Update is a monthly newsletter from the European & Developing Countries Clinical Trials Partnership.



EDCTP Update May 2018 Supported by the European Union



Highlights

- EUR 118 million available for EDCTP 2018 calls
- Response to the Ebola outbreak in DRC
- TRUST ethics project in European Parliament

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EDCTP 2018 Calls represent € 118 million investment

EDCTP published its 2018 calls for proposals after approval of its 2018 work plan. The eleven calls represent an overall investment of €118 million in clinical research and research capacity in sub-Saharan Africa. With these calls the EDCTP grant portfolio will grow to a total of approximately EUR 538 million, excluding additional cash co-funding raised from other sources.

Dr Michel Makanga, EDCTP Executive Director: "This marks the fifth year of implementation of the second programme of EDCTP and I am greatly encouraged by the growing number and quality of projects in our portfolio. I believe that the fresh injection of €118 million will maintain the momentum as we strive to tackle the questions that matter in addressing the unmet medical needs within our mandate."

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First EDCTP 2018 Calls for proposals open June 6

EDCTP will publish its 2018 Calls for proposals on the website in the early days of June.

Calls by opening date:

06/06/2018

- Diagnostic tools for poverty-related diseases
- <u>Advances in product development for effective prevention, treatment and management</u>
 <u>of co-infections and co-morbidities</u>

12/06/2018

- Strategic action for overcoming drug resistance in malaria
- <u>Strategic action for the comparison, selection and development of malaria vaccine</u> <u>candidates</u>
- <u>Vaccines for diarrhoeal diseases or lower respiratory tract infections</u>
- <u>Capacity development to facilitate delivery and uptake of new or improved medical</u> interventions in African health systems

02/08/2018

• Ethics and regulatory capacities

06/08/2018

<u>Career Development Fellowships</u>

25/10/2018

EDCTP Clinical Research and Product Development Fellowships

02/11/2018

- EDCTP-AREF Preparatory Fellowships
- Senior Fellowships

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Response to the Ebola outbreak in DRC

Currently, EDCTP-funded consortia for epidemic preparedness are active in responding to the Ebola outbreak in Democratic Republic of Congo (DRC). The Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (PANDORA-ID-NET) and the African coaLition for Epidemic Research, Response and Training (ALERRT) consortium are both involved in the response to the latest Ebola outbreak. Read more



PANDORA-ID-NET kicked off in Rome on the 21st/22nd May attended by consortium partners from Congo, Zambia, Uganda, Tanzania, Nigeria, Ghana, Sierra Leone, United Kindgom, France, Germany, and Italy.

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TRUST project co-hosts ethics event in European Parliament

The final event of the <u>TRUST project</u> on double standards, the export of non-ethical research practices to low- and middle-income countries, and equity in international research will take place in the European Parliament on 29 June 2018 (09:00-13:00). <u>Register here before 21 June</u>.

EDCTP is a participant in the TRUST project which is coordinated by Prof. Doris Schroeder (<u>Centre for Professional Ethics</u>, University of Central Lancashire, United Kingdom).and funded by the European Union under Horizon 2020 (grant No 664771). Dr Michelle Singh (Project Officer) and Dr Michael Makanga are involved in the project on behalf of EDCTP. The goal of the TRUST Project is to catalyse a global collaborative effort to improve adherence to high ethical standards for research around the world.

The project's strategic deliverables are three sets of tools based on participatory engagement covering all continents:

- 1. <u>a global code of conduct for research in resource-poor settings</u>
- 2. a fair research contracting on-line tool
- 3. a compliance and ethics follow-up tool, which takes limited resources into account

The event in the European Parliament "Ethics Dumping - Looking for Justice" is co-hosted by TRUST and the European parliamentary group <u>GUE/NGL</u> Among the speakers are Prof. Jeffrey Sachs (keynote), Irina Bokova (former Director of UNESCO), Prof. Doris Schroeder, Dr François Bompart (formerly Sanofi/EFPIA, currently DND*i*) and from EDCTP, Dr Michael Makanga and Dr Leonardo Simão (EDCTP High Representative for Africa). Final speaker is Jean-Eric Paquet, Director-General of the DG Research and Innovation, European Commission.



29 JUNE 2018

ETHICS DUMPING LOOKING FOR JUSTICE

Achieving equity in international research is one of the pressing concerns of the 21st century. This event aims to catalyse a global collaborative effort to improve adherence to high ethical standards around the world.



The TRUST project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 664771.



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Recent events

EDCTP | Visit by Thai Ethics Fellows | 18 May 2018

On Friday, 18 May 2018, EDCTP in the Hague received a team of visitors from Thailand led by Prof. Juntra Karbwang, two teaching staff from Mahidol and KhonKaen University and eight fellows from different Ethics Committees in Thailand.

The visiting team is part of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) network in Asia. The EDCTP team in Cape Town who spearhead the ethics and regulatory capacity building activities: Dr. Thomas Nyirenda, Ms. Nuraan Fakier and Dr. Michelle, joined the meeting via teleconference.

The visiting team members shared their ethics experiences and were also briefed about EDCTP's involvement in ethics and regulatory capacity development in Africa, as well as the TRUST ethics project's newly launched tools.

Besides information sharing, this visit provided an opportunity to discuss different ways of facilitating networking and knowledge transfer from other regions towards EDCTP-supported Ethics Research Committees in Africa. The EDCTP team in Cape Town who spearhead the

ethics and regulatory capacity building activities: Dr. Thomas Nyirenda, Ms. Nuraan Fakier and Dr. Michelle Singh, joined the meeting via teleconference.



European Commission | Horizon Birth Day Prize winners | 13 February 2018 | On 13 February 2018, Carlos Moedas, EU Commissioner for Research, Science and Innovation, Mark Suzman, Chief Strategy Officer and President, Global Policy & Advocacy, for the Bill & Melinda Gates Foundation, and Clarisse Lhoste, Managing Director, MSD Belgium and Luxembourg, and MSD for Mothers' senior executive Ambassador awarded the Horizon Birth Day Prize at a <u>ceremony in Brussels, Belgium</u>.

- Winner 1st place (EU Prize): 'QUARITE' a managerial, hospital based, intervention focused on the introduction of audits of maternal death in hospitals accompanied by education and outreach to improve the quality of care and prevent maternal and perinatal deaths in low-income countries (Institut de Recherche pour le Développement, France and Université de Montréal, Canada).
- Winner 2nd place (BMGF Prize): '<u>CHAI MNH Nigeria</u>' a managerial intervention at district level, involving health centres and hospitals and skilled birth attendants. It is an integrated programme focused on ensuring that at risk deliveries occurring in communities or health facilities are referred upwards in the system and dealt with (Clinton Health Access Initiative, Inc, USA).
- Winner 3rd place (MSD For Mothers Prize): <u>†WOMAN Trial</u>' a tested and validated clinical intervention to use Tranexamid Acid (TXA) as a blood clot stabilising drug, as a first line treatment for postpartum haemorrhage (PPH) the leading cause of maternal mortality around the world (London School of Hygiene and Tropical Medicine, UK).

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Funding and training opportunities

DFID-Wellcome Trust | Call for applications | Deadline 11 June 2018

Call for applications for 'Epidemic Preparedness: Social Science Research Protocols'. Please note: Applications are by invitation only!

- Contact Joao Rangel de Almeida at j.rangeldealmeida@wellcome.ac.uk to discuss your proposal.
- Submit you preliminary application by 11 June 2018

This scheme supports social science researchers who want to develop new standardised ways to conduct research for epidemic preparedness and response. The scheme is a joint initiative between the UK Department for International Development (DFID) and Wellcome. <u>Read more</u> \

EDCTP | Training on management of EDCTP2 grants | 12 July 2018, 10:00-17:00 One-day workshop on financial and project management of EDCTP2 grants. The workshop will be held in the Hotel Mercure, The Hague, the Netherlands, on 12 July 2018. Participation in the workshop is open to all but priority will be given to financial or project/technical managers of EDCTP2 projects.

BOOK EARLY! There are 75 places in the training; placement will be in order of application.

EDCTP cannot provide support for travel or accommodation. Participants have to arrange their own travel and accommodation. A block booking with preferential rates has been made by EDCTP at the venue for the training (Hotel Mercure). It will expire on 11 June 2018.

Applicants are advised not to make any bookings before participation in the training has been confirmed. <u>Read more</u>

Kenya Biology of Parasitism course | Wellcome Trust Research Programme | Kilifi, Kenya 3-7 September 2018 | A week long course (KENBOP2018) targeted at PhD students and postdocs interested in interaction between immune system and pathogens, and how this underlies pathogenesis of infectious and non-communicable disease. Intensive learning sessions and symposium on the most recent advances in the immunology & parasitology of malaria, HIV, TB and helminths. Participants will also benefit from grant writing and career sessions run by scientists who have a strong track record in obtaining research grants. <u>Apply before 15 June 2018</u>.

Gulbenkian Science Institute (IGC) | Master's Projects |

Applications for Master Projects at IGC are open until the end of June 2018.

NIH Fogarty International Centre | Open Calls for proposals |

- <u>Global Infectious Disease Research Training Program</u> | Applications from institutions in low- and middle-income countries (LIMCs) are encouraged. Deadline Letter of Intent:30 days prior to Deadline full application: **26 July 2018**.
- Reducing Stigma to Improve HIV/AIDS Prevention, Treatment and Care in Low- and <u>Middle-Income Countries</u> | Applications from non-domestic entities are restricted to higher education institutions and other non-profit organizations in LMICs. Deadline Letter of Intent: 30 days prior to Deadline full application: **01 August 2018**
- <u>Fogarty HIV Research Training Program</u> Sollicitation of applications under three different Funding Opportunities Announcements (FOAs) including for institutions from LMICs Deadline Letter of Intent: 30 days prior to Deadline full application: 23 August 2018
- Fogarty Emerging Global Leader Award | For LUMIC researchers; see eligibility rules. Deadline for Letter of Intent: 30 days prior to Deadline for application: 07 November 2018

European Commission | EIC Horizon Prize | Early Warning for Epidemics | On 26 April 2018, the European Commission launched a <u>EUR 5 million prize to find the best solution</u> for setting up an early warning system for epidemics using Earth observation data and other kinds of geo-located data to forecast and monitor outbreaks of vector-borne diseases such as malaria, zika, dengue or yellow fever. Deadline for applications: 1 September 2020.

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Resources

EDCTP | Acknowledging EDCTP: A guide for grantees | 15 May 2018

Grantees have a contractual obligation to recognise funding by EDCTP and the European Union in all dissemination activities and publications that arise from the research funded wholly or partly by EDCTP and EU. <u>This guide for grantees</u> (PDF) offers practical guidance to ensure acknowledgement of EDCTP and the EU as funders.

EDCTP | Strategic Research Agenda (update for 2017) | 17 May 2018

The <u>Strategic Research Agenda (2017 update)</u> (PDF) gives an overview of EDCTP research funding priorities.

Priorities are set in relation to EDCTP's mission to accelerate the development of new or improved medical interventions against poverty-related infectious diseases, and strengthen clinical research capacity in Sub-Saharan Africa. The Strategic Research Agenda is updated annually. As far as applicable, current EDCTP-funded projects or projects conducted by the EDCTP European member countries addressing specific priorities, are referenced in the agenda.

EDCTP | Strategic Research Business Plan 2014-2024 | 31 May 2018

The Strategic Business Plan 2014-2024 was no longer available in print. We took the opportunity of the reprint to make minor corrections and to put it in our new layout. Many thanks for <u>consulting and disseminating this version</u>.

TRUST project | Global Code of Conduct | 15 May 2018 |

Trust message: "On 15 May 2018, Prof. Doris Schroeder, Leana Snyders and Prof. Klaus Leisinger presented TRUST's <u>Global Code of Conduct for Research in Resource-Poor Settings</u> to the high-profile UN Leadership Council of the Sustainable Development Solutions Network (SDSN). The SDSN met at the Swedish International Development Cooperation Agency (SIDA) "

World Bank | international Vaccines Task Force | 22 May 2018

From the <u>message of the World Bank</u>: "Robust clinical research capacity in low- and middleincome countries is key to stemming the spread of epidemics, according to a new report from the International Vaccines Task Force (IVTF).

The report, entitled <u>Money and Microbes: Strengthening Research Capacity to Prevent</u> <u>Epidemics</u>, lays out how to develop the political support, financing and coordination required to build this capacity as a crucial component of global epidemic preparedness. The IVTF was convened by the World Bank Group (WBG) and the Coalition for Epidemic Preparedness Innovations (CEPI) in October 2017." Dr Michael Makanga participated in the IVTF.

Stop TB Partnership | Advocacy toolkit | 29 May 2018 Stop TB Partnership launches: <u>Advocacy and Communications Toolkit</u> for global and In-country efforts for a successful civil society hearing and <u>United Nations High-Level Meeting on TB</u>

The Future African Medicines Agency AMA

Short video on the future African Medicine Agency (AMA) will be a specialised agency of the African Union. Its overall aim is to ensure the coordination and strengthening of initiatives to harmonize #medicines regulation.



Recently signed projects

Grant agreements have been signed for the following projects that resulted from the 2016 EDCTP Calls for proposals:

Career Development fellowships 2016

- **ABOUT** | Fellow: Dr Jane WanyamaAntiretroviral therapy outcomes, barriers and facilitators of adherence and linkage to care among individuals initiating treatment following test and start guidelines in an urban HIV clinic in Uganda
- **ARA** | Fellow: Dr Obinna Ekwunife Conditional economic incentives and motivational interviewing to improve adolescents' retention and adherence to antiretroviral therapy in south-east Nigeria: a cluster randomised trial.
- **VXMedSSurv |** Fellow: Dr Dan Kajungu Vaccines and medicines utilisation and safety monitoring system in a health and demographic surveillance system, Uganda

Clinical trials to reduce health inequities in pregnant women, newborns and children

- LIFE Study | Project coordinator: Dr Ilesh Jani Neonatal HIV early infant diagnosis (EID) versus standard-of-care EID - Impact on infant health: a feasibility study of point-of-care testing at birth versus at 6 weeks of age on the uptake of ART and infant prophylaxis, and on rate of infant survival, morbidity and retention in care.
- **PROMISE-EPI** | Project coordinator: Prof. Philippe van de Perre Prevention of mother-to-child transmission of HIV-1: program evaluation and innovative rescue intervention integrated in the expanded program of immunization.

Ethics and regulatory capacities 2016

• **SteRN** | Project coordinator: Mr. Yohannes Sitotaw Addisie Strengthening the capacity of the National Research and Ethics Review Committee and the National Regulatory Authority for Clinical Trials in Ethiopia

Research and clinical management of patients in poverty-related disease epidemics in sub-Saharan Africa

 PANDORA-ID-NET | Project coordinator: Prof. Francine Ntoumi Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics.

Vaccines for poverty-related diseases

- PREV-PKDL | Project coordinator: Dr Odile Leroy, EVI, Germany Clinical development of a therapeutic vaccine for prevention of post-kala azar dermal leishmaniasis.
- **priMe** | Project coordinator: Dr Leander Grode, VPM, Germany A multicentre phase III double-blind, randomised, controlled study to evaluate the efficacy and safety of VPM1002 in comparison to BCG.

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Upcoming events

• Swiss TPH | Summer Symposium | Basel, Switzerland, 28 June 2018 The Swiss Tropical and Public Health Institute will hold its <u>summer symposium 2018</u> under the title: 'Clinical research in Resource-limited Settings: Mission Impossible or Role Model for Future Drug Development?' It will take place at the University Hospital ZLF Kleiner Saal, Basel, Switzerland on 28 June 2018, 08:30-17:00. <u>Registration here.</u>

Swiss TPH Spring Symposium 2018

Swiss TPH Stream Stream

Clinical Research in Resource Limited Settings -Mission Impossible or Role Model for Future Drug Development?

June 28, 2018, Zentrum für Lehre und Forschung, University Hospital Basel, Switzerland



Main events EDCTP will contribute to:

- <u>22nd International AIDS Conference (AIDS 2018</u>) in Amsterdam, The Netherlands from 23-27 July 2018;
- <u>49th Union World Conference on Lung Health</u> (with a focus on human rights), in The Hague, The Netherlands, from 24-27 October 2018







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