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EDCTP Update | May 2024



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WHO includes new paediatric treatment option for preschoolers with schistosomiasis in the list of prequalified medicines



Following the <u>positive scientific opinion by the European Medicines Agency</u> in December 2023 for arpraziquantel to treat schistosomiasis in preschool-aged children (3 months to 6 years of age), the EDCTP-funded <u>Pediatric Praziquantel Consortium</u> achieveved another important milestone in May 2024: the World Health Organization (WHO) has now included arpraziquantel in its <u>List of Prequalified Medicines</u>.

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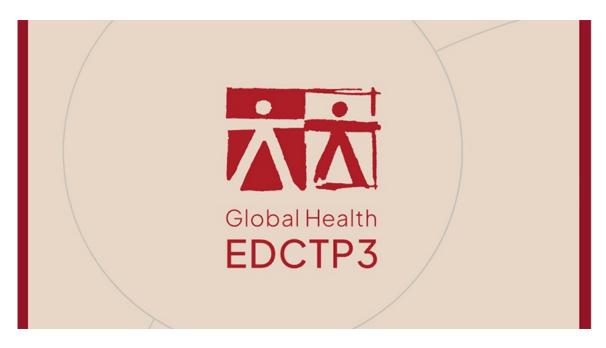
'The Lancet Global Health in conversation with' podcast with Dr Michael Makanga and Prof. Kara Hanson

THE LANCET Global Health in conversation with



Zoë Mullan, Editor-in-Chief of The Lancet Global Health, talked to Professor Kara Hanson of the UK's National Institute for Health and Care Research and Dr Michael Makanga, Executive Director of Global Health EDCTP3, on funding for research involving collaborators in the Global North and Global South and how it can be made more equitable. In the podcast series 'The Lancet Global Health in conversation with,' Editors at The Lancet Global Health, converse with the journal's authors, explore their latest research

Global Health EDCTP3 overall budget increases to €1.86 billion



Global Health EDCTP3 budget grows from €1.6 to €1.86 billion, following an increase of the European Union (EU) and EDCTP Association contributions. Part of the additional budget will be used to support research activities under the 2024 Work Programme.

On 24 May 2024, the Horizon Europe Steering Board approved an increase of the EU financial contribution to Global Health EDCTP3 of €110 million. This raises the overall EU financial contribution to the programme to up to €910 million.

In parallel, the EDCTP Association has increased its contribution to the programme to reach €550 million. Efforts are also being made to raise €400 million through third-party contributions.

The additional funding will have a direct impact on the <u>2024 Work Programme</u> actions, including the <u>Mpox emergency call</u> launched on 30 April to respond to the ongoing Mpox outbreak in the Democratic Republic of Congo (DRC).

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Recent events

Seminar: The journey towards a strengthened and self-reliant African Clinical Trials Ecosystem: EDCTP 20-year experience



On 27 May 2024, Dr Thomas Nyirenda, Strategic Partnerships & Capacity Development Manager and Head of Africa Office, EDCTP Association, participated in a seminar organised by ICGEB International to present the work of the EDCTP programme and to build a case for continued wide support to realise a strengthened and self-reliant African Clinical Trials Ecosystem. The ICGEB International Seminar Programme organises scientific seminars held by international experts from its three locations in diverse fields of the Life Sciences. Lectures are made available for free to PhD and Postdoc students at ICGEB, and to the scientific community at large.



PREPARED Amsterdam Plenary

On 21-23 May 2024, 16 global partners and advisors from the PREPARED research ethics and research integrity consortium met at the Amsterdam University Medical Centre headquarters. Dr Michelle Singh, Project Officer, represented EDCTP at the meeting. Highlights included the launch of an interactive app for ethics in times of crisis, deliberation on the first draft of the PREPARED code for research conduct during pandemics, and the launch of a book on Vulnerability by Professor Doris Schroeder and colleagues. The book challenges the protection-inclusion dilemma in research ethics and presents a community engagement toolkit for leaving no one behind in research. A review of the book by Dr Singh, as well as a link to download the book, are available on the <u>PREPARED website</u>. The <u>interactive app for ethics in times of crisis</u> launched at the meeting is designed to be informative and scientifically grounded whilst challenging the users to question their assumptions and potentially come to new conclusions. The app currently contains three case scenarios and one short course, 'Ethics in 45 minutes'. In the case scenarios, you can reflect on human challenge trials, the use of AI in crisis situations and difficult decisions for research ethics committees during COVID-19. Over the Northern hemisphere summer, two more case studies and an additional short course called 'The TRUST Code in 30 minutes' will be added.



11th HIV Prevention Workshop

On 24-26 April 2024, the Centre for the AIDS Programme of Research in South Africa (CAPRISA), African Health Research Institute (AHRI), HIV Pathogenesis Programme (HPP) and the Ragon Institutes of Massachusetts General Hospital, Harvard, and MIT co-hosted the 11th HIV Prevention Workshop in Drakensberg, South Africa. This workshop brought together a group of leaders in HIV and tuberculosis (TB) prevention research to discuss recent advances, exchange ideas and advance international collaborative studies. The first session addressed the progress in HIV prevention and the roadblocks facing the global goal of ending AIDS as a public threat by 2030. Among the notable advances in the formulation of pre-exposure prophylaxis (PrEP) was the EDCTP2-funded phase I CAPRISA 018 trial, which presented the first in human safety, pharmacokinetic, acceptability and tolerability data on the use of tenofovir alafenamide formulated as a sub-dermal implant. The closing panel discussed the HIV vaccine landscape in the next 5 years. Additionally, the workshop highlighted the importance of international collaboration, building the capacity of young African researchers to compete in a global landscape, and continued funding investments in HIV research. Phindile Ximba, Research Administration Fellow, represented EDCTP at the workshop.

EDCTP2 project news

PEP4LEP presented at LRI meeting

On 30 May 2024, the Leprosy Research Initiative (LRI) held the online event 'Highlights of LRI Spring Meeting',



showcasing six high-impact LRI projects. A presentation from the EDCTP-funded PEP4LEP project was selected for this online session. The project is a highly practical implementation study comparing two possible approaches for screening and identifying people at risk of developing leprosy. The PEP4LEP project was also presented during the LRI Spring Meeting on 17-19 April 2024 by Ephrem Mamo, PhD student in the PEP4LEP project in Ethiopia. In the recent PEP4LEP, Ephrem Mamo, Lara Pandya, Strategic Partnerships (North) and **Communications Manager, EDCTP** Association, and Suzan Trienekens, Coordinator of LRI, shared their reflections on the LRI Spring Meeting.

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WANETAM: Research ethics training in Togo



The WANETAM Networks of Excellence organised in Lome, Togo for a five-day research ethics training from 20-24 May 2024. Bringing together 18 participants from across West Africa, the training aimed to develop review capacities and capabilities of ethics review boards and committees within the WANETAM Network, harmonising policies and procedures and supporting member institutions to effectively deal with ethical issues, especially during pandemics. Supported by EDCTP, the training helped boost participants' understanding of research ethics to better support medical research including clinical trials in their various institutions and beyond.

Dr Christabel Khaemba's PhD Journey in implementing pharmacovigilance within the neglected tropical diseases program in Kenya



Meet Dr Christabel Khaemba, a doctoral student at Karolinska Institutet, Sweden, with a PhD project entitled "Active Safety Surveillance of Drugs Used in Lymphatic Filariasis Control Programme in Kenya." as part of the EDCTP-funded <u>PROFORMA</u> <u>project</u>. Dr Khaemba serves as the Principal Regulatory Officer and Head of Pharmacovigilance at the Pharmacy and Poisons Board, Kenya's national medicine regulatory agency. She has played a pivotal role in coordinating and participating in the development and implementation of Kenya's pharmacovigilance system. She also serves as the Principal Investigator in

the PROFORMA project, representing the Pharmacy and Poisons Board.

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PediCAP: Four-day antibiotic treatment shows promise for childhood pneumonia in Africa



The PediCAP consortium, a global partnership of 14 institutions, presented promising results from its main trial at the ESCMID Global conference held on 27-30 April 2024, in Spain. The PediCAP-A trial enrolled over 1,100 children with severe pneumonia aged 2 months to 6 years across five countries. The trial explored a safe and effective transition from injectable to oral antibiotics once a child had clinically improved. The study found that a total of four days of antibiotic treatment, encompassing both the initial injectable phase and the subsequent oral phase, is generally sufficient for recovery. This allows for earlier discharge from hospitals, alleviating the strain on families and healthcare systems.

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Data from DIAMA project contributes to the endorsement of TB test by WHO



Results of the DIAMA project contributed to the endorsement of a new TB diagnostic test in the latest WHO consolidated guidelines on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis detection. The DIAMA project, which brings together groups in nine sub-Saharan African countries, focuses on the diagnosis and management of patients with multidrug-resistant TB (MDR-TB). The Deeplex[®] Myc-TB test uses targeted Next Generation Sequencing to predict drug resistance of MTBC strains. The consortium implemented this test in reference labs in Benin and Rwanda and the generated data from sputum samples collected in six different African countries contributed to its endorsement by WHO.

Stool4Tb, PreFIT and CAGE-TB join forces for the second consecutive year

For the second year in a row, three EDCTPfunded projects on tuberculosis diagnostics, <u>Stool4TB</u>, <u>PreFIT</u> and <u>CAGE-TB</u>,



joined forces and held their annual consortium meetings in the same week. This led to multiple benefits: increased efficiency (with several staff members collaborating on one or more projects), sharing ideas at networking events, and creating synergy. A highlight of the week was the joint PhD symposium where 9 PhD students presented their research to each other, their supervisors, and staff across all three projects. This led to a fruitful exchange of ideas and plans for further collaboration. Different training activities were organised as side sessions of the annual meetings, which included introductory training on health economics, a scientific writing workshop and a state-ofthe-art TB treatment lecture by Professor Christoph Lange. As all three projects are moving into their final stages, there was exciting science and upcoming dissemination activities to discuss.

Community engagement: a bridge to increasing uptake of IPTp-SP to prevent malaria in pregnancy



The Revive-IPTp project has published a blog post highlighting the project team's work towards empowering communities and pregnant women for healthier pregnancy outcomes. The Revive IPTp project aims to use a policy implementation framework to achieve increased use of IPTp in Kenya, in line with national health policy, by engaging with a range of national stakeholders. The project has recently released a video describing the approaches being used to empower pregnant women through self-care and work with community members to increase the uptake of sulfadoxine-pyrimethamine. Click here to watch the video.

DIAGMAL progress meeting: first results of evaluation new diagnostic platform for malaria presented.



Mobile team of the University of Namibia is conducting a malaria survey in the north of the country

The DIAGMAL consortium held its project progress meeting in Amsterdam, the Netherlands on 11-12 April 2024. The project aims to evaluate the performance of an innovative simple molecular diagnostic test for malaria in different field settings. Three countries (Burkina Faso, Namibia and Kenya) have now completed all recruitments and over 3,000 clinical samples have been tested with the new platform and with routine diagnostic tests in place (RDT and/or microscopy). Currently, reference testing with qPCR is

taking place to determine the diagnostic performance of the DIAGMAL test. Furthermore, the first outcomes of the health economy assessment were also presented and discussed.

Two new Institutional Review Board offices opened



As part of its deliverables, the Botswana Clinical Trials Regulation (BoCTRe) project has successfully trained and established two Institutional Review Board (IRB) offices for Ngamiland District at Letsholathebe Primary Hospital and for Mahalapye District at Mahalapye Primary Hospital in Botswana.

Prior to this activity, IRB trainings were conducted to capacitate committee members on research and ethics governance. These trainings covered topics like ethical principles in research, informed consent, protection of human participants, research misconduct and regulations.

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Publications

EDCTP is a member of <u>Europe PMC</u>. 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. <u>Submit your manuscript through Europe PMC Plus</u>.

- The Lancet. Global Health: <u>Post-exposure prophylaxis in leprosy (PEOPLE): a cluster</u> randomised trial. Hasker, E, et al. 1 June 2024
- PLOS Global Public Health: <u>Comparing patterns of recent and remote</u> <u>Mycobacterium tuberculosis infection determined using the QuantiFERON-TB Gold</u> <u>Plus assay in a high TB burden setting</u>. Amofa-Sekyi, M, et al. 20 May 2024
- PLoS One: Experience of healthcare personnel on Co-payment mechanism and the implications on its use in private drug outlets in Uganda. Ocan, M, et al. 17 May 2024
- PLOS Global Public Health: <u>Defining a malaria diagnostic pathway from innovation</u> <u>to adoption: Stakeholder perspectives on data and evidence gaps.</u> Simmons, B, et al. 16 May 2024
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- PLOS Global Public Health: XBB.1, BQ1.1 and atypical BA.4.6/XBB.1 recombinants predominate current SARS-CoV-2 Wavelets with flu-like symptoms in Cameroon: A snapshot from genomic surveillance. Fokam, J, et al. 10 May 2024
- The Journal of Infection: <u>Baseline and end-of-treatment host serum biomarkers</u> predict relapse in adults with pulmonary tuberculosis. Mutavhatsindi, H, et al. 9 May 2024
- JCI Insight: <u>Immune responses associated with protection induced by</u> <u>chemoattenuated PfSPZ vaccine in malaria-naive Europeans.</u> Mouwenda, YD, et al. 8 May 2024

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- Plos Neglected Tropical Diseases: <u>Simplified molecular diagnosis of visceral</u> <u>leishmaniasis: Laboratory evaluation of miniature direct-on-blood PCR nucleic acid</u> <u>lateral flow immunoassay.</u> van Dijk, NJ, et al. 7 May 2024
- Pharmacogenomics and Personalized Medicine: <u>Association of the Reduced</u> <u>Function Met420del Polymorphism of SLC22A1 with Metformin-Induced</u> <u>Gastrointestinal Intolerance in Ethiopian Patients with Type 2 Diabetes Mellitus</u>. Degaga, A, et al. 3 May 2024
- International Journal of Infectious Diseases: <u>Integrating molecular and radiological</u> <u>screening tools during community-based active case-finding for tuberculosis and</u> <u>COVID-19 in southern Africa.</u> Scott, AJ, et al. 1 May 2024
- BMJ Open: <u>Novel point-of-care cytokine biomarker lateral flow test for the</u> <u>screening for sexually transmitted infections and bacterial vaginosis: study protocol</u> <u>of a multicentre multidisciplinary prospective observational clinical study to evaluate</u> <u>the performance and feasibility of the Genital InFlammation Test (GIFT).</u> Ramboarina, S, et al. 1 May 2024
- Malaria Journal: <u>Access to quality-assured artemisinin-based combination therapy</u> <u>and associated factors among clients of selected private drug outlets in Uganda.</u> Ocan, M, et al. 30 April 2024
- Malaria Journal: <u>Therapeutic efficacy of generic artemether-lumefantrine in the treatment of uncomplicated malaria in Ghana: assessing anti-malarial efficacy amidst pharmacogenetic variations.</u> Thomford, NE, et al. 20 April 2024
- Human Genomics: <u>Meta-analysis of the global distribution of clinically relevant</u> <u>CYP2C8 alleles and their inferred functional consequences.</u> Camara, MD, et al. 22 April 2024
- Heliyon: <u>Performance characteristics of INDICAID antigen rapid diagnostic test on</u> <u>SARS-CoV-2 samples during the omicron wave in Cameroon.</u> Fokam, J, et al. 19 April 2024
- mBio: <u>A panel of recombinant Leishmania donovani cell surface and secreted</u> <u>proteins identifies LdBPK 323600.1 as a serological marker of symptomatic infection.</u> Roberts, AJ, et al. 10 April 2024
- Frontiers in Medicine: <u>Development, assessment and educational impact of a</u> <u>blended e-learning training program on pharmacovigilance implemented in four</u> <u>African countries.</u> Schievano, F, et al. 17 April 2024
- Journal of Pharmaceutical and Biomedical Analysis: <u>Development and validation of</u> <u>an ultra-performance liquid chromatography-tandem mass spectrometry method</u> <u>for the quantification of the antimalarial drug pyronaridine in human whole blood.</u> Schouten, WM, et al. 16 April 2024
- Frontiers in Pharmacology: <u>Availability, pricing, and affordability of essential</u> <u>medicines for pediatric population in Malawi.</u> Chiumia, FK, et al. 11 April 2024
- Viruses: <u>High Prevalence of Hepatitis B Virus Drug Resistance Mutations to</u> <u>Lamivudine among People with HIV/HBV Coinfection in Rural and Peri-Urban</u> <u>Communities in Botswana.</u> Phinius, BB, et al. 11 April 2024
- Antimicrobial Agents and Chemotherapy: <u>Assessing potential drug-drug</u> <u>interactions between clofazimine and other frequently used agents to treat drug-</u> <u>resistant tuberculosis.</u> Kengo, A, et al. 10 April 2024
- Frontiers in Immunology: <u>Bi-isotype immunoglobulins enhance antibody-mediated</u> <u>neutrophil activity against Plasmodium falciparum parasites.</u> Ogwang, R, et al. 8 April 2024
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- Microorganisms: <u>The Incidence and Risk Factors for Enterotoxigenic E. coli Diarrheal</u> <u>Disease in Children under Three Years Old in Lusaka, Zambia.</u> Sukwa, N, et al. 29 March 2024
- Antimicrobial Agents and Chemotherapy: <u>Population-specific variations in KCNH2</u> <u>predispose patients to delayed ventricular repolarization upon dihydroartemisinin-</u> <u>piperaquine therapy.</u> Camara, MD, et al. 28 March 2024
- Current Opinion in Pediatrics: <u>Respiratory adenovirus infections in children: a focus</u> on <u>Africa</u>. van der Zalm, MM, 29 February 2024
- Frontiers in Tropical Diseases: <u>Filariasis research from basic research to drug</u> <u>development and novel diagnostics</u>, over a decade of research at the Institute for

Resources



Collaborative clinical R&D online Clinical research capacity PDF

Fellowships online

- EDCTP | Knowledge Hub: Tools and guidance for conducting clinical research
- EDCTP Alumni Network
- ERUDIT | Planning for Financial Sustainability manual
- Europe PMC webinar | <u>Watch the recording</u> and <u>download the slides</u>
- TRUST project | <u>Video introducing the Global Code of Conduct</u>
- PACTR | Open access clinical trial registry
- PAVIA project | <u>PV strengthening blue-print</u>

Training and funding opportunities

AGHRB: Malaria vaccine implementation studies in Africa | Deadline for application: 3 June 2024

The UK Medical Research Council (MRC) and the Foreign Commonwealth and Development Office (FCDO) are providing funding for studies to undertake implementation research to understand the optimal strategies for roll-out and scale-up of the malaria vaccines RTS,S and R21 to ensure that they are deployed most effectively and equitably for population health benefit. Research should be conducted in at least two sub-Saharan African countries, one of which should have a high malaria burden. <u>More information »</u>

NIH International Research Ethics Education and Curriculum Development Award | Deadline for application: 6 June 2024

The International Research Ethics Education and Curriculum Development Award supports curriculum development for master's level courses at institutions in low- and middle-income countries (LMIC) including courses for skill development, including practicum experiences; and mentoring activities.

More information »

NIH International Bioethics Research Training Program | Deadline for application: 6 June 2024

The International Bioethics Research Training Program supports LMIC-U.S. collaborative institutional bioethics doctoral and postdoctoral research training programs that incorporate didactic, mentored research and career development components to prepare trainees for positions of scholarship and leadership at health research institutions in LMICs. More information »

Mark your calendar

Public Presentation Session of the Lusophone Platform for Clinical Research & Biomedical Innovation (PLICIB) | 26 June 2024

The public presentation session of the Session of the Lusophone Platform for Clinical Research & Biomedical Innovation (PLICIB) will take place on 26 June 2024 at the Portuguese Institute of Hygiene and Tropical Medicine, University of NOVA de Lisboa. PLICIB aims to encourage the competitiveness of the Portuguese scientific community in these areas and review its national strategic positioning in the Global Health EDCTP3 programme, reinforcing its links to Africa (especially the PALOP countries). Ms Lara Pandya, Strategic Partnerships (North) and Communications Manager, EDCTP Association, will speak at this event.

More information (in Portuguese) »

1st Conference on Innovations in Tuberculosis | 3-5 July 2024

The 1st Conference on Innovations in Tuberculosis will be held in Kampala, Uganda from 3-5 July 2024 and will present a high-quality programme on innovations in Tuberculosis with an emphasis on region-specific needs. The meeting aims to provide a platform for scientific interchange, education, and fostering collaborations to advance the field. EDCTP is sponsoring the conference as a Bronze-level supporter and will be represented at the event by Dr Debora Bade, Project Officer, EDCTP Association.

World Congress of Epidemiology | 24-27 September 2024

The World Congress of Epidemiology (WCE2024) will take place in Cape Town, South Africa from 24-27 September 2024. The theme of WCE2024 is "Epidemiology and complexity: challenges and responses" which will engage the full depth and breadth of methods and practice in contemporary epidemiology. The meeting will feature invited speakers presenting plenary lectures, workshops and interactive sessions. The conference invites submission of abstracts for oral or poster presentations showcasing novel research in epidemiology and public health (general abstract submission deadline: 16 February 2023). More information »

EDCTP Communications thanks everyone who provided information for this Update.



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