



EDCTP

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EDCTP Update

January 2021



Highlights

- **Public consultation: Global Roadmap for TB vaccines**
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- **World NTD Day 2021**

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Professor James Gita Hakim passed away

EDCTP joins the HIV clinical research community in Africa and around the globe in mourning the loss of Professor James Gita Hakim who passed away due to complications from COVID-19. We extend our condolences to his family, friends, patients, students, and colleagues.

"I am sad to hear of the unfortunate death of Prof. James Hakim. He has been involved in several EDCTP-funded HIV studies involving Zimbabwe both under our first and our current programme. This is a great loss to Zimbabwe and the global HIV research community. May his soul rest in peace." Dr Michael Makanga, EDCTP Executive Director

Prof. Hakim led several HIV treatment studies, including EDCTP-funded EARNEST and CHAPAS trials. He was known to many as a great HIV scientist and his legacy will stay alive through his immense contribution to evidence-based clinical care of HIV/AIDS patients.

- See also [SAA mourns the death of Board Member, Researcher, Academician and great Professor of Medicine James Gita Hakim](#).
-

Prof. Yazdanpanah head of new French agency on (emerging) infectious diseases

Professor Yazdan Yazdanpanah has been appointed as the Director of a new autonomous agency of Inserm launched on 01 January 2021. The agency will be dedicated to funding and coordinating the research on infectious diseases and emerging infectious diseases. It results from a merger of REACTing and ANRS, the Inserm agency dedicated to research on HIV/AIDs and hepatitis. REACTing, also an agency of Inserm, is a multi-disciplinary collaborative network of French research institutions working on emerging infectious diseases and merged with the ANRS to become 'ANRS – Emerging infectious diseases'. Prof. Yazdanpanah will be succeeding Prof. François Dabis.

Currently, Prof. Yazdanpanah is also the Chair of the EDCTP General Assembly and Chair of the EDCTP Board.

"On behalf of the EDCTP Secretariat, I wish to warmly congratulate Professor Yazdanpanah on this appointment and well-deserved honour to lead a new prestigious research organisation focused on key problems of global health. We look forward to a galvanised

cooperation of 'ANRS - Emerging infectious diseases' with international partners and an even stronger working relationship with EDCTP."

Dr Michael Makanga, EDCTP Executive Director

World NTD Day 2021 – a global call to End the Neglect

On 12 November 2020, the member states of the World Health Organisation (WHO) officially endorsed the new Roadmap to fight neglected tropical diseases (NTD) and end NTDs as a public health burden by 2030. The WHO NTD Roadmap 2021-2030 sets global targets and milestones to prevent, control, eliminate and eradicate 20 neglected tropical diseases (NTDs) and disease groups. Importantly, it stresses integrated approaches instead of siloed single-disease programmes, thus aiming to improve coordination and collaboration. Secondly, it emphasises the need for greater ownership by national and local governments, including communities.

"EDCTP fully supports this agenda and the programme is already investing more than €70 million in NTD research. Moreover, NTDs remain within the scope of the envisaged EDCTP3 - EU–Africa Global Health Partnership under Horizon Europe. Africa carries 40% of the burden inflicted by NTDs which are a direct threat to more than 1.7 billion people globally. In partnership and through collaborative research we can end this neglect."

Dr Michael Makanga, EDCTP Executive Director

[Read more on the EDCTP website.](#)

Prof. Moses Bockarie appointed to Board of The END Fund

From the news item of The END Fund (which seeks to end Neglected Tropical Diseases):
"The END Fund is pleased to announce the appointment of Professor Moses John Bockarie as a board member, and welcomes Dr Caroline Karutu who will be the new Vice President of Programs. Bockarie has been involved in the control of NTDs for more than 30 years while Karutu has extensive experience designing and leading large-scale public health programs."

Prof. Moses Bockarie is the EDCTP Director of International Cooperation (Africa) and head of the EDCTP Africa Office in Cape Town, South Africa.

[Read more on The END Fund website.](#)

Public consultation: Global Roadmap for TB vaccines

EDCTP has commissioned the Amsterdam Institute for Global Health and Development (AIGHD) to develop a Global Roadmap for research and development for tuberculosis (TB) vaccines.

The Roadmap intends to provide global stakeholders such as researchers, funders, industry, regulatory, and policy decision-makers with key actionable priorities that could help guide their activities. It lists both the short-term objectives as well as the long-term strategic objectives for global TB vaccine development and focuses on delivering affordable and effective vaccines for use in low- and middle-income countries where the vast majority of people affected by TB are concentrated.

AIGHD and EDCTP invite researchers and stakeholders, as well as everyone who has been involved in the roadmap development process to **respond to a public consultation** and express their views on aspects of the draft Roadmap before a final version is published.

This is part of the process for developing this Roadmap, which consists of several steps:

- Desk review and stakeholder inventory
- In-depth interviews with selected stakeholders
- A consensus workshop and various rounds of stakeholder consultation on the subsequent draft versions of the Roadmap.

These rounds of consultation included both targeted requests for feedback to selected stakeholders and the current public consultation. The contributions will be published on the AIGHD website (in cases where consent was provided) and will be used to complete the final version of the Roadmap.

[More information on the EDCTP website.](#)

Recently signed grants

[Mobilisation of funding for COVID-19 research in sub-Saharan Africa – 2020](#)

- **ASCENT** | Coordinator Prof. Yves Levy | Acceleration of novel coronavirus serological test development and seroprevalence study: an African-European initiative
- **MozCOVID** | Coordinator Dr Inacio Mandomando | COVID-19 surveillance in rural Mozambique for prompt and effective response.

[Ethics and regulatory capacities -2019](#)

- **SNEFCA** | Coordinator: Dr Mbih Jerome Tosam | Strengthening National Ethics Committees in West and Central Francophone Africa.

[Career Development Fellowships – 2019](#)

- **COPSMEDS** | Fellow: Dr Felix Khuluza | Countering the prevalence of substandard and falsified medicines in Malawi
- **e-MANIC** | Fellow: Dr François Kiemde | Development and evaluation of an electronic algorithm using a combination of a two-step malaria rapid diagnostic test

detecting PfHRP2 and pLDH, and other rapid diagnostic tools for the management of febrile illness in children under 5 years attending outpatient facilities in Burkina Faso

- **ISAMIMA** | Fellow: Dr Azizath Mousilliou | Impact of seasonal malaria chemoprevention on the acquisition and maintenance of immunity against malaria among children in northern Benin.

AREF/EDCTP Preparatory Fellowships – 2019

- **FM-DIALLO** | Fellow: Dr Salou Diallo | TMA2019PF-2739 DIALLO.
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Project news

ASCEND | Project Kick-off meeting | 26/11 2020

The Tanzania Medicines and Medical Devices Authority (TMDA) held a kick-off meeting of the ASCEND project in Dar es Salaam on 26 November 2020. A total of 60 participants from the seven consortium members and other stakeholders were invited.

The consortium partners are:

- Tanzania Medicines and Medical Devices Authority
- National Institute for Medical Research
- Muhimbili University of Health and Allied Sciences
- Kilimanjaro Clinical Research Institute
- Zanzibar Food and Drug Agency
- Zanzibar Health and Research Institute
- all in the United Republic of Tanzania, and
- St. Andrews University, United Kingdom.

The two and half year EDCTP-funded project aims at strengthening the capacity of clinical research; ethics review frameworks and medicines regulatory bodies in Tanzania. The project will improve linkage amongst participating institutions, promote adoption and domestication of harmonised guidelines for clinical trials control including those promulgated by the African Vaccines Regulators Forum.

The kick-off meeting discussed the current status of the oversight of clinical trial research and pharmacovigilance, and the roles and tasks to be undertaken by the collaborating members of the project according to the work packages.

The consortium members also discussed the way to establish a mechanism that will help to improve communication among members and facilitate the sustainability of the project when the project period of 30 months ends.

The ASCEND project will ensure that Tanzania's capacity to assess and approve clinical trials of drugs for registration is developed whilst learning from the experience of partners in both the global South and North.

The photo below shows consortium members and other stakeholders at the ASCEND kick-off meeting. At the centre is a chief Pharmacist, Mr Daudi Msasi from the Ministry of Health Community Development, Gender, Elderly and Children, and on his right is seated the Director-General of the Tanzania Medicines and Medical Devices Authority, Mr Adam M. Fimbo.



DPP | Kick-off meeting (virtual) | 17/12 2020

The Developing Paediatric Primaquine (DPP) project is funded under the EDCTP call on paediatric formulations for neglected tropical diseases launched in 2019. The online kick-off meeting took place on 17 December 2020 with a welcome note from Prof. Taylor, followed by presentations from the different participating institutions.

The consortium includes the following partners:

- University of Oxford (UOXF, UK)/Mahidol-Oxford Research Unit (MORU, Thailand) - project coordinator, responsible for the conduct of the bioequivalence study
- Groupe de Recherche Action en Santé sarl. (GRAS, Burkina Faso) – responsible for the conduct of the transmission blocking study
- Armauer Hansen Research Institute (AHRI, Ethiopia) – responsible for the conduct of the radical cure study
- Association de l'École de Biologie Industrielle (EBI, France) – contextualisation: Aroma selection & Acceptability
- Université de Bordeaux (UBx, France) – conceptualisation: Granulation & Packaging
- Réseau Médicaments et Développement (ReMeD, France) – Communication, Dissemination and Exploitation.

In the introductory presentation, Prof. Taylor explained the aims and objectives of the DPP consortium and highlighted that the main goal of the project is to get a quality-assured paediatric primaquine formulation following the WHO Expression of Interest and guidance as set out in their meeting of March 2019. Primaquine (PQ) is recommended as a radical cure of *Plasmodium vivax* and *P. ovale* malaria and transmission-blocking of *P. falciparum* malaria.

Moreover, the consortium expects that the project generates data supporting the access of quality-assured primaquine to patients of all ages and accelerate malaria elimination in Africa and worldwide.

The kick-off meeting was attended by 17 investigators and it was an opportunity for all partners to introduce themselves, highlight their roles in the consortium and provide updates on their plans towards the objectives of the project. Dr Montserrat Blázquez-Domingo, EDCTP Senior project officer, took part in the meeting.



PYRAPREG | First trial patients enrolled | 04/01 and 12/01 2021

The PYRAPREG study has enrolled its first patients, on 4 January 2021 in the study site located in San, Mali, and on 12 January 2021 in the Nazoanga site, Burkina Faso.

The PYRAPREG project - Efficacy and Safety of a newly registered Artemisinin-Based Combination (Pyronaridine-Artesunate-PYRAMAX®) for the treatment of uncomplicated malaria in African pregnant women - is coordinated by Prof. Kassoum Kayentao of the Université des Sciences, des Techniques et des Technologies de Bamako, Bamako, Mali.

Partners in the consortium are from Burkina Faso, Mozambique, the Netherlands, the Republic Democratic of Congo, Spain, The Gambia, and the United Kingdom. Recruitment sites are in San/Segou and Bougoula/Sikasso, (Mali), Nanoro (Burkina Faso), Lisungi (Democratic Republic of Congo), Manhiça (Mozambique), and Basse (The Gambia).

In a recent development, Dr Maminata Traoré-Coulibaly, Scientific Director of the Regional Direction of IRSS, based at the Clinical Research Unit of Nanoro (Burkina Faso), and Study Coordinator of the PYRAPREG study at IRSS, has been appointed on 10 January 2021 as the new Minister delegate for Research and Innovation of the newly formed government in Burkina Faso. Her new role will not allow her to continue her tasks at IRSS and she will resign as a member of the PYRAPREG consortium.

STOOL4TB | Project kick-off meeting | week of 11 January 2021

Stool4TB, a large international project which aims to evaluate a new stool-based qPCR for the diagnosis of tuberculosis (TB) in children and people living with HIV, held its kick-off virtual meeting over 3 days in January.

The four-year EDCTP-funded project is coordinated by ISGlobal. The project has two European and three African partners:

- Amsterdam Institute for Global Health and Development, the Netherlands
- Research Center Borstel, Germany
- Centro de Investigação em Saúde de Manhiça, Mozambique
- Makerere University, Uganda, and
- Baylor Foundation Eswatini, Eswatini.

Also, Baylor College of Medicine in Houston, United States, will be a collaborating institution of Stool4TB.

TB continues to be a leading cause of morbidity and mortality among children and people living with HIV (PLHIV). Despite significant progress in TB diagnostics, TB laboratory confirmation is particularly challenging in children and PLHIV. This is because of the difficulty in obtaining sputum samples and the paucibacillary nature of the disease.

As a consequence, bacteriological confirmation of pulmonary TB in young children and immunosuppressed PLHIV remains disappointingly low. Inability to bacteriologically confirm TB results in both i) under-diagnosis which leads to worse outcomes including increased mortality and ii) over-diagnosis and poor resource allocation. Therefore, new tools need to be developed using easy-to-collect non-respiratory specimens which could improve bacteriological confirmation.

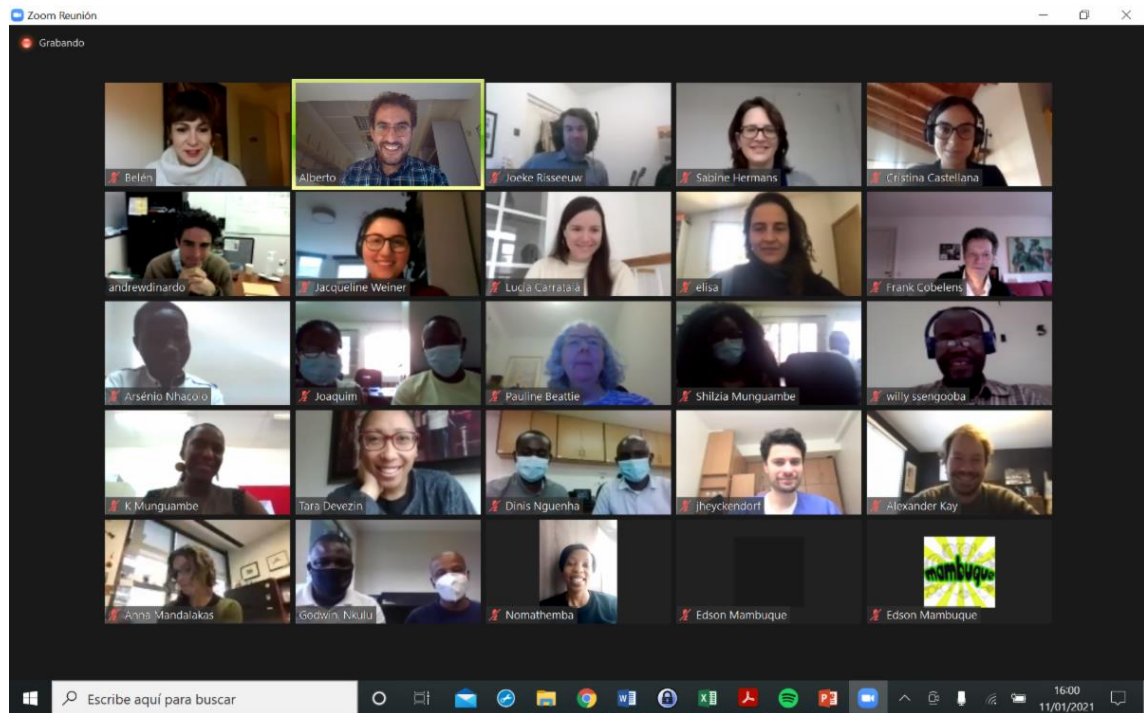
Stool4TB will validate an innovative stool homogenization and DNA isolation method that yields a highly sensitive and specific Mtb qPCR-based diagnostic. STool4TB will evaluate this platform in the high-TB/HIV-burden settings of Mozambique, Eswatini, and Uganda, under the hypothesis that it will narrow the large TB case detection gap by improving TB confirmation rates in children and HIV positive adults while proving feasible and acceptable.

Preliminary data suggest that this platform adds value to existing sputum-based diagnostics and increases rates of bacteriological confirmation. It has the potential to be adapted to a point-of-care diagnostic and thus easily implemented in resource-constrained basic healthcare centres. Moreover, the project will assess the feasibility,

usability, and acceptability of stool collection from both the patient and the health system perspective.

This item is based on the news items of ISGlobal and AIGHD:

- ISGlobal, [STool4TB Will Evaluate an Innovative TB Diagnostic Tool in Children and People Living with HIV](#), 21 January 2021
- AIGHD, [Successful kickoff meeting launches international STOOL4TB project](#), 15 January 2021.



MIMVac | First annual meeting | 21/01 2021

The MIMVaC-Africa - A multilateral initiative to foster the clinical development of effective malaria vaccine candidates in Africa - consortium held its first (virtual) annual meeting on 21 January 2021.

This important event brought together the following partnering institutions:

- Group de Recherche Action en Santé, Burkina Faso, the coordinating Institute
- Centre de Recherche Médicale de Lambaréné, Gabon
- Manhica Health Research Centre, Mozambique
- Ifakara Health Institute, Tanzania
- European Vaccine Initiative and EKUT, Germany
- Luxembourg Institute of Health, Luxembourg
- Leiden University Medical Centre, the Netherlands
- University of Oxford/KEMRI, United Kingdom
- Osaka University, Japan.

Members of the External Independent Scientific Advisory Group and representatives of funder EDCTP and SANARIA Inc, a subcontracted institution, were also involved.

The meeting aimed at discussing progress made within the project work packages, after one year of implementation, and identifying challenges and opportunities in the way forward. In a context where the COVID-19 pandemic has hampered most of the activities not related to COVID-19, the consortium has made noticeable progress in establishing its management structures, initiating seroepidemiological field activities, and making good progress in the preparations of the phase I trials in Europe and Africa.

Overall, achievements in terms of project deliverables were deemed satisfactory and participants renewed their commitment for an upcoming exciting year.

Read more on the [MIMVac project website](#).

CHAPAS-4 information video for children

The EDCTP-funded CHAPAS-4 project studies 'Pharmacokinetics and acceptability of simple antiretroviral regimens' in children with HIV in Africa. The study is coordinated by Dr Mutsa Bwakura-Dangarembizi, University of Zimbabwe, College of Health Sciences, in Zimbabwe, with partners from the Netherlands, South Africa, Uganda, United Kingdom, and Zambia.

The project developed an animation to explain the CHAPAS pharmacokinetics studies to (potential) study participants (children with HIV). The animated video below is meant for older children and was approved by the ethics committee in Zimbabwe. The project intends to make different versions with voiceovers in different languages.



EDCTP Fellows in times of COVID

Dr Olumide Ajibola - SiDIC study

I am a Senior Lecturer based at the First Technical University, Ibadan, Nigeria investigating the 'Role of Schistosomiasis in dysbiosis, inflammation, and bacterial translocation in children from Nigeria', the SiDIC study.

I received my PhD training on Infection and Immunity at the University of Glasgow, United Kingdom. My research interests focus on using genomic tools to understand complex host-parasite interactions for infectious diseases of public health importance in sub-Saharan Africa.



The EDCTP Career Development fellowship has allowed me to return to the Nigerian University system and support my transitioning to independence after about 2 years of postdoctoral experience at the MRC Unit The Gambia at the London School of Hygiene and Tropical Medicine (LSHTM).

My fellowship started on the 1st of September 2020, and I have kickstarted activities despite the challenges faced amid the COVID-19 pandemic. Ethical approval for the SiDIC study has been obtained and preparations for sample collection have begun. We have successfully carried out the first community survey for children infected with urogenital schistosomiasis and we will be following these kids up for at least 9 months.

I am also in the process of setting up sample collection from the hospital in children that may be co-infected with urogenital schistosomiasis and the bacteria *Salmonella*. Molecular analysis to determine the presence of *Schistosoma* and *Salmonella* will be carried out, following which I will spend some time of the second year at Brown University for metagenomic sequencing of faecal DNA. I anticipate that the findings from this study will shed more light on the mechanisms guiding interactions between *Schistosoma* parasites and susceptibility to bacterial infections.

Dr Olumide Ajibola, EDCTP Career Development Fellow

Publications

Dr Babatunde Adeagbo

Dr Babatunde published results from his Career Development Fellowship project: Babatunde Ayodeji Adeagbo*, Akintunde Oluseto Akinlalu, Tony Phan, Jeff Guderian, Gerhardt Boukes, Elize Willenburg, Caryn Fenner, Oluseye Oladotun Bolaji, and Christopher B. Fox: [Controlled Covalent Conjugation of a Tuberculosis Subunit Antigen \(ID93\) to Liposome Improved In Vitro Th1-Type Cytokine Recall Responses in Human Whole Blood](#) *ACS Omega* 2020, 5, 48, 31306–31313, November 19, 2020

Dr Babatunde Adeagbo is an EDCTP Career Development Fellow working on the [development of a candidate TB vaccine](#).

Prof. Wendy Burgers

Thomas C. Williams* and Wendy A Burgers, [SARS-CoV-2 evolution and vaccines: cause for concern?](#) The Lancet, Comment, published 29 January 2021

Prof. Wendy Burgers is an EDCTP Senior Fellow, conducts research on '[Characterising the spectrum of TB and co-infection with HIV – the role of Th22 cells](#)'.

Resources



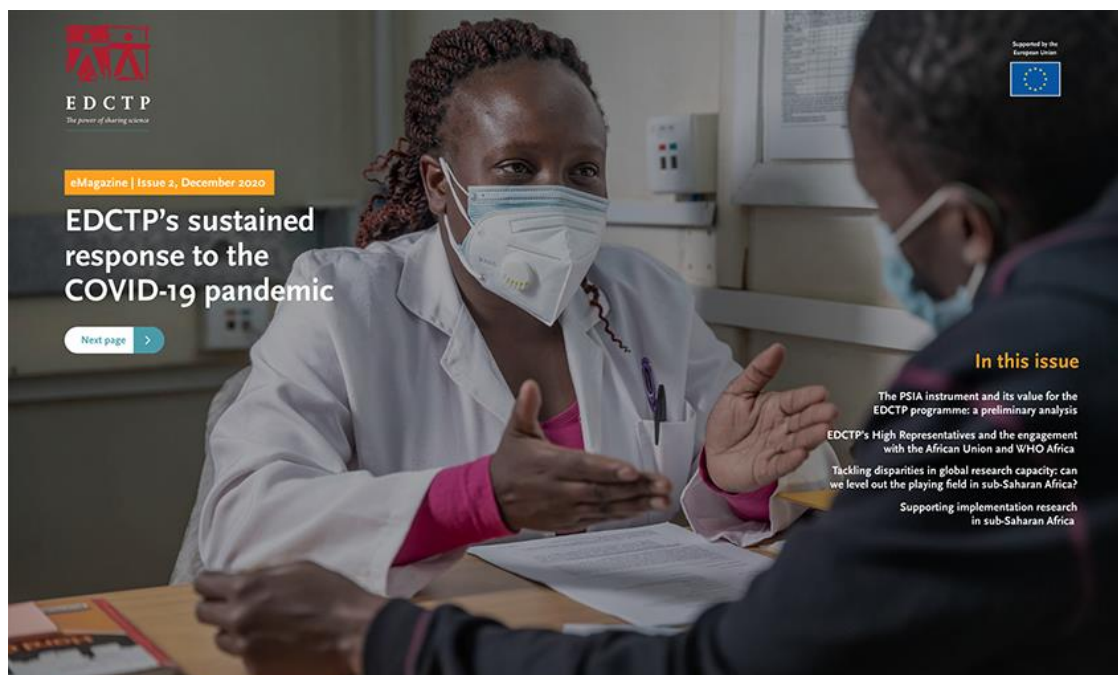
[Collaborative clinical R&D](#) online



[Clinical research capacity](#) PDF



[Fellowships](#) online





EDCTP | Guidelines for grantees - Progress report

EDCTP Guidelines for grantees on how to best use the online progress reporting facility in EDCTPgrants, EDCTP's grant management system. Go to the publication [Online Progress Report in EDCTPgrants – Guidelines for beneficiaries](#).

Publications

Jointly supported by the WHO-AFRO-EDCTP collaboration, we published an article on health research governance in Africa:

- Juliet Nabyonga-Orem (WHO), James Avoka Asamani (WHO) & [Michael Makanga](#) (EDCTP), **The state of health research governance in Africa: what do we know and how can we improve?** [Health Research Policy and Systems volume 19, Article number: 11 \(2021\)](#).
- The European Medicines Authority has published its draft [Public guidance on the parallel application for EU-M4all \(Article 58\) opinion and Centralised Marketing Authorisation procedure](#) for a 1-month [public consultation](#). Article 58 of Regulation (EC) No 726/2004 provides "that the European Medicines Agency (EMA) may give a scientific opinion for medicines intended to be used outside the European Union, primarily for low- and middle-income countries. This work is done in cooperation with the World Health Organization, and with regulators and experts from the LMICs where the medicines are intended to be used. It is now called EU Medicines for All or EU-M4all."

- Updated! [UNAIDS/WHO guidance on Ethical considerations in HIV prevention trials](#)
- A viewpoint on the guidance was published in [JAMA](#) and another opinion piece: [HIV prevention research and COVID-19: putting ethics guidance to the test.](#)

Dr Pauline Beattie (EDCTP Operations Manager) participated in the meeting in November 2019 which involved also many of EDCTP grant holders (past and current), as well as Prof. Cate Hankins (Amsterdam Institute for Global Health and Development and currently Chair of the EDCTP Scientific Advisory Committee). A working group of experts drafted the guidelines based on discussions and all feedback received. EDCTP-funded [PrepVacc trial](#) was mentioned at the November meeting as a good example of an innovative, ethical trial design.

Funding opportunities

Africa Oxford initiative | AfOx Travel grants, 2019+ | Ongoing call

AfOx Travel Grants support the establishment of new collaborations between researchers in African countries and their collaborators at the University of Oxford. Travel Grants are open to all disciplines and open all year round. So far we have awarded over 100 travel grants to researchers from the African continent and the University of Oxford.

[More information](#)

TDR | implementation research: call for proposals | Deadline 19/02 2021

TDR has opened a Call for identification of good practices in engaging communities in research for implementation and in social innovation in health in low- and middle-income countries

[Read more](#)

GSK - Novartis and SAMRC | Project Africa GRADIENT: call for proposals | Deadline 01/03/2021

Project Africa GRADIENT (Genomic Research Approach for Diversity and Optimising Therapeutics) was initiated in 2018 as a collaboration between GSK and Novartis. The primary aim was to establish a consortium to collaborate with expert academic centres and organisations in Africa to support high-quality research on African genetic diversity of relevance to drug therapeutics.

The primary focus will be to evaluate genetic diversity as the contributing factor to variability in exposure, efficacy and/or safety to drugs used to treat tuberculosis (TB) and malaria in Africa. All datasets collated or generated through the program are intended to be released in a public database.

GSK and Novartis have partnered with the South African Medical Research Council (SAMRC) to facilitate the administration of Project Africa GRADIENT. Funding for up to 5 years, in two independent stages with the possibility of extensions.

[More information](#)

MRC UK | Improving health in LMIC countries | Deadline: 14/04 2021

This call will open on 01 February 2021. Apply for funding for research that will benefit the health of people living in low- and middle-income countries (LMICs).

Particularly welcome are proposals that combine expertise from more than one sector to meet a global health challenge. There is no limit to the amount of funding you can apply for. You can submit a proposal of any size, from a small seed-funding proposal to a large-scale programme grant.

You can apply if you are:

- an LMIC-based principal investigator
- a UK-based principal investigator working in partnership with LMIC investigators.

[More information](#)

COURSES

East African Pharmacovigilance Initiative (EAPI) | online short courses

East African Pharmacovigilance Initiative (EAPI) is a partnership between the Pharmacy and Poisons Board and the University of Nairobi funded through the EDCTP-funded EAPI project.

The courses have interactive features like journaling for participants to document their experiences, interactive video content, and interactive text materials. Future content will be expanded to level 3 interactivity, which includes online simulations and practice sessions. The platform also has a forum section for participants.

- The pharmacovigilance (PV) course has three variations: 1) Advanced PV, which is focused on pharmacy professionals working in the PV space; 2) Basic PV course - five modules and tailored to non-pharmacy medical professionals; 3) This course can also be taken by the general public.
- The snakebite course has seven modules that enable the participant to learn more about the prevention and clinical management of snake bites.

[More information](#)

Upcoming events

Virtual Global Forum on TB Vaccines | 20-22/04 2021

The Virtual 6th Global Forum on TB Vaccines will take place from 20-22 April 2021. It provides an important and unique opportunity to review the state of the field, share the latest research findings, and identify new and innovative approaches to TB vaccine R&D, with the end goal of developing and deploying new TB vaccines as quickly as possible.

The Virtual Global Forum program will include presentations and panel discussions focused on progress and key issues in TB vaccine R&D against the backdrop of the COVID-19 pandemic. Sessions will be made available on-demand for registered participants following the Global Forum so that you can view sessions that you were unable to join at the scheduled time.

[More information on the Forum website.](#)

EDCTP Communications thanks the colleagues who provided information for this Update.



EDCTP | Anna van Saksenlaan 51, Den Haag, 2593 HW Netherlands

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