soon as possible. EDCTP's membership of Europe PMC is financed through the Swedish International Development Cooperation Agency (Sida) for a duration of five years.

Europe PMC organised a training webinar for EDCTP grantees on 16 March 2022. You can now <u>watch the recording</u> of the webinar and <u>access the slides</u> that were presented during the session.

International Women's Day 2022: EDCTP efforts to break the bias in health research



On this year's International Women's Day, EDCTP joined the global health community in celebrating women's achievements, raising awareness against bias, and taking action for equality. We celebrate the rising number of female researchers throughout our funded projects and especially in our individual fellowship grants to develop scientific leadership and world-class competitiveness.

Read more »

TRUST project video on Global Code of Conduct for Research in Resource-Poor settings

GLOBAL CODE OF CONDUCT FOR RESEARCH IN RESOURCE-POOR SETTINGS Image: State of the state

The EU-funded <u>TRUST project</u> aimed to counteract 'ethics dumping' or the application of double standards in research by co-developing with vulnerable populations tools and mechanisms for the improvement of research governance structures. In 2018, the 13 partner teams within the consortium developed the Global Code of Conduct (GCC) for Research in Resource-Poor Settings, which was adopted by the European Commission and

EDCTP (a TRUST partner), among others.

In March 2022, the consortium released two new teaching videos. A two-minute <u>GCC</u> <u>overview</u> takes you on the TRUST journey from concept and co-creation to the European Parliament. A second video elaborates on the <u>23 articles of the code</u> with voice-overs provided by members of the TRUST consortium. It is envisaged that these simple tools will greatly enhance the understanding, teaching and dissemination of the code across multidisciplinary research settings globally.

Recent events

AVAREF/MRCT Centre virtual training course on research ethics | 22 March – 14 April 2022

The African Vaccines Regulatory Forum (AVAREF) and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) are hosting a comprehensive <u>virtual training course on research ethics</u>. This is the second 'train-thetrainer' course hosted by AVAREF – MRCT Center and intends to build capacity of individuals currently serving as members and chairs in research ethic committees (RECs), ethicists involved in research ethics review, and ethics educators. The training includes 60 participants from 19 African countries, including Algeria, Benin, Burundi, Cameroon, Congo, Ethiopia, Ghana, Guinea, Kenya, Liberia, Malawi, Mali, Niger, Senegal, South Africa, Tanzania, Uganda, Rwanda and Tunisia. On 22 March 2022, the training kicked off the curriculum with case-based learning and course materials that were developed and vetted by the AVAREF-MRCT Committee for Ethics Training (CET). Dr Thomas Nyirenda, EDCTP Strategic Partnerships and Capacity Development Manager, is a CET member and one of the trainers.

Science|Business event 'Shared vision: What can the Europe – Africa ST&I partnership achieve?' | 29 March 2022

On 29 March 2022, EDCTP Executive Director Dr Michael Makanga was one of the speakers who shared their perspectives and recommended concrete steps on how to further strengthen the EU-Africa strategy for research and innovation. This hybrid meeting, organised by Science|Business network, brought together members of research, industry and policy to explore how to make the most effective use of the resources available, and how the reinforced EU-Africa Research and Innovation partnership becomes sustainable in the long run.

Joint EDCTP-SAMRC event at the SAMRC UHC/NHI Forum Monthly Webinar Series | 31 March 2022

Dr Thomas Nyirenda, EDCTP Strategic Partnerships & Capacity Development Manager, was a special guest at the SAMRC UHC/NHI Discussion Forum on 31 March 2022. The Forum is an open meeting for those interested in developments, learning and collaboration related to the universal health coverage and the national health insurance in South Africa, regionally and globally. At the Forum, Dr Nyirenda addressed EDCTP's ethics and

GAP-f Strategy launch event | 1 March 2022

regulatory systems capacity development in sub-Saharan Africa.

On 1 March 2022, the Global Accelerator for Paediatric Formulations (GAP-f), hosted by the World Health Organization, organised an event to launch its three-year strategy (2022–2024). Ms Lara Pandya, EDCTP Senior Strategic Partnerships Officer, was one of the panellists in a roundtable discussion on "Investing in paediatric medicines to leave no child behind", which considered the value of supporting GAP-f to leverage and expand the impact of ongoing investments and reflected on the challenges and opportunities for GAP-f to catalyse more resources in support of the paediatric medicine's agenda.

Read the GAP-f 2022–2024 strategy » Access the slides from the event » Watch the recording of this event »

6th Global Forum on Tuberculosis Vaccines | 22-25 February 2022

EDCTP was a silver sponsor of the 6th Global Forum on Tuberculosis Vaccines in Toulouse, France from 22 - 25 February 2022. EDCTP Executive Director Michael Makanga co-chaired a plenary session entitled "Issues in clinical development of new TB vaccines", that covered a number of timely topics in clinical research, including a newly developed roadmap for development of TB vaccines in people living with HIV, assessing non-specific effects of new TB vaccines during clinical development, the impact of targeted preventive therapy on clinical trial design, strategies for effective community engagement, and modeling costeffectivenes of routine immunisation of adolescents, a key population for new TB vaccines. In addition, several oral and poster presentations were provided by the EDCTP-funded trials of the <u>POR-TB</u> consortium and <u>MTBVAC</u>.

Project news

PEDVACiNTS first annual meeting



The <u>PEDVAC-iNTS</u> consortium held its first annual consortium meeting on 2 March 2022. PEDVAC-iNTS is a public-private consortium of seven partners who aim to advance a novel vaccine against Invasive non-typhoidal salmonellosis (iNTS) a paediatric phase I/II study in Ghana. The project discussed the project's progress and plans.

Read more »

Uppsala Monitoring Centre #DrugSafetyMatters podcast on PROFORMA



Professor Eleni Aklillu and Dr Abbie Barry of <u>PROFORMA</u>, an EDCTP-funded project on pharmacovigilance in East Africa, were the first external guests in Uppsala's Monitoring Centre #DrugSafetyMatters podcast on 'Advancing pharmacovigilance in Africa'. This in-depth episode explores among others specific pharmacovigilance challenges in the East African region and how to improve collaboration among public health programmes, academia and pharmacovigilance regulatory bodies.

Listen to the podcast »

CANTAM3 steering committee meeting

The Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM) Regional Network of Excellence held its first in-person steering committee meeting in Dubai, United Arab Emirates on



23 - 24 February 2022. The aim of the meeting was to evaluate the first seven months of phase 3 of the grant (July 2021 – February 2022). The travel restrictions that were in place during the COVID-19 pandemic have impacted the implementation of the consortium's activities in the field. The meeting enabled the consortium's members to put in place corrective actions required to ensure smooth implementation of the project and to explore new opportunities for collaboration with institutions of various countries.

Read more »

BCA-WA ETHICS II: White Book of recommendations for gender mainstreaming in NRECs in West Africa

LIVRE BLANC

RECOMMANDATIONS POUR L'INTÉGRATION DU GENRE DANS LES COMITÉS NATIONAUX D'ÉTHIQUE DE LA RECHERCHE D'AFRIQUE DE L'OUEST



The **BCA-WA ETHICS II** project (Building the capacities of West Africa in research ethics) has published a White Book of recommendations on gender mainstreaming for West African national research ethics committees (NRECs). The White Book presents practical recommendations for gender mainstreaming in NREC governance, organisational culture, education programmes for members and local researchers, and the monitoring and evaluation of gender mainstreaming interventions, especially those included in an institutional gender equality plan. It is expected to be the cornerstone document for all Francophone West African ethics committees.

Read the White Book (PDF, in French)

BCA-WA ETHICS II: Third scientific congress on research ethics during COVID-19



On 22 - 25 March 2022, the BCA-WA ETHICS II project organised its third scientific congress on research ethics during the COVID-19 pandemic. The conference was attended by 40 African and European scientists, bioethicists, and gender experts representing 11 different countries and National Research Ethics Committees. The contributions and exchanges highlighted the need for capacity-building in research ethics review and regional harmonisation of health research evaluation, particularly during health emergencies. The congress report and book of abstracts will be available

soon!

Read more »

BCA-WA ETHICS II webinar on sex and gender data visualisation

Live webinar

Sex and gender data visualization for health research: part l

In this webinar, we are going to learn the fundamentals of the GBDcompare software, developed by the University of Washington. We will use it to retrieve and visualize sexdisaggregated data related to health research.



The BCA-WA ETHICS II project organised a webinar on 'Sex and gender data visualization for health research: part I'. The webinar was held in French on 8 March, and in English on 9 March. The webinar focused on the fundamentals of the GBDcompare software developed by the University of Washington to retrieve and visualise sex-disaggregated data related to health research.

More information (English) More information (French)

WANECAM-2 second annual meeting



The WANECAM-2 consortium held its second annual investigators meeting at the Centre de Recherches Médicales de Lambaréné (CERMEL) in Lambaréné, Gabon on 15 - 16 March 2022. The main meeting objective was to provide updates on clinical trials of a novel antimalarial combination comprising KAF156 (ganaplacide) and lumefantrine (LUM-SDF) in a once-daily formulation in four participating African countries: Burkina Faso, Gabon, Mali and Niger. KAF156 has demonstrated the potential to treat resistant malaria and to be administered as a single dose. Progress was discussed in the phase II trial per study site and the preparation of the phase III study protocol. The meeting was attended by 40 investigators, including representatives from Novartis, the Medicines for Malaria Venture (MMV) and EDCTP (virtually).

Read more »

SPaRCS project team meeting



After almost two years of working together, the Strengthening pharmacovigilance and regulatory capacities in four Southern African countries (SPaRCS) project team met for their first in-person meeting in Cape Town from 16 -18 March 2022. SPaRCS is a three year project which aims to strengthen pharmacovigilance (PV) systems and clinical trials oversight of

national regulatory authorities (NRAs) in Eswatini, Namibia, South Africa, and Zimbabwe. The project started in April 2020, just after the COVID-19 lockdown came into force. Fortunately, access to digital technologies enabled the team to meet many of their project milestones during this time.

Read more »



LusoAfro-BioEthics ethics for health research course

From 14 - 18 March 2022, the <u>LusoAfro-BioEthics</u> project organised a virtual course on ethics in health research. The course covered, among others, the history of ethics in health research and the legislative framework in the PALOP (Portuguese speaking African countries or Países Africanos de Língua Oficial Portuguesa) countries, and the functioning of and the documents to submit to the ethics committees in Angola, Cape Verde, Guinea-Bissau, Mozambique, Portugal and São Tomé and Príncipe. EDCTP's High Representative for Africa, Dr Leonardo Simão opened the course.

Read more (PDF)

Publications

- DSW: In conversation with Prof. Francine Ntoumi. (3 March 2020)
- J Antimicrob Chemother: Effect of dihydroartemisinin/piperaquine for malaria intermittent preventive treatment on dolutegravir exposure in pregnant women living with HIV. Clifford G. Banda *et al.* (15 March 2022)
- Expert opinion on drug metabolism & toxicology: An update on pharmacogenetic factors influencing the metabolism and toxicity of artemisinin-based combination therapy in the treatment of malaria. L Pernaute-Lau *et al.* (14 March 2022)
- Malaria Journal: <u>A single low dose of primaquine is safe and sufficient to reduce</u> <u>transmission of *Plasmodium falciparum* gametocytes regardless of</u> <u>cytochrome P450 2D6 enzyme activity in Bagamoyo district, Tanzania.</u> RO Mwaiswelo *et al.* (12 March 2022)
- Malaria journal: <u>Resurgent and delayed malaria</u>. B Greenwood *et al.* (9 March 2022)
- BMC research notes: <u>Plasma Neuron-Specific Enolase is not a reliable biomarker</u> <u>for staging Trypanosoma brucei rhodesiense sleeping sickness patients.</u> CD Kato et al. (7 March 2022)
- Mbio: Broad Neutralization of SARS-CoV-2 Variants, Including Omicron, following Breakthrough Infection with Delta in COVID-19-Vaccinated Individuals. T Lechmere et al. (17 March 2022)
- Wellcome Open Res: <u>Maintaining laboratory quality assurance and safety in a</u> <u>pandemic: Experiences from the KEMRI-Wellcome Trust Research Programme</u> <u>laboratory's COVID-19 response.</u> H Gumba *et al.* (16 March 2022)
- Front Immunol: Phenotype definition for 'resisters' to Mycobacterium

tuberculosis infection in the literature – a review and recommendations. J Gutierrez *et al.* (25 February 2021)

- IJID: World TB Day 2022: Revamping and Reshaping Global TB Control <u>Programs by Advancing Lessons learnt from the COVID-19 pandemic</u>. E. Petersen *et al.* (3 March 2022)
- Lancet Infect Dis: World Tuberculosis Day 2022: aligning COVID-19 and tuberculosis innovations to save lives and to end tuberculosis. F Ntoumi et al. 3 March 2022)
- Lancet Respir. Med.: Making a case for investing in post-tuberculosis lung health in children. E Nkereuwem et al. (23 March 2022)
- Nature: African leadership improves trust in malaria drug trial (10 March 2022)
- Global Health: Science and Practice: <u>Funders' Perspectives on Supporting</u> <u>Implementation Research in Low- and Middle-Income Countries</u>. A Cardoso-Weinberg *et al.* (March 2022)

Recently signed grants

<u>Clinical Research and Product Development Fellowships (CRDF) – Joint call with</u> <u>WHO/TDR, the Special Programme for Research and Training in Tropical Diseases</u> <u>2019</u>

- **Fellow:** Dr Adebanjo Adegbola (Nigeria) | **Host organisation:** KEMRI-Wellcome Trust Research Programme, Kenya
- Fellow: Mr Aloye Costantine (Tanzania) | Host organisation: European Vaccine Initiative, Heidelberg, Germany
- Fellow: Ms Norah Mawoko (Botstwana) | Host organisation: Pfizer

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 | <u>Planning for Financial Sustainability manual</u>
- Europe PMC webinar | <u>Watch the recording</u> and <u>download the slides</u>

• TRUST project | Video introducing the Global Code of Conduct

Training and funding opportunities

- <u>BCA-WA ETHICS & AVAREF training on clinical trial protocol evaluation</u> (<u>French</u>) | 5, 6 and 8 April 2022 | 11:00-14:00 CET Formation virtuelle sur les outils AVAREF pour l'évaluation des protocoles de recherche Clinique The EDCTP-funded project 'Building the capacities of West Africa in research ethics' (BCA-WA ETHICS) and AVAREF are organising an online training on AVAREF tools for the evaluation of clinical research protocols. Members of ethics committees and national regulatory authorities and health researchers based in Africa are invited to attend this training.
- Bioethics MSc and PhD/postdoctoral training programmes (Fogarty International Center) The Fogarty International Center has re-issued the funding announcements for international bioethics training programmes at the masters or PhD/postdoctoral level aimed at research intensive institutions and scholars in low and middle-income countries (LMIC):

International Research Ethics Education and Curriculum Development Award (masters level training) » International Bioethics Research Training Program (PhD/postdoctoral level) »

Mark your calendar

Donald Mackay Medal talk: Professor Eleni Aklillu | 6 April 2022, 13:00-13:45 CET (Virtual)

In this webinar, Professor Eleni Aklillu's Donald Mackay Medal talk will cover the topic 'Treatment optimization of major tropical infectious diseases with a focus on sub-Saharan Africa population: Role of genetic variations and environmental factors'. Prof. Aklillu is a current member of the Swedish Research Council's Committee for Development Research, Scientific working group for WHO-TDR, Fellow of The Royal College of Physicians Edinburgh and Fellow of The African Academy of Sciences, and former vice-chair of the Strategic Advisory Committee for EDCTP.

Read more »

BRCCH webinar: Community-based COVID-19 testing in Lesotho and Zambia | 27 April 2022, 15:30-17:00 CEST (Virtual)

The Botnar Research Centre for Child Health (BRCCH) cordially invites you to join an online webinar looking at Community-based COVID-19 testing in Lesotho and Zambia. This event will highlight research progress of the collaborative project between Dr Kwame Shanaube (Zambart) and Dr Klaus Reither (Swiss TPH) on the effects of community-led interventions in the COVID-19 epidemic in Lesotho and Zambia. This is one of three projects funded through a partnership between the BRCCH and EDCTP on a new joint initiative to support multi-national collaborations for research to mitigate COVID-19, particularly in low- and middle-income countries.

Read more about and register for the event » Read more about the BRCCH-EDCTP Collaboration Initiative »

EDCTP Communications thanks everyone who provided information for this Update.

