



EDCTP Update | August 2024



Contents

- Save the date: EDCTP session at SSUNGA79
- Global Health EDCTP3 launches research projects to combat Mpox
- EDCTP2 project news
- EDCTP Fellows
- Publications
- Resources
- Training and funding opportunities
- Mark your calendar

Save the date: EDCTP session at SSUNGA79









































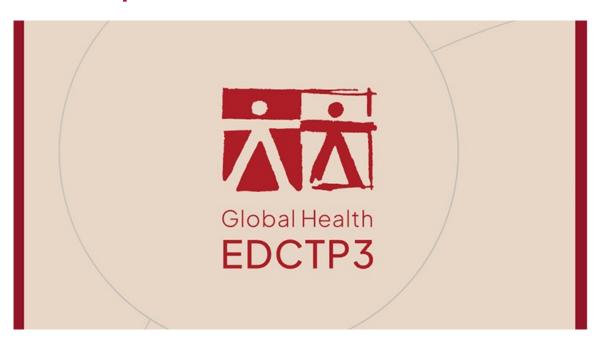
Science Summit at UNGA79

10 - 27 September 2024

EDCTP is organising a virtual meeting titled EDCTP: Investing in clinical research in Africa to develop local solutions against the global challenge of Antimicrobial Resistance (AMR), on 26 September 2024 from 17:00-19:00 (CEST). This EDCTP session aims to illustrate the value of investing in clinical research and the development of accessible and affordable antibiotics, diagnostics, and vaccines for addressing unmet medical needs in Africa through a global partnership such as EDCTP. The event will be part of the Science Summit during the 79th United Nations General Assembly (UNGA79). Registration to attend the sessions is free.

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Global Health EDCTP3 launches research projects to combat Mpox



Global Health EDCTP3 is one of the global stakeholders spearheading the response to the Mpox outbreak by supporting a portfolio of research projects to address some of the most pressing challenges posed by the outbreak. In light of the recently declared Public Health Emergency of International Concern, these projects have taken on even greater significance. Through a fasttrack process to fund the best scientific proposals, Global Health EDCTP3 funded five projects which started on 1 of August 2024.

The budget of the emergency funding call for proposals was €6.5 million, including a contribution of €500.000 from ANRS Maladies infectieuses émergentes (MIE) and a €1 million cash contribution from the EDCTP Association.

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EDCTP2 project news

DPP consortium: first participant has been recruited for the Bioequivalence clinical study



The <u>Developing Paediatric Primaquine</u> (<u>DPP</u>) consortium aims to develop and deploy quality-assured, child-friendly primaquine (PQ) across a range of doses in optimised regimens for transmission-blocking and radical cure in line with WHO guidelines recommendations. The DPP consortium is led by Dr Bob Taylor of the University of Oxford, with partners from Burkina Faso, Ethiopia, and France.

The Bioequivalence (BE) clinical study recruited its first participant on 31 July 2024 in a referral hospital in Kolfe Keranyo district, Addis Ababa, Ethiopia. Recruitment is expected to complete by August 2024. The BE study aims to demonstrate if a new generic form of primaquine, produced by IPCA (India) is equivalent to the one currently on the market, manufactured by Sanofi (France).

CALINA trial featured in article



Source: Novartis

The CALINA trial, part of the PAMAfrica project, was highlighted in the article 'Tackling The Challenge Of Malaria Clinical Trials In Africa' by Citeline. The article focuses on how Novartis is helping to tackle the challenge of malaria clinical trials in Africa. In April, Novartis and Medicines for Malaria Venture (MMV) announced positive data from the Phase II/III CALINA trial, which evaluated a new formulation of Coartem to treat the smallest babies (under 5kg) with acute uncomplicated malaria for whom there is no approved treatment. The data from the study, which was conducted in Burkina Faso, the Democratic Republic of the Congo (DRC), Kenya, Mali, Nigeria, and Zambia, have been submitted for regulatory review.

Stool4TB reaches 75% recruitment in the paediatric study



The <u>Stool4TB</u> study is testing an innovative method for identifying TB infections in children and adults living with HIV. Early in 2024, the Stool4TB study team announced the completion of recruitment in its trial on adults. In August 2024, the team announced that the paediatric cohort study had reached 75% of the target sample size. With recruitment at a strong and steady pace, the study sites are aiming to complete recruitment by the end of 2024. More details about the study are available in the recently published <u>study protocol</u>.

EACCR3 annual scientific project implementation and steering committee meeting



The Network of Excellence EACCR3 (East African Consortium for Clinical Research) held its third annual scientific project implementation and steering committee meeting on 12-13 August 2024 in Kigali, Rwanda. The meeting brought together representatives from all partner organisations to discuss the progress and achievements of the clinical research supported by EACCR.

UNIVERSAL data supports Laurus Labs US FDA submission for approval of novel protease inhibitor



The work of the UNIVERSAL project contributed to Laurus Labs' application to the US Food and Drug Administration (FDA) for the tentative approval of paediatric Darunavir/ritonavir (pDRV/r (120/20 mg)). UNIVERSAL is the first product development project from the World Health Organisation's (WHO) GAP-F project GAP-f which was established to promote the development of safer, more effective and more durable paediatric formulations made available for children at a faster rate. Data produced through UNIVERSAL's modelling and simulation data, submitted to the FDA earlier this year by Penta, CHAI, PHPT and AP-HP, will support their decision on the drug's registration. This is promising news for children with HIV who are taking dolutegravir (DTG) but finding that is not working.

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STI specialists recommend GIFT device for asymptomatic screening in low-resource areas



A point-of-care test is optimally suited for screening asymptomatic cases of bacterial vaginosis (BV) and sexually transmitted infections (STIs) in low and middle-resource settings. That was the consensus from a survey conducted by the team of the EDCTP-funded GIFT study that sought the opinions of expert healthcare workers, researchers, and policymakers on how to roll out the novel Genital Inflammation Test (GIFT) device in real-world settings.

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EDCTP Fellows

Dr Oghenebrume Wariri's PhD thesis published



Career Development Fellow Dr Oghenebrume Wariri (The Gambia) has published his PhD thesis 'Timeliness of Routine Childhood Vaccination in The Gambia: Examining the Burden, Spatial Pattern, Determinants and the Impact of COVID-19 Pandemic', as part of the EDCTPfunded TIMELY study. The study investigates the timeliness of receiving routine childhood vaccinations in The Gambia and understand the contribution of demand-side and suply-side factors, geographic accessibility to immunisation clinics, and the ongoing COVID-19 pandemic. The study findings were published in **Plos One** and provide an important step towards research on childhood vaccinations in The Gambia.

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 compliance with EDCTP grant requirements to make publications openly accessible as soon as possible. <u>Submit your manuscript through Europe PMC Plus</u>.

Lancet Glob Health: Community-based strategies to increase coverage of

- intermittent preventive treatment of malaria in pregnancy with sulfadoxinepyrimethamine in sub-Saharan Africa: a systematic review, meta-analysis, metaethnography, and economic assessment. Koita, K, et al. 1 September 2024
- Clin Infect Dis: <u>Evaluation of C-Reactive Protein and Computer-Aided Analysis of Chest X-rays as Tuberculosis Triage Tests at Health Facilities in Lesotho and South Africa</u>. Bosman, A, et al. 27 August 2024.
- Drug Safety: <u>Short-Term Training</u>, a <u>Useful Approach for Sustainable</u>
 <u>Pharmacovigilance Knowledge Development in Tanzania</u>, <u>Kenya</u>, <u>Ethiopia and Rwanda</u>. van Puijenbroek, E, et al. 20 August 2024
- Health Research Policy and Systems: Evaluating the impact of the global evidence, local adaptation (GELA) project for enhancing evidence-informed guideline recommendations for newborn and young child health in three African countries: a mixed-methods protocol. Kredo, T, et al. 19 August 2024
- The European Respiratory Journal: <u>Blood transcriptomic signatures for symptomatic tuberculosis in an African multicohort study.</u> Muwanga, VM et al. 15 August 2024
- BMC Infectious Diseases: Expanding Xpert MTB/RIF Ultra® and LF-LAM testing for diagnosis of tuberculosis among HIV-positive adults admitted to hospitals in Tanzania and Mozambique: a randomized controlled trial (the EXULTANT trial).
 Mangu, C, et al. 15 August 2024
- Discover Public Health: <u>Lessons from enriching Tanzania's clinical research ethics</u> <u>clinical trials oversight and pharmacovigilance through the ASCEND project.</u> Fimbo, A, et al. 12 August 2024
- The Journal of Infection: Replication, safety and immunogenicity of the vectored <u>Ebola vaccine rVSV-ΔG-ZEBOV-GP in a sub-Saharan African paediatric population: a randomised controlled, open-label trial in children aged 1-12 years living in Lambaréné, Gabon. Alabi, A, et al. 7 August 2024</u>
- Heliyon: <u>Tuberculosis patients with diabetes co-morbidity experience reduced</u> <u>Mycobacterium tuberculosis complex clearance</u>. Danso, EK, et al. 6 August 2024
- PLOS Global Public Health: Mild and moderate COVID-19 during Alpha, Delta and Omicron pandemic waves in urban Maputo, Mozambique, December 2020-March 2022: A population-based surveillance study. Ingelbeen, B, et al. 5 August 2024
- PLoS One: <u>An unclosed loop: Perspectives of community engagement in infectious disease clinical trials in sub-Saharan Africa.</u> Späth, C, et al. 2 August 2024
- BMC Infectious Diseases: <u>Drug-induced hepatotoxicity and association with slow</u> acetylation variants NAT2*5 and NAT2*6 in Cameroonian patients with tuberculosis and <u>HIV co-infection</u>. Cho, FN, et all. 31 July 2024
- Open Forum Infectious Diseases: <u>Reflex Xpert MTB/XDR Testing of Residual</u> <u>Rifampicin-Resistant Specimens: A Clinical Laboratory-Based Diagnostic Accuracy</u> <u>and Feasibility Study in South Africa</u>. Centner, C M, et al. 31 July 2024
- Research Integrity and Peer Review: <u>Perceptions, experiences, and motivation of COVID-19 vaccine trial participants in South Africa: a qualitative study.</u> Nkosi, T, et al. 29 July 2024
- International Journal of Molecular Sciences: <u>Can We Exploit Inflammasomes for Host-Directed Therapy in the Fight against Mycobacterium tuberculosis Infection?</u>
 Cebani, L, et al. 27 July 2024
- Journal of the Pediatric Infectious Diseases Society: <u>Population pharmacokinetics of Dolutegravir in African Children: results from the CHAPAS-4 trial.</u> Waalewijn, H, et al. 27 July 2024
- Diagnostic and Prognostic Research: <u>Evaluating diagnostic accuracy of an RT-PCR</u> test for the detection of SARS-CoV-2 in saliva. Samsunder, N, et al. 24 July 2024
- Drug, Healthcare and Patient Safety: <u>Adverse Drug Reactions Related with Antibiotic Medicines in Malawi: A Retrospective Analysis of Prevalence and Associated Factors.</u>
 Chiumia, FK, et al. 23 July 2024
- ERJ Open Research: <u>Low tuberculosis treatment initiation after positive tuberculosis lipoarabinomannan results.</u> Gils, T, et al. 22 July 2024
- Trials: <u>Update: Vitamin D3 and calcium carbonate supplementation for adolescents with HIV to reduce musculoskeletal morbidity and immunopathology (VITALITY trial): study protocol for a randomised placebo-controlled trial.</u> Dzavakwa, N V, et al. 22 July 2024
- BMC Infectious Diseases: <u>Safety and pharmacokinetics of subcutaneous</u>
 <u>administration of broadly neutralizing anti-HIV-1 monoclonal antibodies (bNAbs),</u>
 <u>given to HIV-1 exposed, uninfected neonates and infants: study protocol for a phase</u>
 <u>I trial. Goga, A, et al. 20 July 2024</u>
- Paediatric Respiratory Reviews: Post-tuberculosis lung disease in children and

- adolescents: A scoping review of definitions, measuring tools, and research gaps. Nkereuwem, E, et al. 18 July 2024
- Access Microbiology: <u>HIV-DRIVES: HIV drug resistance identification, variant</u> evaluation, and surveillance pipeline. Kanyerezi, S, et al. 17 July 2024
- International Journal of Molecular Sciences: <u>Functional Characterisation of Surfactant Protein A as a Novel Prophylactic Means against Oncogenic HPV Infections.</u> Carse, S, et al. 14 July 2024
- Biomedicines: Molecular Characterization of Hepatitis B Virus in People Living with HIV in Rural and Peri-Urban Communities in Botswana. Phinius, BB, et al. 14 July 2024
- Open Forum Infectious Diseases: <u>Single and Combined Serum Proteins Expressed in TB Infection are Candidates for Point-of-care Diagnostic Testing of Active TB Patients in Lambaréné, Gabon.</u> Essone, P N, et al. 13 July 2024
- Southern African Journal of Infectious Diseases: <u>COVID-19 in children: Clinical</u> <u>presentation and hospital course at a district hospital in South Africa.</u> Nieuwoudt, M, et al. 8 July 2024
- Biomedicines: Microvascular Changes during Viral Infections: A Systematic Review of Studies Using Retinal Vessel Diameter Assessments. Saloň, A, et al. 5 July 2024

Resources







Collaborative clinical R&D online

Clinical research capacity
PDF

Fellowships online

- EDCTP | Knowledge Hub: Tools and guidance for conducting clinical research
- EDCTP | <u>Alumni Network</u>
- 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
- PACTR | Open access clinical trial registry
- PAVIA project | <u>PV strengthening blue-print</u>

Training and funding opportunities

PREPARE happy hour webinar

The PREPARED project is conducting a public engagement webinar to introduce the draft PREPARED Code - A Global Code of Conduct for Research during Pandemics - and provide an opportunity for attendees to influence the final draft of the Code. The PREPARED Code is for researchers, research ethics committees and research integrity offices. The next webinar will take place on 12 September 2024 at 16:00 (CEST).

More information »

Basics of Clinical Trial Management | 3-18 September 2024

BIO Ventures for Global Health (BVGH) will host an 11-session digital lecture series focused on clinical trial management basics. This course is designed for professionals in low- and middle-income countries (such as physicians, nurses, research coordinators, research pharmacists, and data managers) who are interested in conducting clinical trials for any disease or condition but have limited experience in doing so.

More information »

ICGEB DSI WE-STAR Cape Town Postdoctoral Fellowships | Deadline for applications: 13 September 2024

The International Centre for Genetic Engineering and Biotechnology (ICGEB) and the South African Department of Science and Innovation (DSI) have partnered to offer early-career women scientists from the African Continent, with the exception of South Africa, mobility fellowships for 12 months (non-renewable) at the ICGEB laboratories in Cape Town (South Africa), to perform research work on biotechnology and related fields, including Health (Infectious Diseases and Non-Communicable Diseases), Sustainable and Effective Agriculture as well as Bioinformatics.

More information »

ODA Research Management Capacity Strengthening | Deadline for applications: 30 October 2024

The British Academy is inviting proposals which seek to embed and enhance working practices and systems within and between institutions to support equitable partnerships in international research through support for skills collaboration between research offices and research management functions. Awards of 18-24 months in duration and up to £50,000 are available. The deadline for submissions and UK institutional approval is 30 October 2024 (17.00 UK time).

More information »

Mark your calendar

8th Global One Health Congress | 20-23 September 2024

The 8th Global One Health Congress will take place in Cape Town, South Africa from 20-23 September 2024 and will bring together One Health stakeholders, from science researchers, policymakers, representatives of international institutions, civil society to the private sector from around the world. The agenda includes parallel tracks addressing one health science, antimicrobial agents and resistance, and science policy interface, amongst others. It will enable discussing major One Health challenges, as well as sharing research data and policy developments. The congress will provide a great opportunity to look at global One Health science and policy through an African lens. The final deadline to submit late breaker abstracts is 4 August 2024.

More information »

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 »

4th International Conference on Public Health in Africa (CPHIA 2024) | 26-**29 November 2024**

CPHIA 2024 aims to support building strong, resilient and equitable health systems, preparing Africa for the next pandemic and accelerating the local manufacturing of vaccines, therapeutics and diagnostics in Africa. This year's conference, scheduled to take place from 26-29 November in Rabat, Morocco, offers a unique opportunity to showcase your work, ideas, and innovations on an African-led platform dedicated to public health. CPHIA 2024 is now accepting submissions for abstracts, side events, and exhibitions. The deadline for submissions is 23 September 2024.

More information »

EDCTP Communications thanks everyone who provided information for this Update.









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