Esteemed Stakeholders,

We have had an exciting first quarter of 2017 as we work on our plans to bridge research and development gaps for poverty-related infectious diseases. This newsletter features our recently signed grants, the kick-off of two new major clinical studies, and outlines our planned 2017 calls for proposals. It reflects our progress as a funder of R&D for medical interventions against poverty-related diseases.

The launch of the 2016 G-FINDER report on neglected disease R&D, again underpinned the need to support R&D on the neglected diseases if we are to make global progress towards sustainable development goals. Against a worrying downward global trend, the European Union (EU) encouragingly increased its contribution to this research and its contribution to EDCTP is part of this. The EU is now the second-largest global public funder in this field.

This issue also shows our strategic support of research excellence as well as research ethics review capacity. The plans for 2017 offer an even richer range of approaches for the systematic development of careers and leadership of scientists in Africa. Secondly, the growing geographical spread of our activities clearly demonstrates our purposeful strengthening of national ethics and regulatory authorities and increasing their cooperation, in order to improve the review and oversight of clinical trials activities in sub-Saharan Africa.

Moreover, the EU-funded TRUST project supported the development of a unique community-based code of research ethics. The San organisations and communities in South Africa launched the code in Cape Town, South Africa on 3 March 2017.

Around the same time, Prof. Christiane Druml, the current UNESCO Chair of bioethics in Austria (and the representative for Austria to the EDCTP General Assembly) organised an international conference on bioethics in Vienna, Austria on 2-3 March. EDCTP contributed to this meeting on 70 years of medical ethics and its future in Europe and globally.

Importantly, initiatives by EDCTP member countries offered opportunities to discuss their future pursuit of joint activities under the EDCTP programme. In February, the All-Parliamentary Group on Global Health in the United Kingdom hosted a meeting on the benefits of the programme. In March, at the initiative of several member countries, a workshop in Vienna for all European Participating States discussed possibilities of intensifying their involvement and to further better alignment of relevant research national programmes.

The coming months are even more exciting and I encourage our readers to closely follow new developments on our website.

Dr Michael Makanga
Executive Director
Newly signed grants

**Call: Ethics and regulatory capacities**

**East Africa pharmacovigilance initiative**
University of Nairobi, Kenya with a partner also from Kenya  
**Acronym:** EAPI  
**Project coordinator:** Dr Kefa Bosire (University of Nairobi, Kenya)  
**Starting date:** 1 March 2017  
**Duration:** 36 months  
**Grant amount:** EUR 300,000  
**Grant agreement:** CSA-Ethics-876

**Renforcement de l’Éthique des Essais Cliniques en Afrique de l’Ouest** [Strengthening research ethics of clinical trials in West Africa]  
Ministry of Health and Public Hygiene, Mali with partners from France, Ghana, Guinea, and Mali  
**Acronym:** REECAO  
**Project coordinator:** Professor Ogobara Doumbo (Malaria Research & Training Center, Mali)  
**Starting date:** 1 April 2017  
**Duration:** 36 months  
**Grant amount:** EUR 299,881  
**Grant agreement:** CSA-Ethics-880

**Call: 2015 Career Development Fellowships**

Cluster randomised community-based trial of annual versus biannual single-dose ivermectin plus albendazole against Wuchereria bancrofti infection in human and mosquito populations  
**Career Development Fellow:** Dr Dziedzom K. de Souza  
Noguchi Memorial Institute for Medical Research (NMIMR), Accra, Ghana  
**Starting date:** 1 April 2017  
**Duration:** 36 months  
**Grant amount:** EUR 149,885  
**Grant agreement:** CSA-Ethics-880

**Call: 2015 Senior Fellowships**

Novel biomarkers predictive of susceptibility and treatment response in patients with MDR-TB  
**Senior Fellow:** Prof. Keertan Dheda  
University of Cape Town, South Africa  
**Starting date:** 1 April 2017  
**Duration:** 60 months  
**Grant amount:** EUR 400,224  
**Grant agreement:** CSA-Ethics-880

Malaria research and capacity building for field trials in Tanzania  
**Senior Fellow:** Dr John Lusingu  
National Institute for Medical Research (NIMR), Tanzania  
**Starting date:** 1 April 2017  
**Duration:** 60 months  
**Grant amount:** EUR 498,750  
**Grant agreement:** CSA-Ethics-880

What is the feasibility, accuracy, and optimal manner in which next-generation tests for tuberculosis can be used in high-burden settings?  
**Senior Fellow:** Prof. Grant Theron  
Stellenbosch University, Stellenbosch, South Africa  
**Starting date:** 1 April 2017  
**Duration:** 60 months  
**Grant amount:** EUR 498,902  
**Grant agreement:** CSA-Ethics-880

Harnessing parasite diversity and naturally acquired protective immunity against Plasmodium falciparum malaria for the development of highly effective vaccines  
**Senior Fellow:** Prof. Faith Osier  
Kenya Medical Research Institute, Kenya  
**Starting date:** 1 April 2017  
**Duration:** 60 months  
**Grant amount:** EUR 498,760  
**Grant agreement:** CSA-Ethics-880

**Call: Improved treatment and clinical management of poverty-related diseases**

Children with HIV in Africa – Pharmacokinetics and acceptability of simple antiretroviral regimens  
University of Zimbabwe, College of Health Sciences (UZCHS), Zimbabwe with partners from the Netherlands, South Africa, Uganda, United Kingdom, and Zambia  
**Acronym:** CHAPAS 4  
**Project coordinator:** Dr Mutsa Bwakura-Dangarembizi (University of Zimbabwe, Zimbabwe)  
**Starting date:** 1 July 2017  
**Duration:** 66 months  
**Grant amount:** EUR 7,556,256  
**Grant agreement:** TRIA-2015-1078

PanACEA, a drug development programme to shorten and simplify treatment of tuberculosis  
Stichting Katholieke Universiteit [Foundation Catholic University] (RUNMC), Netherlands with partners from Gabon, Germany, Malawi, Mozambique, South Africa, Switzerland, Tanzania, Uganda, and United Kingdom  
**Acronym:** PanACEA  
**Project coordinator:** Professor Martin Boeree (Radboud University Nijmegen Medical Centre, Netherlands)  
**Starting date:** 1 March 2017  
**Duration:** 60 months  
**Grant amount:** EUR 11,394,775  
**Grant agreement:** TRIA-2015-1102

**Please note:** grant amounts represent EDCTP’s contribution to the project.
EDCTP aims to strengthen cooperation between European and sub-Saharan African countries on the topic of clinical research ethics. It aims in particular to build the African capacity for conducting high-quality innovative clinical research consistent with fundamental ethical principles and international regulatory standards. EDCTP is currently part of the TRUST ethics project in which EDCTP collaborates with other global partners in the ethics field. It is also actively funding the strengthening of ethics and regulatory capacity in Africa through the Horizon2020 Coordination and Support Action funding instrument.

TRUST, an EU-funded global ethics consortium supported the development of the San code of research ethics by the South African San Institute and the South African San Council in collaboration with three South African San groups— the Khomani, !Xun and the Kxew. On 2 March 2017, the code was launched at the TRUST meeting in Cape Town, South Africa. Project Officer Dr Michelle Singh represented EDCTP at the meeting. The San research ethics code aims to prevent exploitative research within San communities.

From 2-3 March 2017, Dr Michael Makanga, EDCTP Executive Director participated in a global conference celebrating Medical Ethics in the 70 years after the Nuremberg Code, 1947. The conference was held in Vienna, Austria, hosted by the Medical University of Vienna and convened by Dr Christiane Druml, the Austrian representative to the EDCTP General Assembly and UNESCO Chair of bioethics in Austria. The conference covered important topics from ethics codes to bioethics which included among more the role of the Council of Europe, the World Medical Association and its declaration of Helsinki, and the UNESCO Universal declaration on bioethics and human rights. Dr Druml presented bioethics in Austria and its European context and the UNESCO Universal declaration on bioethics and human rights.

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First findings from IMPACT and IMPP-ACT projects

Two EDCTP projects funded under the call ‘Maximising the impact of EDCTP research: translation of research results into policy and practice’ have published their first findings.

Stability of antimalarial tablet fractions

The IMPACT team, led by Dr Anja Terlouw (Liverpool School of Tropical Medicine, UK), published the results of a study assessing the stability of halved tablets of the antimalarial dihydroartemisinin–piperazine (DP, Eurartesim®) at 37°C and 70% humidity, i.e. under tropical climate conditions as found in malaria-endemic countries.

DP is recommended for the treatment of uncomplicated malaria. But because of the narrow therapeutic dose range and available tablet strengths, the World Health Organization (WHO) recommends breaking tablets into halves for dosing children according to their body weight. The major concern with tablet fractions, apart from inaccurate dosing resulting from imprecise breaking of the tablets, is the actual stability of broken tablets of DP under tropical climate conditions.

The authors concluded that the current IPTp-SP coverage remains low even though antenatal care is offered across much of Africa. The settings where SP efficacy remains near perfect represent two-thirds of the intrinsic malaria burden. Therefore, in most areas, even with the current declines in malaria transmission, malaria in pregnancy unfortunately remains an important public health issue and the benefits of providing IPTp-SP in many parts of Africa remain substantial.

1. This was the first call for Research and Innovation Actions (RIA) under EDCTP2
New TB studies launched: PanACEA2 and Predict-TB

The PanACEA consortium (Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics), led by Professor Martin Boeree of the University of Nijmegen, held a kick-off meeting in Cape Town, South Africa from 7–8 March 2017. The meeting gathered 80 delegates from all beneficiaries of the grant to discuss the tasks for the next five years. The project received an EDCTP contribution to almost €11.4 million. The German and Swiss governments will contribute directly to PanACEA2 to the amounts of almost 3 million euro and 336,000 euro, respectively.

The PanACEA2 project building on results from the consortium’s first portfolio of clinical trials, aims to develop at least two promising TB-treatment regimens to the point where they can be tested in a phase III clinical study. Secondly, it aims to advance one new agent to a phase IIB study. The project will make use of innovative trial designs, new microbiological markers of treatment response, pharmacokinetic-pharmacodynamic analyses and modelling techniques. This approach could accelerate drug development processes by several years. Clinical trial activities will be conducted at 11 research sites in 6 countries in sub-Saharan Africa (Gabon, Malawi, Mozambique, South Africa, Tanzania, and Uganda) with integrated research capacity development.

The Predict-TB project was launched in Cape Town, South Africa, on 16 and 17 March 2017. EDCTP is investing €7.7 million in the project which is led by Professor Gerhard Walzl of Stellenbosch University. In order to qualify for this grant, the project had to have secured substantial (50%) financing from other funders. Together, the Bill & Melinda Gates Foundation, EDCTP, the National Institutes of Health (NIH), and NIAID fund the South African component of the study, while the Gates Foundation funds the Chinese component of the larger trial. The overall project value is more that 25 million euro.

The Predict-TB study hypothesises that a combination of microbiological and radiographic markers (PET/CT, the Xpert/MTB-RIF assay and bacterial load markers) will be able to identify the 80–85% TB patients who will most likely be cured at 16 weeks of conventional therapy. Sufficiently accurate prediction of treatment success would allow most TB-patients to shorten their treatment well before the current standard treatment duration of 24 weeks. Predict-TB will also test new biomarkers for predicting treatment outcome using high-tech tools. As PET/CT scans are both expensive and not readily available, the final objective of the study, if successful, will be to develop a point-of-care device that could be implemented in resource-limited settings. In this way, the results of this high-tech project would be directly translated into a straightforward tool for healthcare and TB control. This has also the potential to contribute to a change of WHO guidelines for TB treatment.

2016 G-FINDER report shows increased EU investments in R&D

The 2016 G-FINDER report Neglected disease research and development: A pivotal moment for global health analyses global investment in innovative R&D for poverty-related and neglected infectious diseases (2007-2015), and for Ebola and other African viral haemorrhagic fevers (2014-2015). According to the report, published by Policy Cures, a total of $3,041 million was invested in 2015. Approximately 71% was invested in HIV, tuberculosis and malaria research. Private sector investment was the highest ever recorded in the history of the G-FINDER survey, in absolute terms and as percentage of global funding.

The report shows the United States, the United Kingdom and the European Union (EU) to be the top three public funders of research and development (R&D) for poverty-related and neglected infectious diseases in 2015. These three funders combined contributed over two-thirds of the total public R&D investment ($1,378M). The report shows a significant increase of the EU’s investments (up $21M) reflecting the EU’s expanded contribution to the second EDCTP programme.

A launch event of the report hosted by Friends of Europe took place in Brussels, Belgium on 16 February 2017. A high-level panel included Bill Gates (Co-Chair of the Bill & Melinda Gates Foundation), Carlos Moedas (European Commissioner for Research, Science and Innovation), Dr Nick Chapman (Executive Director, Policy Cures Research), Dr Ruxandra Draghia-Akli (European Commission Deputy Director General, Research & Innovation), Dr Catharina Boehme (Chief Executive Officer, Foundation for Innovative New Diagnostics), and Luc Debruyn (President of Global Vaccines, GlaxoSmithKline). Dr Michael Makanga, Executive Director, and Dr Ole Olesen, Director of North-North Cooperation, represented EDCTP at the meeting.

The report is available at www.policycuresresearch.org/g-finder-2016.
EDCTP intends to launch a total of 11 calls for proposals in 2017 to support clinical research and related activities against poverty-related diseases (PRDs). Details of the call texts will be published on the website in June 2017, pending approval of the EDCTP work plan for 2017 by the European Commission and the EDCTP General Assembly. All dates and budget amounts are therefore indicative.

**Planned 2017 calls for proposals**

**Treatment innovations for poverty-related diseases**

**Purpose:** to provide funding for the clinical evaluation and development of new and innovative drug candidates for HIV/AIDS, malaria, tuberculosis, diarrhoeal infections or lower respiratory infections, including co-infections.

**Call budget:** EUR 30M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Two-stage application procedure
**Open to applications:** 1 June 2017
**Deadline for applications:** 5 September 2017

**Targeting control and elimination of NIDs through clinical trials**

**Purpose:** to provide funding for clinical trials to accelerate the development of new or improved therapeutics for neglected infectious diseases (NIDs) in sub-Saharan Africa.

**Call budget:** EUR 18.8M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Single-stage application
**Open to applications:** 4 July 2017
**Deadline for applications:** 31 October 2017

**Targeting control and elimination of NIDs through product-focused implementation research**

**Purpose:** to provide funding for product-focused post-registration implementation studies for NIDs in sub-Saharan Africa.

**Call budget:** EUR 11.2M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Single-stage application
**Open to applications:** 4 July 2017
**Deadline for applications:** 31 October 2017

**Strategic actions supporting large-scale clinical trials**

**Purpose:** to support strategic actions (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, diagnostics, vaccines, microbicides) for PRDs.

**Call budget:** EUR 43M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Two-stage application
**Open to applications:** 1 June 2017
**Deadline for applications:** 13 October 2017

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

**Purpose:** to accelerate the adaption and/or optimisation of treatment and prevention products (excluding vaccines) for PRDs in sub-Saharan Africa for use in pregnant women, newborns and/or children. This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases and lower respiratory infections.

**Call budget:** EUR 38.23M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Two-stage application
**Open to applications:** 4 July 2017
**Deadline for applications:** 13 October 2017

**Ethics and regulatory capacities**

**Purpose:** to support sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies for use in humans.

**Call budget:** EUR 2.5M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Single-stage application
**Open to applications:** 3 August 2017
**Deadline for applications:** 21 November 2017

**Senior Fellowships**

**Purpose:** to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior researchers with emphasis on hands-on research training linked to clinical trials activities conducted in sub-Saharan Africa.

**Call budget:** EUR 3.5M
**Funding level:** Up to 100% of eligible costs
**Procedure:** One-stage application
**Open to applications:** 2 March 2018
**Deadline for applications:** 13 October 2017

**EDCTP-GSK Senior Fellowships for co-morbidities between PRDs and non-NCDs**

**Purpose:** This joint call by EDCTP and GlaxoSmithKline (GSK) aims to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior researchers with emphasis on hands-on research training linked to clinical trials activities in sub-Saharan Africa in the area of prevention, therapeutic management and prognosis of PRD and NCD co-morbidities.

**Call budget:** EUR 3.5M
**Funding level:** Up to 100% of eligible costs
**Procedure:** One-stage application
**Open to applications:** 26 October 2017
**Deadline for applications:** 1 February 2018

**Career Development Fellowships**

**Purpose:** to support junior to mid-career researchers (‘fellows’) to train and develop their clinical research skills.

**Call budget:** EUR 2.5M
**Funding level:** Up to 100% of eligible costs
**Procedure:** Single-stage application
**Open to applications:** 3 November 2017
**Deadline for applications:** 2 February 2018

**EDCTP-AREF Preparatory Fellowships**

**Purpose:** This joint call by EDCTP-AREF (Africa Research Excellence Fund) aims to enhance the competitiveness of up-and-coming post-doctoral African scientists and clinicians aspiring to win international/regional/national fellowships or grant support through short-term placements at a host organisation in EU Member States, in countries associated to Horizon 2020 or in sub-Saharan Africa which will be contracted by the home organisation to host the fellow.

**Call budget:** EUR 800,000
**Funding level:** Up to 100% of eligible costs
**Procedure:** Two-stage application
**Open to applications:** 14 July 2017
**Deadline for applications:** 31 October 2017

**EDCTP-TDR Clinical Research and Development Fellowships**

**Purpose:** This joint call by EDCTP and the Special Programme for Research and Training in Tropical Diseases (TDR) aims to support researchers and key members of clinical trial research teams from low- and middle-income countries to acquire specific skills in clinical trials research through placements in pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs.

**Call budget:** EUR 3.5M
**Funding level:** Up to 100% of eligible costs
**Procedure:** One-stage application
**Open to applications:** 26 October 2017
**Deadline for applications:** 1 February 2018
UK All-Party Parliamentary Group on Global Health hosted EDCTP

On 27 February 2017, Dr Daniel Poulter MP of the UK All-Party Parliamentary Group on Global Health hosted a meeting on EDCTP as an ‘African-European partnership for global health benefit’ at the Houses of Parliament in London, United Kingdom. More than 100 participants attended the meeting, including members of the UK Parliament, representatives of UK-based funders, UK researchers, NGOs, private foundations, and participants from the private sector. Presentations on two clinical trials, CHAPAS-1 and CHAPAS-3, made the case for the impact of the programme. A short video demonstrated the direct benefits of the research for the lives of patients. It showed a small boy from Malawi who benefited dramatically from access to these paediatric antiretroviral formulations, regaining the opportunities of a healthy life.

CHAPAS-1 developed a paediatric fixed-dose combination therapy for HIV-infected children. This resulted in the first paediatric antiretroviral formula which was rolled out on a large scale. CHAPAS-3 developed paediatric formulations for a new generation of antiretrovirals. The trials were presented by Dr Veronica Mulenga, paediatrician at the University Teaching Hospital in Lusaka, Zambia, and Professor Diana Gibb, programme leader of the Paediatric Programme of trials and cohorts at the MRC Clinical Trials Unit at University College London, United Kingdom.

A panel comprising Dr Leonardo Simão (EDCTP High Representative for Africa), Professor Marcel Tanner (EDCTP High Representative for Europe), Dr Cissy Kityo, (Deputy Executive Director of the Joint Clinical Research Centre, Uganda), Dr Line Matthiessen (Acting Director for Health Research in the Directorate General Research & Innovation at the European Commission), and Sir Brian Greenwood (Professor of Clinical Tropical Medicine at the London School of Hygiene & Tropical Medicine, United Kingdom) emphasised the value of EDCTP in generating new evidence on medical interventions against poverty-related diseases.

A summary of the meeting is available at www.edctp.org. The video is available on the EDCTP YouTube channel EDCTPmedia.

Scientific Advisory Committee

The EDCTP Scientific Advisory Committee (SAC) held its first meeting of 2017 on 30-31 March in Amsterdam. EDCTP Executive Director Michael Makanga welcomed the fourteen members present at the meeting, including seven new members and the new chair, Prof. Catherine Hankins. Two new vice-chairs were elected: Professor Clara Menéndez Santos (Barcelona Centre for International Health Research (ISGlobal), Spain) and Professor John Gyapong (University of Health and Allied Science, Ghana).

The main topics of discussion at the meeting were the update of the EDCTP Strategic Research Agenda, the EDCTP three-year planning cycle (2018-2020), preparations for the Ninth EDCTP Forum, as well as the planning for SAC activities in 2017. More details about the SAC membership and can be found on the EDCTP website.

EDCTP member countries organise workshop on PSIAs

Several member countries of the EDCTP Association took the initiative to organise a workshop for all member countries of the EDCTP Association in Vienna, Austria. On 21-22 March 2017, representatives from Austria, Denmark, France, Germany, Italy, Mozambique, Norway, Portugal, Spain, Switzerland, and the United Kingdom, attended the workshop to discuss their own research activities which fall within the scope of EDCTP. The European Commission and EDCTP were also represented, the latter by Prof. Eleni Akilliu (Scientific Advisory Committee), Dr Ole Olesen (Director of North-North Cooperation) and Dr Gabrielle Breugelmans (North-North Networking Manager).

Research activities within the scope of the EDCTP programme funded and implemented separately from EDCTP by one or more member countries, can be submitted to be incorporated in the annual EDCTP work plans. These so-called Participating States’ Initiated Activities (PSIAs) are important as they demonstrate the commitment of the member countries to EDCTP and promote research collaboration in Europe and sub-Saharan Africa. Taken together, the PSIAs also provide an accessible overview of research activities on poverty-related diseases. This facilitates better coordination, alignment and, where appropriate, integration of relevant national programmes, one of the key objectives of EDCTP. Financially, the European PSIAs count towards matching the EU funding of EDCTP.

With these objectives in mind, suggestions were made for ways to improve information on the funding schemes in the member countries. The meeting also discussed opportunities and potential mechanisms to promote better alignment of national activities, including harmonisation of capacity building activities and a joint Participating States’ funding scheme to foster new partnerships.