

EDCTP Update May 2019



EDCTP

Highlights

- Four major calls open in June
- World Health Assembly EDCTP reception
- EDCTP Newsletter published on Fellows and Fellowships

Contents

- Four major calls for clinical trials
- Recently signed projects
- Projects
- Recent events
- Funding
- Resources
- Upcoming events

Four major EDCTP calls open in June

Four major Calls for proposals for Research and Innovation Actions (clinical trials) will open in June 2019. These actions aim to support projects which include clinical trials:

Strategic actions supporting large-scale clinical trials

Open to application: 03 June 2019 - Call budget: EUR 20 million

The purpose is to support clinical research activities that are part of a large-scale clinical trial with the potential to achieve rapid advances in the clinical development of new or improved medical interventions (drugs, vaccines, microbicides) or diagnostics, including multiplex diagnostic platforms, for poverty-related infectious diseases.

New drugs and vaccines for priority pathogens in antimicrobial resistance

Open to application: 03 June 2019 - Call budget: EUR 18 million

The purpose is to provide funding for clinical trials to be conducted in sub-Saharan Africa which aim to develop new or improved medicinal products (drugs and vaccines) or combinations thereof against pathogens on the WHO priority list that also fall within the scope of the EDCTP2 programme, specifically Campylobacter, Salmonella, *Streptococcus pneumoniae*, and *Mycobacterium tuberculosis*.

Paediatric drugs formulations for poverty-related diseases

Open to application: 10 June 2019 - Call budget: EUR 18 million

Proposals should focus on the adaptation of existing medicinal products (drugs), including offpatent products, to the specific needs of children (0-17 years of age). Proposals may address any of the poverty-related infectious diseases within the scope of the EDCTP2 programme.

Strategic actions on product-related implementation research

Open to application: 10 June 2019 - Call budget: EUR 20 million

The purpose is to support distinct strategic actions to translate medical interventions of proven efficacy (diagnostics, drugs, vaccines, and microbicides) into routine care. Proposals may include testing of delivery methods to increase population coverage, retention in care and adherence to the intervention. Proposals must focus on poverty-related infectious diseases in the scope of the EDCTP2 programme and should leverage major support from other funders.

Back to top

Recent EDCTP publications

The **EDCTP 2019 Work plan**, after final approval by the General Assembly of the EDCTP Association on 22 May 2019, has been published on the website. It contains not only the calls for proposals but also other EDCTP-planned activities and research projects by EDCTP member countries (PSIAs).

Read the work plan 2019

The **EDCTP quarterly Newsletter** (Vol 14, 1 - April 2019) has been published on the website. The main topic of the issue is scientific leadership and the ways it is developed through the EDCTP fellowship scheme. Furthermore, information on the EDCTP Alumni platform and activities.

Read the Newsletter



EDCTPNEWSLETTER

European & Developing Countries Clinical Trials Partnership

April 2019 • Volume 14 • No. 2

In this Newsletter:

- · Ninth EDCTP Forum abstracts published
- EDCTP Alumni network: connecting African researchers
- EDCTP fellowship programme
- Alumni Network meeting in Lisbon
- · Alumni Network working groups
- Career profiles
- · 2019 calls for proposals; coming soon

Ninth EDCTP Forum abstracts published

Scientific leadership

Dear partners and friends,

Development of scientific excellence and leadership is a key driver to building sustainable and impactful research and development. This issue celebrates the EDCTP fellows as part of the transformative success stories of our partnership.

The large EDCTP-funded clinical research projects as a rule offer integrated and collaborative post-graduate training for Master's and PhD students, as well as post-doctoral mentorship. Beyond this is a comprehensive fellowship scheme for current and aspiring African scientific leaders. To date, EDCTP has invested in more than 160 fellows from sub-Saharan Africa who are connected through the

product development and closely related fields while also training and mentoring junior researchers.

It is worth noting that we have introduced the novel element of a tandem fellowship in the Senior Fellowships to address the capacity equity gap. The 2019 call 'Senior Fellowships Plus' asks senior fellows to train and mentor not only junior researchers at their institution but also a Trainee Fellow at a

institution but also a Trainee Fellow at a host institution in another country. This requirement — a separate work package — aims to address a geographical and gender imbalance in the proposals we receive, which usually come from better-resourced African countries.

We expect to publish the ten 2019 calls for proposals in full shortly and I would

Recently signed projects

Clinical trials to reduce health inequities in pregnant women, newborns and children - 2017

- Neo bnAb | Coordinator: Dr Arne Kroidl | Effectiveness, efficacy and operational feasibility of passive transfer of VRC01-LS antibody to prevent intra-/postpartum HIV mother-to-child transmission during the breastfeeding period in HIV-exposed infants from Tanzania and Mozambique: a prospective, randomised, double-blind placebocontrolled proof-of-concept trial
- PediCAP Trial | Project coordinator: Prof. Carlo Giaquinto | Impact of duration of antibiotic therapy and of oral step-down to amoxicillin or co-amoxiclav on effectiveness, safety and selection of antimicrobial resistance in severe and very severe childhood community-acquired pneumonia (CAP): a randomised controlled trial

Treatment innovations for poverty-related diseases (2017)

 INTENSE-TBM | Coordinator: Prof. Fabrice Bonnet | Intensified tuberculosis treatment to reduce high mortality of tuberculous meningitis in HIV-infected and uninfected patients

Senior Fellowships (2017)

• H-CRIS | Fellow: Dr George Kyei | Identification of novel HIV reactivation agents: towards building translational HIV cure research infrastructure in Ghana

Career development fellowships (2017)

• Latent HIV-1, Viral Suppress and Hope for HIV Cure | Fellow: Dr Edward Maina | Investigation of the impact of inducible, replication-competent latent HIV-1 as an impediment to HIV/AIDS cure in the context of sustained viral suppression.

Back to top

Projects

BU-RPA | EDCTP Fellow Dr Michael Frimpong | 01 February 2019

Dr Michael Frimpong, a 2015 EDCTP Career Development Fellow, who is working on 'Rapid detection of Mycobacterium ulcerans infection by recombinase polymerase amplification' published in *Plos Neglected Tropical Diseases:* Frimpong et al.: 'Rapid detection of Mycobacterium ulcerans with isothermal recombinase polymerase amplification assay'

See also the explanatory video <u>Field-deployable recombinase polymerase amplification assay for rapid detection of Buruli ulcer</u> by Prof. Richard Phillips and Dr Michael Frimpong (video Kumasi Center for Collaborative Research, Ghana)



Field-deployable recombinase polymerase amplification assay for rapid detection of Buruli ulcer

ETEC | Enterotoxigenic Escherichia coli vaccine trial starts | 18 April 2019

The company Scandinavian Biopharma announced the <u>start of the EDCTP-funded clinical</u> <u>evaluation of the candidate vacine against the pathogen Enterotoxigenic Escherichia</u> <u>coli (ETEC)</u> which causes diarrhoea, a major cause of morbidity and mortality among young children in endemic areas.

In May 2019, the project starts with a phase I age-descending trial in Zambia (as a sequel to the already successful age descending phase I/II trial in 500 Bangladeshi participants down to 6 months of age). The study will be led by Dr Roma Chilengi, Chief Scientific officer at CIDRZ in Zambia. This study will immediately be followed by a Phase IIb study in approximately 5,000 children 6-18 months of age in The Gambia. The objective of this study is to investigate the protective efficacy of the vaccine over a 1-2-year period against moderate to severe diarrhoea caused by ETEC.

See also a press release on a related trial in travellers.

PZQ4PSAC | More funding for praziquantel paediatric formulation | 09 May 2019

The Pediatric Praziquantel Consortium secured more funding from GHIT to prepare the regulatory dossier for submission to the European Medicine Agency and to scale up manufacturing.

EDCTP is one of the co-funders of a phase III clinical trial of a new praziquantel orally disintegrating tablet formulation suitable for preschool-aged children with schistosomiasis. See press release.

PROFORMA | Annual meeting in Rwanda | 13 May 2019

PROFORMA - Pharmacovigilance infrastructure and post-marketing surveillance system capacity building for regional medicine regulatory harmonization in East Africa - held its annual meeting in Rwanda, hosted by the University of Rwanda, Kigali.

See project description on CORDIS and tweet.

PYRAPREG | Consortium kick-off meeting, Bamako, Mali | 27 May 2019

On Monday 27 May, the PYRAPREG consortium had its kick-off meeting in Bamako, Mali. PYRAPREG is coordinated by Professor Kassoum Kayentao from the Malaria Research and

Training Centre (MRTC) - Parasitology / University of Sciences, Techniques and Technologies of Bamako (USTTB).

PYRAPREG brings together eight academic partners, five in Africa and three in Europe. All partners have a long history of collaboration in medical research. The research team comprises Prof Kayentao (study coordinator) (USTTB, Mali), Prof. Halidou Tinto (IRSS,Burkina Faso), Prof. Umberto D'Alessandro (MRC Unit The Gambia & United Kingdom), Dr Hypolite Muhindo (UNIKIN, Democratic Republic of Congo), Prof. Esperança Sevene (CISM, Mozambique), Prof. Clara Menéndez (ISGlobal, Spain), Prof. Henk Schallig (AMC, the Netherlands), and Dr Thomas Dorlo (NKI, the Netherlands).

Read more in media (French):

 MRTC-Parasitologie lance PYRAPREG pour lutter contre le paludisme chez les femmes enceintes

AMBITION-cm | Investigators' meeting | 28-29 May 2019

The AMBITION-cm project (High-dose ambisome on a fluconazole backbone for cryptococcal meningitis induction therapy in sub-Saharan Africa: a randomised controlled non-inferiority trial) coordinated by Dr Joseph Jarvis of the London School of Hygiene & Tropical Medicine, United Kingdom, held its annual investigators' meeting in Paris, France, on 28-29 May 2019. This meeting is held as the project is mid-term and well underway: the trial is ongoing at all sites (Botswana, Malawi, South Africa, Uganda and Zimbabwe) and updates from all sites on the agenda of the meeting. Dr Johanna Roth (EDCTP Project Officer) participated in the meeting. See also the press release on the kick-off meeting in Botswana in 2017; and the project webpage on the website of Institut Pasteur.

LusoAfro Bioethics | new website and newsletters | May 2019

The LusoAfro Bioethics project (Strengthening Bioethics committees in the Lusophone-African region | Reforçando os comités de Bioética da região da África Lusófona) which is coordinated by Prof. João Schwalbach (CNBS, Maputo, Mozambique), has a website and published two newsletters.

Back to top

Recent events

INTEREST | 13th conference, Accra, Ghana | 14-17 May 2019

At the 13th Interest Conference (Accra, Ghana; 14-17 May 2019) EDCTP organised one of the early morning sessions on 17 May, on 'Grantspersonship'. Lara Pandya (EDCTP) and two Career Development Fellows, Joseph Fokam and Agnes Kiragga, presented.



Dr Joseph Fokam with the poster of the EDCTP project

ECRIN - FCRIN | Clinical trials conference | Paris, 20 May 2019

In celebration of International Clinical Trials Day, the European Clinical Research Infrastructure Network (ECRIN) and its French scientific partner F-CRIN held a conference on patient stratification studies in Paris on 20 May 2019.

Governance | Scientific Advisory Committee and General Assembly meet | 21-23 May 2019

The <u>EDCTP Scientific Advisory Committee</u> (SAC) held its spring meeting with seven new members. On the 22nd of May the SAC met the <u>General Assembly</u> (GA) members in a joint meeting. This was followed by the spring meeting of the GA of the EDCTP Association.

Various topics such as the next Forum and the future of the EDCTP programme were discussed while also a new chair and vice-chairs were elected by the Assembly.



The new Chair and Vice-Chairs of the General Assembly and EDCTP Board and two more Board members (left to right): Yazdan Yazdanpanah (France, Chair), Christane Druml (Austria), Michael Makanga (EDCTP Executive Director), Morven Roberts (United Kingdom, Vice-Chair), Godfrey Biemba (Zambia) and Jeffrey Mphahlele (Souh Africa, Vice-Chair).

World Health Assembly | EDCTP reception | 27 May 2019

In the setting of the World Health Assembly (WHA), the annual governance meeting of the World Health Organization in Geneva, Switzerland, from 20-28 May 2019, EDCTP hosted a reception for members of the WHA delegations from EDCTP Member Countries and other interested parties on 27 May 2019. The aim of the informal meeting was to strengthen cooperation with WHO and alignment with relevant WHO activities.

EDCTP was represented by its High Representatives Dr Leonardo Simão (former Minister of Health and Minister of Foreign Affairs and Cooperation of Mozambique). Prof. Marcel Tanner (President of the Swiss Academy of Sciences and Director Emeritus and President of the R. Geigy Foundation, Swiss Tropical and Public Health Institute), Dr Michael Makanga, EDCTP Executive Director), Dr Ole Olesen (EDCTP Director of International Cooperation Europe) and Lara Pandya (EDCTP Strategic Partnerships Officer).



Left to right: Leonardo Simão, Magaran Bagayoko (WHO AFRO Director Communicable Diseases Cluster), John Reeder (Director of TDR), Michèle Boccoz (WHO Director-General Envoy for Multilateral Affairs), Michael Makanga, Dr Soumya Swaminathan (WHO Chief Scientist), Ren Minghui (Assistant Director-General, Universal Health Coverage, Communicable and Noncommunicable Diseases), Marcel Tanner, Zabulon Yoti (WHO AFRO Emergency Response), Mwele Ntuli Malecela (WHO Director Global Programme for Neglected Tropical Diseases), HRH Princess Cristina of Spain, Pedro Alonso (Director of the WHO Global Malaria Programme).

Back to top

EDCTP 2109 Calls for proposals published

The General Assembly of the EDCTP Association approved the EDCTP work plan 2019 on 23 May 2019. The 2019 Calls for proposals are now officially published on the EDCTP website.

EDCTP will have 10 calls for proposals to support clinical research and related activities on poverty-related diseases. These calls for proposals are supported through three distinct types of Horizon 2020 'actions':

- * Research & Innovation Actions (RIA) are multicentre clinical trials conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.
- * Coordination & Support Actions (CSA) support activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.
- * Training & Mobility Actions (TMA) are fellowships that focus on the career development of individual researchers or research team members.

Calls for proposals

Strategic actions supporting large-scale clinical trials (RIA)

Open to application: 03 June 2019

Deadline for application: 07 November 2019

New drugs and vaccines for priority pathogens in antimicrobial resistance (RIA)

Open to application: 03 June 2019

Deadline for application: 07 November 2019

Paediatric drugs formulations for poverty-related diseases (RIA)

Open to application: 10 June 2019 Deadline for application: 10 October 2019

Strategic actions on product-related implementation research (RIA)

Open to application: 10 June 2019

Deadline for application: 21 December 2019

Vaccines against Lassa virus - joint call with CEPI (RIA)

Open to application: 02 November 2019 Deadline for application: 07 April 2020

Ethics and regulatory capacities (CSA)

Open to application: 02 August 2019

Deadline for application: 22 November 2019

Career development fellowships (TMA)

Open to application: 06 August 2019 Deadline for application: 27 November 2019

EDCTP-AREF Preparatory fellowships (TMA)

Open to application: 06 August 2019

Deadline for application: 27 November 2019

EDCTP-TDR Clinical research & product development fellowships (TMA)

Open to application: 01 October 2019 Deadline for application: 28 February 2020

Senior fellowships Plus (TMA)

Open to application: 02 November 2019 Deadline for application: 01 February 2020

Back to top

Resources

WHO | Compendium of WHO malaria guidance | April 2019

WHO: "The Global Malaria Programme has just launched a <u>Compendium of WHO malaria guidance</u>. The publication provides, for the first time, a complete list of all formal WHO policy recommendations on malaria in a single resource. It also serves as a catalogue of all WHO publications on malaria prevention, diagnosis, treatment, surveillance and elimination." The Global Malaria Programme has also created a new section on the website dedicated to explaining its policy-making process.

TRUST | Global Code of Conduct | published in Open access

One of the deliverables of the TRUST project has now been published in book format - Doris Schroeder, Kate Chatfield, Michelle Singh, Roger Chennells, Peter Herissone-Kelly: Equitable Research Partnerships A Global Code of Conduct to Counter Ethics DumpingForeword by Klaus Leisinger. Michelle Singh is Project Officer at EDCTP. The book can be found here

New EDCTP resources

EDCTP quarterly Newsletter EDCTP 2019 work plan EDCTP 2019 Grants manual EDCTP guidance material for Financial management of grants

Other EDCTP resources

- The added value of EDCTP to Europe
- The added value of EDCTP to Africa
- <u>Tackling infectious disease in sub-Saharan Africa. EDCTP-funded clinical</u> studies for medical interventions 2003-2018
- EDCTP Corporate brochure 2018
- EDCTP Annual Report 2017 Maintaining momentum
- Short animated video on EDCTP
- Moving forward and consolidating gains for an EDCTP successor programme(Report on EDCTP High-Level meeting in Lisbon, Portugal, 17 September 2018)
- Engaging African governments to strengthen national health research systems with complementary international cooperation (Report on Dakar High-Level Meeting, 30 August 2018)
- Development and strengthening of the national health research systems in sub- <u>Saharan Africa</u> (Report on the EDCTP-WHO meeting in Accra, Ghana, 9-10 July 2018)
- Ninth EDCTP Forum abstracts published in supplement of BMJ Global Health (Vol. 4, April 2019, Suppl. 3
- Strategic Research Agenda (2017 update)
- Strategic Business Plan 2014-2024
- EDCTP2 policy on clinical trials registration, publication and data sharing
- Acknowledging EDCTP: A guide for grantees
- Guide financier à l'intention des bénéficiaires
- Guidance for applicants on preparing full proposals and annex 1 of the grant agreement (available with all 2018 calls)

Back to top

Upcoming events

Wellcome Trust | Survey on clinical trials | open till 14 June 2019

Wellcome is exploring how best to support public health and clinical interventions to improve global health. One way is a current survey to hear ideas about what the next 10 years of global health trials might look like. Wellcome wants to hear your biggest and boldest ideas!

What are the pivotal trials that can transform global health?

Which health interventions have the potential to truly transform the health of people living in low- and middle-income countries? Wellcome is looking for large-scale evaluations of interventions which are in development but have not yet been formally evaluated (whether these be a product such as a diagnostic tool, drug, vaccine, a behavioural intervention, and be targeted at individuals, communities or a combination.

European Commission | European Development Days 2019 | 18-19 June 2019

Europe's leading forum on development since 2006 is organised by the European Commission. EDD 2019's title is "Addressing inequalities: building a world which leaves no one behind".

See the EDD website

EDCTP | Training on management of EDCTP2 grants | 5 July 2018

EDCTP will organise a one-day workshop on financial and project management of EDCTP2 grants. The workshop will be held in the Mercure Hotel, The Hague, the Netherlands, on 5 July 2019. 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 70 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 but please wait for confirmation of participation. Event page on EDCTP website.

IAS2019 | Mexico City | 21-24 July 2019

The 10th IAS conference on HIV science will take place in Mexico City, Mexico, from 21 to 24 July 2019.

- Registration information <u>here</u>
- Join the IAS2019 conversation: @IAS2019 #IAS2019 Facebook mailinglist

ECTMIH2019 | Liverpool United Kingdom | 16-20 September 2019

The 11th European Congress on Tropical Medicine and International Health will take place in Liverpool, United Kingdom, from 16-20 September 2019. Every two years, communities of health professionals, researchers, scientists and students come together from academic, clinical, NGO and industry settings across the world to attend ECTMIH, which is an initiative of the Federation of European Societies of Tropical Medicine and International Health (FESTMIH). The Royal Society of Tropical Medicine and Hygiene (RSTMH) will host the ECTMIH 2019.

EC Research and Innovation | European R&I Days | 24-26 September 2019

The European research & innovation days will take place in Brussels, Belgium, from 24-26 September 2019. Besides a science and invention fest, the event will also provide an opportunity for stakeholders to suggest ideas pertaining to the strategy for Horizon Europe, the European Commission's proposal for the next EU research and innovation programme (2021-2027) with a budget of €100 billion.

More on the EC web pages for the event

SCOMRA 2019 | Medical products regulation in Africa | 30/09-01/10 2019

Register now for the 4th SCoMRA conference (the 4th Scientific Conference on Medical products Regulation in Africa) organised by NEPAD in Victoria Falls, Zimbabwe, from 30 September to 1st October 2019-Victoria Falls Zimbabwe, abstract submission closing soon. More information

ICASA 2019 | Intern. Conf. on AIDS and STIs in Africa | 2-7 December 2019

The 20th ICASA conference is the biggest HIV/AIDS conference in Africa. ICASA2019 will be held in Kigali, Rwanda from 2-7 December 2019. The conference theme "AIDS Free Africa - Innovation, Community, and Political Leadership". "It engages all stakeholders in the Post-SDG Framework, where sustainability of the response in reaching 90, 90, 90 will not be possible if human rights are not a key priority". Abstract submission closes on 30 July 2019. More on the website.

Back to top