

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



## EDCTP Update

June 2018

Supported by the European Union



E D C T P

### Highlights

- **[TRUST ethics project in European Parliament](#)**
- **[Assessing national health research systems](#)**
- **[Ninth EDCTP Forum \(draft\) Programme published](#)**

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### Research ethics event in European Parliament: TRUST project

The final event of the [TRUST project](#) on double standards, the export of non-ethical research practices to low- and middle-income countries and equity in international research, has taken place in the European Parliament, Brussels, on 29 June 2018.

The event in the European Parliament "Ethics Dumping - Looking for Justice" was co-hosted by TRUST and the European parliamentary group [GUE/NGL](#). Among the speakers were Prof. Jeffrey Sachs (keynote), Irina Bokova (former Director of UNESCO), Prof. Doris Schroeder, Dr François Bompard (formerly Sanofi/EFPIA, currently DNDi) and from EDCTP, Dr Michael Makanga and Dr Leonardo Simão (EDCTP High Representative for Africa). Final speaker was Wolfgang Bartscher (Deputy Director General) who represented Jean-Eric Paquet, Director-General of the DG Research and Innovation, European Commission.

Tweets via [#ethicsdumping](#)



EDCTP is a participant in the TRUST project which is coordinated by Prof. Doris Schroeder ([Centre for Professional Ethics](#), 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 main deliverable of the TRUST project was the development of a [Global code of conduct for research in resource-poor settings](#) which soon will be available in several languages.



# 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.

**Ethics  
Dumping**

**Looking for  
Justice**

**Prof. Jeffrey  
Sachs**

**Global Ethics**

**Protecting  
Vulnerable  
Populations**

**European Parliament**

**29 June 2018**

**9:30 – 13:00**

**Room number tbc**

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## EDCTP 2018 Calls for proposals - six opened in June

**6/06/2018**

- [Diagnostic tools for poverty-related diseases](#)
- [Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities](#)

**12/06/2018**

- [Strategic action for overcoming drug resistance in malaria](#)
- [Strategic action for the comparison, selection and development of malaria vaccine candidates](#)
- [Vaccines for diarrhoeal diseases or lower respiratory tract infections](#)

- [Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems](#)

### Two more calls will open in August:

**02/08/2018**

- [Ethics and regulatory capacities](#)

**06/08/2018**

- [Career Development Fellowships](#)

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## Assessing National Health Research Systems in Africa

EDCTP will work closely with African government entities and the WHO Regional Office for Africa (WHO AFRO) to develop a conceptual framework for the development and strengthening of national health research systems (NHRS) in sub-Saharan Africa.

The [Ghana Health Service](#) of the Ministry of Health Ghana, will host a kick-off meeting for policymakers and health professionals from African countries that are members of the EDCTP Association. The delegates, including strategic partners in the African Union and regional economic communities, will meet in Accra, Ghana from 9-10 July as a first step towards developing the framework.

A main objective of the meeting is to prepare surveys to assess the national health research capacities in the 17 African EDCTP member countries. Government institutions will conduct this assessment through implementation of the NHRS barometer, an assessment tool developed by WHO AFRO. Thirty-four health professionals are expected to be prepared to complete NHRS assessment surveys in the African EDCTP member countries.

### Background

- Joses Muthuri Kirigia et alii: Developing the African national health research systems barometer, *Health research and policy systems* 2016; 14: 53 ([pub. online 22 July 2016](#))
- [EDCTP Workplan 2018](#): 3.8 Development and strengthening of the national health research systems of African Partner States of EDCTP

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## Looking ahead: A new EU innovation strategy

On 05 June 2018, the 2018 [Science|Business framework conference](#) took place in Brussels, Belgium. The aim of the conference was to debate the policies and programmes Europe will need for a prosperous future, including an important engine for future growth: research and innovation.

Main topics in the plenary sessions were research and innovation in the new European Union budget, mechanisms for financing innovation, and how Horizon Europe clusters can support achieving the United Nation's sustainable development goals.

With financing research and innovation as central topics, the conference was attended by the Commissioner responsible for the EU budget, Günther Oettinger and Werner Hoyer, the President of the European Investment Bank. Other speakers included Christian Ehler, three-term MEP who is a member of the crucial European Parliament's Committee for Industry, Energy and Research; Prof. Mariana Mazzucato (University College London, UK), who is the special advisor on mission-driven science and innovation to Carlos Moedas, Commissioner for Research and Innovation, European Commission; Jean-Eric Paquet, Director-General of the DG Research and Innovation, European Commission; and Phil Mjwara, the Director General of the South African Department of Science and Technology.

Dr Michael Makanga, EDCTP Executive Director, was one of the panel speakers for the workshop 'Open to the world? How to make Horizon Europe more international?' .



Furthermore he was part of the panel in the afternoon session on 'What's our mission? What goals should we set for the next Framework Programme? Other speakers were: Prof. Mariana Mazzucato, Christian Ehler, Ilkka Niemelä, President of Aalto University (Finland) and Dr Heinz Seyringer, (CEO of V-Research, Austria). (For the introduction by Prof. Mazzucato, see also below, under Resources).



Jean-Eric Paquet and Michael Makanga

## Projects

### **PREV\_PKDL consortium | Kick-off meeting | 6-7 June 2018**

The PREV-PKDL consortium which prepares clinical trials of a candidate vaccine to prevent chronic dermal leishmaniasis in patients treated for visceral leishmaniasis, held its kick-off meeting in York (UK) on 6-7 June 2018. The EDCTP Project Officer for the project, Dr Michelle Helinski, participated in the meeting.

The promising vaccine has been developed by Prof. Paul Kaye and his team at the University of York, United Kingdom. EDCTP invested EUR 8 million in the project (2018-2023) to prevent post kala azar dermal leishmaniasis (PKDL). The project is coordinated by Dr Odile Leroy, Executive Director of the European Vaccine Initiative (Germany).

[Read more](#)

### **EXIT-TB | Translating research into policy for TB screening | 4-5 July 2018**

EXIT-TB, the large project to study how to scale up "evidence-based multiple focus integrated intensified TB screening to end TB in the East African Region" will have its consortium kick-off meeting in Arusha, Tanzania, on 4 and 5 July 2018. The project is coordinated by Dr Esther Ngadaya of the National Institute for Medical Research of Tanzania. EDCTP Project-Officer, Michelle Nderu will contribute to the meeting.

EDCTP invested almost EUR 3 million in the project which receives an equal amount of African and European co-funding from: the University of Addis Ababa (Ethiopia), the Centre for Global Health Research - KEMRI (Kenya), the University of Bergen (Norway), the Institute of Endemic Diseases - University of Khartoum (Sudan), the Kilimanjaro Clinical Research Institute (Tanzania), the National Institute for Medical Research (Tanzania), and the Infectious Diseases Institute - Makerere University (Uganda).

### **REECAO | Ethics review network in West Africa | 2 July 2018**

[First results of REECAO project](#), a research ethics network for West Africa and a [tribute to the late Professor Ogobara Doumbo](#), its coordinator.

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## Recent events

### **European Commission | EOSC Summit 2018| Brussels, 11 June 2018 |**

The European Open Science Cloud summit 2018 took place with the support of the EOSC High Level Expert Group and of the FAIR Data Expert Group, that are both advising the Commission on the way forward with the implementation of the European Open Science Cloud (EOSC).

### **EDCTP | Workshop on GCP - GCLP | Johannesburg, SA, 12-14 June 2018 |**

The EDCTP Africa Office organised a workshop on Good Clinical Practice/Good Clinical Laboratory Practice for mid-career researchers/scientists and research nurses already trained and experienced in GCP, GCLP and health research ethics and would benefit from the workshop to become a 'trainer-of-trainers'.

[Read more](#)

### **Neglected Infectious Diseases | ISNTD d3 2018 | London, UK, 25-26 June 2018**

The International Society for Neglected Tropical Diseases organised its 2018 d3 conference on Drug discovery & development, diagnostics and vaccines for tropical diseases in London on 25 and 26 June. The programme focused on recent developments, gaps and future needs of paediatric drug discovery, treatments and diagnostics (day 1: drug discovery & development, vaccines & synthetic biology; day 2: diagnostics beyond diagnosis, i.e. evaluation, surveillance & monitoring).

Dr Magda Moutaftsi, EDCTP Strategic Partnerships Officer, was invited to open the first day with an introduction of EDCTP as a 'a funding mechanism for the development of medicinal products for Sub-Saharan Africa'.

EDCTP2 funded already six projects for NTDs with a total value of €23.4 million. Large projects have been funded in four diseases - human African trypanosomiasis, schistosomiasis, cysticercosis/taeniasis and leishmaniasis - while fellowships have been awarded for research projects on schistosomiasis, Buruli ulcer, leishmaniasis and lymphatic filariasis. Two calls for

proposals were launched in 2017 that will expand the neglected infectious diseases portfolio: at least six more projects will be funded in 2018 with an estimated value of €22.7 million.

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## Funding and training opportunities

### NIH Fogarty International Centre | Open Calls for proposals |

- [Global Infectious Disease Research Training Program](#) | Applications from institutions in low- and middle-income countries (LMICs) 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 Middle-Income Countries](#) | 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**
- [Fogarty HIV Research Training Program](#) Solicitation 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 [EUR 5 million prize to find the best solution 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 resources:

- [Acknowledging EDCTP: A guide for grantees](#)
- [Strategic Research Agenda \(2017 update\)](#)
- [Strategic Business Plan 2014-2024](#)
- [EDCTP Corporate brochure 2018](#)

**Prof. Mariana Mazzucato | Mission-driven research | 05 June 2018**



Prof. M. Mazzucato What's our mission? What goals should we set for the next Framework Programme? Science|Business conference, Brussels, 05 June 2018

### **Medical Ethics | Conference publication | 08 June 2018 |**

An impressive overview of '*Medical Ethics in the 70 Years after the Nuremberg Code, 1947 to the Present*' was published online as a supplement of The Central European Journal of Medicine / wiener klinische Wochenschrift on 8 June 2018. The publication is the result of an international conference on the topic at the Medical University of Wien on 2-3 March 2017. It contains contributions describing the development from post-war prosecution of medical war crimes to the development of modern bioethics codes and the global situation.

[Czech, H., Druml, C. & Weindling, P. Wien Klin Wochenschr \(2018\) 130\(Suppl 3\): 159.   
<https://doi.org/10.1007/s00508-018-1343-y>](#)

EDCTP authors contributed: Claire Whitaker, Michelle Singh, Nuraan Fakier, Michelle Nderu, Michael Makanga, 'The development of bioethics in Africa: the role of the European and Developing Countries Clinical Trials Partnership.'

### **Open Science | New open preprint service for African scientists | 25 June 2018 |**

[AfricArXiv](#) and [Centre for Open Science](#) launched a moderated preprint service to advance African science on 25 June 2018. From Nature News: "AfricArxiv is the latest of a number of open publishing platforms launched since the beginning of 2018. In March, the African Institute for Mathematical Sciences, and Elsevier announced that they would create the open-access journal Scientific African, and in April, the African Academy of Sciences (AAS) and F1000 launched AAS Open Research, which publishes manuscripts that go through an open peer review process."

[More in Nature News](#)

### **Data Science | NIH | Strategic Plan for Data Science | 04 June 2018**

From the [NIH press release](#): "Storing, managing, standardizing and publishing the vast amounts of data produced by biomedical research is a critical mission for the National Institutes of Health. In support of this effort, NIH today released its first Strategic Plan for Data Science that provides a road map for modernizing the NIH-funded biomedical data science ecosystem. " [Download the PDF.](#)

**Stop TB Partnership | Advocacy toolkit | 29 May 2018** Stop TB Partnership launches: [Advocacy and Communications Toolkit](#) for global and In-country efforts for a successful civil society hearing and [United Nations High-Level Meeting on TB](#)

**Careers | MRC grant applications: recognition of research staff | 20 June 2018 |**

The Medical Research Council (United Kingdom) announced that it has introduced a new status category 'researcher co-investigator' for its grant applications (as from 23 July 2018) to enable recognition of the contribution of research staff.

[Read more](#)

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## 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 Wanyama Antiretroviral 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.
- **ChoVaxim**: Fellow: Dr Caroline C. Chisenga Immunogenicity to cholera vaccine with a population at risk in Zambia: mapping the kinetics of immune responses over time
- **ESSLDPQ P4502D6**: Fellow: Dr Richard Mwaiswelo Single low-dose primaquine efficacy and safety for treatment of uncomplicated *Plasmodium falciparum* malaria based on cytochrome P450 2D6 activity in Bagamoyo district, Tanzania
- **Evaluate 4mTB**: Fellow: Dr Fanie Malherbe Evaluating the response to 4 and 6 month treatment of pulmonary tuberculosis by 18F-FDG PET/CT lung imaging
- **Geographical differences in the immune response**: Fellow: Dr Mustapha Mbow Immune responses in rural to urban gradient: identifying geographical footprints of the immune system to improve vaccine development
- **IPTP-SP+**: Fellow: Dr Jean-Bertin Kabuya Safety and efficacy of intermittent presumptive treatment with sulphadoxine-pyrimethamine using rapid diagnostic test screening and treatment at first antenatal visit
- **Maquisard**: Fellow: Dr Justin Nono Komguez Identification of host regulators of tissue fibroproliferative pathology in schistosomiasis-diseased children in Africa
- **MIDAS**: Fellow: Dr Aida Sivro Mucosal type 1 IFN desensitisation and the risk of HIV acquisition
- **PSOP24-377**: Fellow: Dr Kingsley Badu PSOP24-377: An infectious bite marker for sensitive malaria detection and population level surveillance  
Read [Congratulatory and background AREF press release](#)
- **SAEFRIF**: Fellow: Dr Christine Sekaggya Safety and efficacy of high-dose rifampicin in TB-HIV co-infected patients on efavirenz-based antiretroviral therapy
- **SecBILE**: Fellow: Dr Alexander Kwarteng Impact of secondary bacterial infection in the development of filarial lymphedema among Ghanaian patients
- **SPATOMA**: Fellow: Assistant Prof. Yaya Kassogue Study of pharmacogenetics of ARVs treatment outcomes in Mali, West Africa

- **TRACING:** Fellow: Dr Evaezi Okpokoro  
Mycobacterium tuberculosis infection rates among health care workers in a HIV care and treatment centre in Nigeria
- **VXMedSSurv** | Fellow: Dr Dan Kajungu  
Vaccines and medicines utilisation and safety monitoring system in a health and demographic surveillance system, Uganda

### Senior Fellowships 2016

- **EvaLAMP & db-NALFIA** | Fellow: Ass. Prof. Dawit Wolday  
Evaluation of the LAMP & db-NALFIA for the diagnosis and/or as test-of-cure in patients with visceral leishmaniasis in Ethiopia

### 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

### **EDCTP | Training on management of EDCTP2 grants | 12 July 2018 |**

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. On 03 July, there are still 5 places available.

### **EDCTP | Grant proposal writing workshop | Côte d'Ivoire | 16-18 July 2018**

In collaboration with [ISGLobal](#) (Barcelona Institute for Global Health), the [Pasteur Institute of Côte d'Ivoire](#), and the [Swiss Centre for Research in Côte d'Ivoire](#), EDCTP will organise a workshop on EDCTP Calls for Proposals and grant proposal writing. The workshop will be held in Abidjan, Côte d'Ivoire from 16-18 July 2018. Approximately 40 early-career researchers from French-speaking countries in sub-Saharan Africa will participate in the workshop.

[Read more](#)

### **EDCTP | Information event | Abidjan, Côte d'Ivoire, 17 July 2018 |**

The [Pasteur Institute of Côte d'Ivoire](#) in collaboration with EDCTP and the [Swiss Centre for Research in Côte d'Ivoire](#) (CSRS) will organise an information event for researchers at the [University Félix Houphouët-Boigny](#) (Abidjan) on 17 July 2018, 0900-11:30.  
[Read more](#)

### **AIDS2018 | 22nd International AIDS Conference | 23-27 July 2018 |**

The [AIDS2018](#) conference will be held in the RAI Amsterdam exhibition and congress centre in Amsterdam, the Netherlands. The AIDS2018 [programme is online](#). EDCTP will share a booth with the European Commission.

### **AIDS2018| Joint EDCTP - South African MRC session | 26 July 2018, 07:00 |**

EDCTP and the [South African Medical Research Council](#) will jointly contribute a session (#1436) on '[Breaking down barriers: HIV interventions in sub-Saharan Africa](#)'. The session will be co-chaired by [Prof. Catherine Hankins](#) (Deputy Director for Science, Amsterdam Institute for Global Health and Development) and [Prof. Quarraisha Abdool Karim](#) (Associate Scientific Director of CAPRISA, South Africa).

### **AIDS2018 | Invitation to EDCTP drinks reception | 24 July 2018, 18:30-20:30 |**

EDCTP would be delighted to have friends and colleagues at AIDS2018 to join us for a drinks reception. It will be hosted by Dr Michael Makanga, EDCTP Executive Director. The event will take place at the the Rotisserie Terrace at The Roast Room (Europaplein 2, 1078 GZ Amsterdam), directly next to the RAI Conference Centre, on Tuesday, 24 July 2018 at 18:30-20:30.

### **Union | 49th World Conference on Lung Health | The Hague, the Netherlands |**

<http://thehague.worldlunghealth.org/>

### **EDCTP Ninth Forum | Programme (session level) published | Forum website**



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