



# **EDCTP Update | February 2023**



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# **Eleventh EDCTP Forum: Call for abstracts and EDCTP Prizes competition**

From 7-10 November 2023, the Eleventh EDCTP Forum will take place in Paris, France. This Forum will mark EDCTP's 20th Anniversary and will be hosted by France – one of the

founding European EDCTP Association <u>member states</u> – through the French Research Agency <u>ANRS | Emerging Infectious Diseases</u>, and will be jointly supported by the second EDCTP programme (EDCTP2) and the <u>Global Health EDCTP3 Joint Undertaking</u> (GH EDCTP3 JU).

We are happy to announce that a call for abstracts and a call for nominations for the EDCTP Prizes competition are now open. We invite you to read the following information carefully:

#### **Call for abstracts**

EDCTP invites submission of abstracts for oral presentations or e-poster presentations of original contributions on innovations and impact in global health research, relevant to the scope of EDCTP, and on research capacity strengthening and partnerships. Investigators working on projects supported under EDCTP2, the Global Health EDCTP3 programme, Horizon 2020 and Horizon Europe are encouraged to use this opportunity to share new developments and results from their projects. We also welcome submissions from stakeholders working worldwide on health research in Africa. The deadline for abstracts is **3 May 2023 at 17:00 CEST**.

#### More information »

#### **EDCTP 2023 Prizes: Call for nominations**

Every two years, EDCTP awards four prestigious international prizes to recognise outstanding individuals and research teams from Africa and Europe who have made significant achievements in their research field. A call for nominations with a deadline of **31 May 2023 at 17:00 CEST** is open for the following prizes, which will be awarded at the Eleventh EDCTP Forum:

- Dr Pascoal Mocumbi Prize
- Outstanding Female Scientist Prize
- Scientific Leadership Prize
- Outstanding Research Team Prize

#### Read the official announcement »

#### Forum website, call for scientific symposia, registration

The Eleventh EDCTP Forum website will be launched soon, as well as a call for scientific symposia. More information on registration will follow in the coming weeks. Regular updates will be provided through the monthly <u>EDCTP Updates</u> and through our social media channels (<u>Twitter\_and LinkedIn</u>).

# Mrs Inmaculada Peñas Jiménez steps down as European Commission EDCTP Policy Officer

The EDCTP Association would like to express its sincere appreciation to Mrs Inmaculada Peñas-Jiménez, who is stepping down in February 2023 as a Policy Officer in the Unit Combatting Diseases of the Directorate General of Research and Innovation (DG RTD) at the European Commission. Since 2017, Mrs Peñas-Jiménez has been responsible for overseeing the contribution of the European Union to EDCTP and she was already engaging in EDCTP activities prior to this. Among other activities, Mrs Peñas-Jiménez has facilitated the review, consultation and adoption process for the annual EDCTP2 work plans, as well as the review and approval of the annual EDCTP2 interim progress reports.



She has coordinated two interim independent evaluations of the EDCTP2 programme, commissioned by the European Commission in 2016 and 2022, and been a regular contributor to EDCTP events, including active participation in meetings of the EDCTP

Association constituency bodies – the General Assembly, Board and Scientific Advisory Committee. Most recently, she has played a critical and complementary role in the preparations for the EDCTP2 successor programme, Global Health EDCTP3.

We thank Mrs Peñas-Jiménez for the excellent cooperation with the broader EDCTP family over the years. As a true champion of EDCTP, her commitment, dedication, and invaluable contribution to the success of the EDCTP2 programme and the realisation of Global Health EDCTP3 is greatly appreciated. We wish her all the very best with her future endeavours.

We also take this opportunity to extend a warm welcome to Dr Jan Paehler, Policy Officer in the Unit Combatting Diseases of the Directorate General of Research and Innovation at the European Commission, who will succeed Mrs Peñas-Jiménez as EDCTP focal person and with whom we look forward to a continued harmonic relationship.

# Reading tip: EDCTP eMagazine



The sixth issue of EDCTP's digital magazine was just published. We invite you to browse through the magazine The articles in this sixth issue discuss:

- · Impact of EDCTP-supported activities on policy and practice
- EDCTP's strategic collaboration with pharmaceutical industry partners
- · Involvement of Portuguese speaking countries in EDCTP-supported activities
- · Emergency funding for epidemic preparedness: the Ebola 2018 outbreak

#### Interviews in this eMagazine:

Professor Marcel Tanner, EDCTP High Representative for Europe and President of the Swiss Academies of Arts and Sciences

Dr Jutta Reinhard-Rupp, Head of the Global Health Institute at Merck and former EDCTP Scientific Advisory Committee member

Dr Lutz Hegemann, President of Global Health & Sustainability at Novartis Mrs Maria Hermínia Cabral – Director of the Calouste Gulbenkian Foundation's Partnerships for Development Programme

Prof. Paulo Ferrinho, Director of the Global Public Health Department at the Institute of Hygiene and Tropical Medicine (Universidade NOVA, Lisbon, Portugal) and member of the EDCTP Scientific Advisory Committee

Read the eMagazine »

# Mandatory submission of initial clinical trials in EU via Clinical Trials Information System

From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022.

Read the full European Medicines Agency (EMA) press release »

# Public consultation on a multi-stakeholder platform to improve clinical trials in the EU

On 3 February 2023, EMA, the <u>Heads of Medicines Agencies (HMA)</u> and the European Commission (EC) launched a public consultation on the establishment of a multistakeholder platform to improve clinical trials in the European Union (EU). The multistakeholder platform is a deliverable of the joint initiative <u>Accelerating Clinical Trials in the EU (ACT EU)</u>. Stakeholders are invited to send their comments on the <u>ACT EU multistakeholder platform concept paper</u>, advise on the key priorities for discussion and express their interest to join the platform via an <u>online form</u> until 3 March 2023 at midnight CET.

# **Project news**

# MIMVaC-Africa second annual meeting



The MIMVaC-Africa consortium held its second annual meeting on 17–18 January 2023. The overall objective of the MIMVaC-Africa consortium is to accelerate the development of highly effective malaria vaccines that meet the goals set by the WHO Malaria Vaccine Technology Roadmap. In a unique effort, vaccines developers, malariologists, trialists from sub-Saharan Africa, Europe, USA and Asia, are joining forces to comparatively assess malaria vaccine candidates.

Read the full article »

### **GELA** annual meeting



The annual GELA meeting was held in Malawi in January 2023, hosted by Kamuzu University Health Sciences. The GELA project aims to enhance evidence-informed guideline recommendations for newborn and young child health in three countries in sub-Saharan Africa. The meeting was broadcast by the Malawi Broadcasting Corporation national news.

#### **PrEPVacc consortium meeting**



The <u>PrEPVacc</u> consortium meeting took place in Durban, South Africa, from 30 January to 1 February 2023. PrEPVacc is an African-led, European-supported HIV prevention study running in East and Southern Africa from 2018 to 2024. For the first time, it is combining evaluation of experimental HIV vaccines and pre-exposure prophylaxis (PrEP) at the same time. During three days, participants discussed the progress made towards the project objectives, the challenges, successes and the way forward.

#### **DPP consortium: First Investigators Meeting**



The Developing Paediatric Primaquine (DPP) consortium held its first Investigators Meeting at the Pharmaceutical Sciences Unit of the University of Bordeaux, France on 24-26 January 2023. The DPP 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 and coordinated by Dr Bob Taylor of the University of Oxford, with partners from Burkina Faso, Ethiopia and France.

Read the full article »

## **PYRAPREG: Subject recruitment completed**

The PYRAPREG study completed recruitment on 3 February 2023, achieving a sample size of 1,875 pregnant women. The last patient last visit (LPLV) is expected to occur by January 2024 for the mothers. PYRAPREG is a phase III open-label, multicentre, randomised, non-inferiority clinical trial comparing pyronaridine-artesunate (PA) with artemether-lumefantrine (AL) and dihydroartemisinin-piperaquine (DP) for the treatment of *falciparum malaria* in women in the second and third trimesters of pregnancy. The study is conducted in five countries: Burkina Faso, Democratic Republic of Congo, Mali, Mozambique and The Gambia.

### **BCA-WA-ETHICS II: Call for papers African Journal of Bioethics**



The <u>BCA-WA-ETHICS II</u> project has published a call for papers for the <u>African Journal of Bioethics (AJB)</u>. The AJB is a peer-reviewed journal providing open access to all published articles. It aims to encourage Pan-African harmonisation in pertinent bioethical issues affecting Africa, enhance the standards of experimental and observational research ethics in the African continent, and promote robust discussions on emerging bioethical issues. The journal invites the

submission of high-quality articles in English and French from authors from anywhere in the world under various disciplines of Bioethics.

More information »

### **SEA-RAFES:** international emergency ethics review workshop



The 'Strengthening and enhancing the Réseau Africain Francophone d'Ethique en Santé' (SEA-RAFES) project organised a one-week workshop in Guinea from 12-16 December 2022. The aim of the workshop was to harmonise the procedures for submitting and studying research protocols in health emergencies. This workshop brought together all members of the network and experienced guests who shared their experiences and recommendations.

The workshop was featured on Espace TV Guinée (at 9:20) »

#### **CECaBI: Establishment of consultation framework**

The Côte d'Ivoire Ethics Capacity Building Initiative (CECaBI) met with partners and stakeholders to discuss and draft a consultation framework to support the National Ethics Committee in its work with health research actors. The framework has been developed with CECaBI's key partners including WHO, the European Union, the Félix Houpouët-Boigny University and many others. The meeting took place under the chairmanship of the Deputy Director of Cabinet of the Ministry of Health, Public Hygiene and Universal Health Coverage of Côte d'Ivoire.

Read the full article »

#### **ADAM Video**



In this video from the <u>ADAM</u> project, In this video, Pedro Aide, Lídia Marilia Nhamussua and Felisbela Materrula Ferreira talk about how the project is implementing the Mass Drug Administration (MDA) campaign against malaria in Chidenguele (District of Manjacaze, province of Gaza). The ADAM project is supporting the introduction into routine programmatic use of a malaria elimination strategy that has proven highly effective in reducing the incidence of malaria. It will act as a demonstration project, generating learning that will facilitate the wider rollout of the strategy across Mozambique.

Watch the video »

## **Projects at CROI**

Several EDCTP-supported projects presented their work and results at the Conference on Retroviruses and Opportunistic Infections (CROI) which took place from 19-22 February 2023 in Seattle, Washington (USA), among which:

The <u>VirTUAL</u> consortium <u>presented</u> the primary analysis of their dose-escalation clinical trial. The VirTUAL study is combining modelling and clinical research to identify the optimal drug treatments for pregnant women, children and adolescents with HIV and TB. The trial was conducted to determine the drug doses necessary for antiretroviral concentrations to be high enough to effectively suppress HIV replication.

The <u>PROMISE-EPI</u> project presented the results of their randomised controlled trial. The PROMISE-EPI study aimed to evaluate an innovative rescue intervention for the prevention of mother-to-child transmission of HIV, integrated in the expanded programme of immunisation. The trial showed that the intervention nested in EPI combining POC measurement of maternal viral load and, when unsuppressed, same-day infant single PNP initiation, was safe and reduced the period at high risk by more than 90%.

The <u>PanACEA II</u> project presented study results of the SUDOCU combination dose-finding trial showing that sutezolid is a safe oxazolidinone.

The <u>LIFE</u> project <u>presented</u> findings from it study on Maternal Point of Care viral load testing at delivery and its impact on neonatal prophylaxis regimen. The LIFE study is assessing whether use of new rapid diagnostic tests for HIV leads to quicker and better treatment of infants with HIV.

The <u>SimpliciTB</u> project presented <u>results</u> from a clinical trial to evaluate the potential of the BPaMZ regimen, consisting of bedaquiline (B), pretomanid (Pa), moxifloxacin (M), and pyrazinamide (Z), to shorten treatment times for both drug-sensitive and drug-resistant TB. The trial results showed that the BPaMZ regimen was highly potent against the TB bacteria, meeting its primary endpoint with DS-TB participants 2.93 times more likely to culture convert by week 8. However, the 4-month experimental BPaMZ regimen did not meet the secondary endpoint of noninferiority in percent favorable outcomes compared to 6 months of HRZE in DS-TB due to adherence challenges associated with side effects.

## **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.

Submit your manuscript through Europe PMC Plus

- BMC Health Serv Res: Regulation of community advisory boards during conduct of clinical trials in Uganda: a qualitative study involving stakeholders. Mijumbi AO et al. (6 February 2023)
- Microorganisms: An Archetypical Model for Engrafting Bacteroides fragilis into Conventional Mice Following Reproducible Antibiotic Conditioning of the Gut Microbiota. Osagie A Eribo et al. (10 February 2023)
- BMC Health Serv Res: Regulation of community advisory boards during conduct of clinical trials in Uganda: a qualitative study involving stakeholders. Mijumbi AO et al. (6 Feb 2023)
- Sci Rep: Effect of pharmacogenetic variations on praziquantel plasma concentration and safety outcomes among school children in Rwanda. Barry A et al. (26 Jan 2023)
- PLoS Med: <u>The cost and cost-effectiveness of novel tuberculosis vaccines in low- and middle-income countries</u>: A modeling study. Portnoy A et al. (24 Jan 2023)
- PLoS Negl Trop Dis: Rodent trapping studies as an overlooked information source for understanding endemic and novel zoonotic spillover. Simons D et al. (23 Jan 2023)
- Systematic Reviews: A systematic review of risk factors for mortality among tuberculosis patients in South Africa. Nicholson TJ et al. (23 Feb 2023)

• Infect Dis Poverty: Establishing a standard method for analysing case detection delay in leprosy using a Bayesian modelling approach. Hambridge T et al. (20 Feb 2023)

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

# **Training and funding opportunities**

# TDR Clinical Research Leadership fellowship programme | Deadline: 15 March 2023

A call for application is open for TDR's newly launched Clinical Research Leadership (CRL) fellowship programme. This new fellowship programme will maximise the value of the clinical research skills obtained through the placement at a Training Partner Organisation (TPO) by focusing on research leadership, with fellows using their clinical research skills, in conjunction with competencies and capabilities to effectively communicate with, and support, members of a multidisciplinary team. The deadline for applications is **15 March 2023, 17:00 CET**.

More information »

# Wellcome Trust (UK) Funding Opportunities for Applicants from LMICs Wellcome Early-Career Awards

This scheme provides funding for early-career researchers from any discipline who are ready to develop their research identity. Through innovative projects, they will deliver shifts in understanding that could improve human life, health and wellbeing. By the end of the award, they will be ready to lead their own independent research programme. Application deadline: **18 May 2023** 

**Wellcome Career Development Awards** 

This scheme provides funding for mid-career researchers from any discipline who have the potential to be international research leaders. They will develop their research capabilities, drive innovative programmes of work and deliver significant shifts in understanding that could improve human life, health and wellbeing.

Application deadline: 4 April 2023 (next application deadline: 27 July 2023)

#### **Wellcome Discovery Awards**

This scheme provides funding for established researchers and teams from any discipline who want to pursue bold and creative research ideas to deliver significant shifts in understanding that could improve human life, health and wellbeing.

Application deadline: **11 April 2023** (next application deadline: 25 July 2023)

#### ADVAC (Advanced Course for Vaccinology) | 8-19 May 2023

ADVAC is an annual two-week training programme for decision-makers, including academia, industry, governmental and non-governmental agencies. With support from the Swedish International Development Cooperation Agency (Sida), EDCTP will provide fellowships for selected candidates from Sub-Saharan African countries.

More information »

# Mark your calendar

#### **EDCTP** events

#### **Eleventh EDCTP Forum | 7-10 November 2023**

From 7-10 November 2023, EDCTP will hold its Eleventh EDCTP Forum, hosted in Paris, France, at the <u>Palais des Congrès de Paris</u>. The Forum theme is "Partnering for Global Health Research Innovation and Impact in Africa - Celebrating EDCTP: two decades and beyond". A <u>call for abstracts</u> and a call for nominations for <u>EDCTP prizes</u> is now open and we invite you to share the calls widely. More information on registration and on scientific symposia will follow soon.

#### Other events

# Impact and intersection of the COVID-19 and tuberculosis pandemics | 10 & 11 March 2023, virtual

On 10-11 March 2023, the webinar 'Impact and intersection of the COVID-19 and tuberculosis pandemics in Brazil, Russia, India and South Africa' will take place, during which preliminary findings from the IMPAC19TB study will be shared and discussed. More information »

#### VolREthics global meeting | 24 & 25 April 2023, Brussels (Belgium)

The <u>VolREthics</u> Initiative on Healthy Research Volunteers and Ethics is organising an onsite plenary global meeting at the European Commission premises in Brussels (Belgium) on 24-25 April 2023. The main objective of the event will be to take stock of what has been learned so far through the five regional VolREthics seminars, and to pave the way for international guidelines development for the protection of heathy volunteers in biomedical research. Registration for this event is free, but mandatory through e-mail to hyworkshop.disc(at)inserm.fr

#### INTEREST 2023 | Maputo, Mozambique, 9-12 May 2023

The 17<sup>th</sup> International Conference on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings (INTEREST) conference will take place in Maputo, Mozambique from 9-12 May 2023. INTEREST brings together scientists involved in HIV treatment, pathogenesis, and prevention research in Africa to share pivotal findings, promote collaboration, and transfer experiences across several fields and countries. More information »







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