



EDCTP NEWSLETTER

European & Developing Countries Clinical Trials Partnership

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EDCTP

The power of sharing science

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Open calls for proposals

The following calls are open for applications:

Senior Fellowships

Type	Training & Mobility Actions (TMAs)
Call budget	€5 million
Funding level	100% of eligible costs
Open date	2 November 2018
Close date	28 February 2019

EDCTP Clinical Research and Product Development Fellowships

Type	Training & Mobility Actions (TMAs)
Call budget	€1.5 million
Max. funding	€100,000
Funding level	100% of eligible costs
Open date	23 November 2018
Close date	7 March 2019

More information about calls for proposals is available at www.edctp.org. To apply, visit www.edctpgrants.org.

Consolidation

Dear colleagues, partners and friends,

We have started 2019 with renewed energy and enthusiasm. 2018 presented a milestone for EDCTP as we celebrated our 15th anniversary and the fifth year of EDCTP2.

This year, our project portfolio grew by more than a third, and researchers in 19 European and 36 sub-Saharan African countries are now working on EDCTP-funded projects addressing the key infectious disease threats facing Africa. Their work will make a real difference to the lives of people across the continent.

Our investment in clinical trials has reached €395.83 million (82 large-scale trials). Phase II and III trials form just over 50%, many targeting key populations, including pregnant women, newborns, children and adolescents. A further 12% of projects are post-licensing (phase IV) studies, including product-focused implementation studies, generating evidence highly relevant to policymakers.

To support the career development of current and aspiring African scientific leaders, we have now invested in 90 fellowship grants. We are also strengthening national and regional regulatory and ethical review capacities, with 24 countries benefiting from 20 such grants to date. We awarded grants to 4 regional networks of excellence, 3 projects for national pharmacovigilance and 6 grants for capacity to use research evidence in policymaking.

The Ebola outbreaks in the Democratic Republic of the Congo are a reminder of the continuing threat posed by emerging infections. In 2018, we launched an emergency Ebola funding initiative, supporting 24 institutions in Africa and Europe. In addition, two large EDCTP-funded consortia – ALERRT and



PANDORA-ID-NET – are working to enhance the capacity of African regions to prepare for and respond to infectious disease outbreaks.

Partnership is at the core of our work. Since the start of EDCTP2, membership of the EDCTP Association has increased from 14 to 16 African countries with Nigeria and Ethiopia as new members. Angola has become an aspirant member. At the end of 2018, 230 African and 139 European institutions in 61 countries were involved in EDCTP projects.

The total cash contribution from EDCTP member countries had grown to €121 million by the end of 2018 while they also contribute to the programme via designated national research activities. In addition, we have leveraged €170 million in project contributions (total cash and in-kind) from global partners, including the US National Institutes of Health, the President's Emergency Fund for AIDS Relief, the Gates Foundation, and the TB Alliance. Our ninth EDCTP Forum was held with support from the Portuguese Foundation for Science and Technology and the Calouste Gulbenkian Foundation.

Looking forward, we have begun to consider a successor programme to EDCTP2, building on the unique features and successes of its forerunners.

To conclude, I would like to take this opportunity to thank everyone involved in EDCTP for their efforts during the year and for their contributions to our achievements. I would particularly like to thank the outgoing and continuing members of the Scientific Advisory Committee, and welcome aboard our new members. I wish you all a happy, healthy and productive 2019.

Dr Michael Makanga
Executive Director

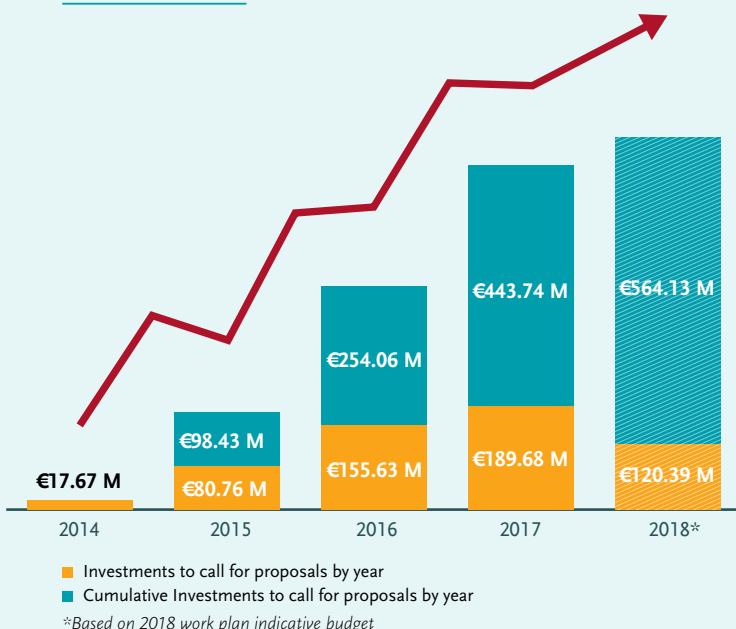
Supported by the
European Union



EDCTP investments in clinical research

(2014-2018)

Investments in calls for proposals



Clinical studies



€ 395.83 M

to support 64 projects with large-scale clinical trials and clinical research projects conducted by European-African consortia.

Clinical research capacity



€ 30.40 M

to support 39 projects to strengthen the enabling environment for clinical trials and clinical research.

Developing research leadership



€ 20.81 M

to support 89 projects fellowships that focus on the career development of individual researchers.

A seven-day call

By Jean Marie Vianney Habarugira (EDCTP Project Officer)

If someone walks into the EDCTP Office now and asks how we responded to the tenth Ebola outbreak in the Democratic Republic of Congo (DRC), my answer will be simple: with a seven-day call.

DRC outbreaks - from ninth to tenth

The ninth outbreak had been declared on 8 May 2018, following confirmation of two cases of Ebola virus disease in the country's north-west. Led by the Congolese Ministry of Health and involving many international initiatives, the response was effective, the ninth outbreak was defeated, and its end was declared by WHO on 24 July 2018. Not long after, while the research community was still assessing and discussing what went right or wrong in the response to the outbreak, the DRC Ministry of Health declared the tenth outbreak on 1 August 2018, this time in the north-eastern part of the country.

Activation of the emergency funding mechanism

As the numbers of suspected and confirmed cases were increasing, EDCTP had a role to play based on its aim to fund research for prevention and treatment of poverty-related diseases, including emerging or re-emerging infectious diseases, prevalent in sub-Saharan Africa. A special feature of the EDCTP 2018 work plan, as part of the research activities supported by the European Commission, was the mobilisation of research funds in case of public health emergencies. In the news item on the outbreak released on 31 August 2018, WHO confirmed that as of 29 August 2018, the public health risk was high at the national and regional levels and low globally. At that point, the EDCTP Association agreed to activate the emergency funding mechanism to support clinical research projects as part of the European response to the emergency. With an indicative budget of EUR 2.25 million, the mechanism was activated to support key research priorities, and we called for proposals that would address the most pressing questions raised by responders to this public health emergency.

How did we do it?

After internal consultation and approvals, we activated our EU-supported emergency funding mechanism for the first time and launched an emergency call on 3 September and closed it on 10 September 2018*. This seven-day call allowed the research community to submit proposals to address some of the most pressing questions raised by various teams fighting the virus on the ground. Of course, we wondered if seven days would be enough for consortia to prepare and submit their proposals. Some were saying that it was too short. However, we believed there was no more time to waste, no more time to wait, no more time for discussion and meetings to decide what to do. In the announcement of the seven-day call, we made a promise. We promised potential applicants that "proposals will be subject to an expedited review procedure by an expert panel convened by EDCTP within 10 days of the deadline for proposal".

A call open for just seven days is very unusual, not only for EDCTP but for any funding organisation. That is why I went back with a few questions to those whose proposals were positively evaluated and recommended for funding. Most respondents agreed that the seven-day window was not a problem, and in some cases said it became a driver for quick and efficient action. Below are some of their comments:

"Well aligned and timed for the cause. Speaks aloud about an emergency response action."

“What I have appreciated is that during these 7 days, we have concentrated all our efforts on this proposal and then it was done, instead of having 3 months and [...] work hard the last week before the deadline.”

“The turnaround from call launch to outcome notification had the shortest interval of any grant application I have previously participated in. Nevertheless, the call documents were clear, and instructions were well laid out. Limited relevant research had been conducted during previous EVD outbreaks partly due to funding constraints. It was gratifying to know that a mechanism was in place to rapidly turn around research alongside outbreak response.”

“This time was just appropriate. This kind of calls are intended for people working in the specified field. To them, it's easy to put up a response within 48 to 72 hours. I got wind about the call 3 days to the close and was able to place in a spirited responsive proposal.”

What did we get?

Through the seven-day call, five proposals were positively evaluated and recommended for funding:

The **AdjustEBOVGP-Dx project** (Biochemical adjustments of native EBOV glycoprotein in patient sample to unmask target-epitopes for rapid diagnostic testing) is developing biochemical treatments that adjust native Ebola Virus glycoprotein (EBOV GP) in patient sample as a target for rapid diagnostic tests (RDTs). The project could yield the first prototypes of RDTs for the duo-detection of Ebolavirus and Marburgvirus which are required to ensure early detection, response and control of the on-going and future outbreaks. For the prototype testing, the project will use samples collected from the ongoing EVD outbreak.

The **EPIRISK-Ebov project** (Epidemic preparedness and risk assessment for Ebola Virus Disease outbreaks in the Republic of the Congo) is assessing the Ebola Virus cross-sectional seroprevalence and the incidence of a longitudinal seroconversion with a geographical focus on the area along the Congo River at the border between the Republic of the Congo and the Democratic Republic of the Congo.

To prepare staff and outbreak responders, the project will give training workshops on diagnostics, biosafety, serology, flow cytometry and social science. The project is expected to generate high-quality data on Ebola surveillance and epidemiological characteristics of viral, bacterial and parasite genotypes, and cellular immune responses to EBOV antigens in populations living in the study area.

The **CAPA-CT 2 project** (Leveraging capacity for early phase clinical trials for filoviruses in Uganda) will generate local clinical pharmacokinetic data that is needed for interpretation of pharmacokinetic data generated through MEURI (monitored emergency use of unregistered and investigational interventions), drug interactions with antiretroviral drugs and to inform future treatment optimisation approaches. With a geographical focus on the area along the border between DRC and Uganda, the project is using diagnostic approaches

to strengthen surveillance for especially dangerous pathogens in Uganda. As part of its contribution to the national response, CAPA-CT 2 will describe a capacity building model for rapid acquisition of competencies for enhanced laboratory biosafety, and infection prevention and control for case management, using a low-cost mentorship strategy.

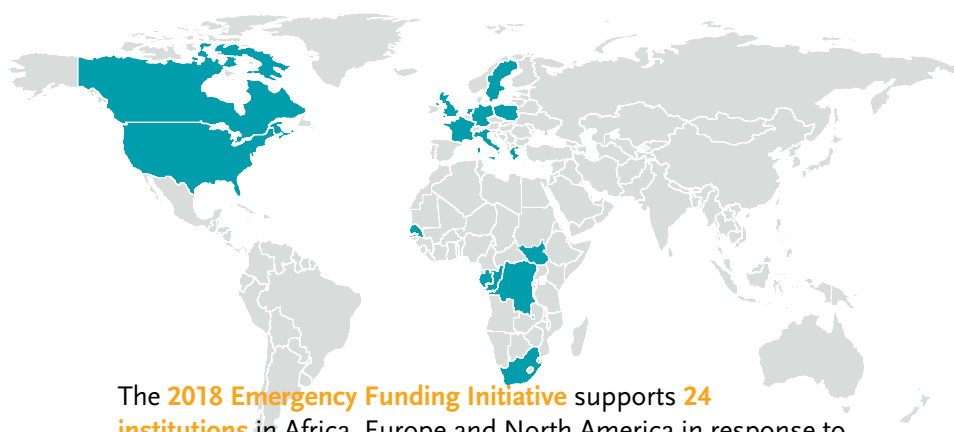
The **PEAU-EBOV-DRC project** (Improved management of Ebola Virus Disease in emergency situations in the Democratic Republic of Congo: from MEURI protocol to randomised controlled trials) is part of the DRC Ebola research plan developed following the ninth outbreak, to ensure a proper coordination of research on experimental emergency interventions for EVD in the country. Specifically, the project aims 1) to coordinate the design and support the rapid implementation of efficacy trials to evaluate candidate therapeutic products and 2) to strengthen the country's capacity for the safe handling, diagnosis and reporting of major diseases caused by Haemorrhagic Fever Viruses (HFVs).

The **MobEBO-DRC project** (Mobile point-of-care diagnostic testing for Ebola virus disease in DRC) is using isothermal amplification (Recombinase Polymerase Amplification (RPA)) integrated in a suitcase mobile lab for Ebola detection. The lab which was successfully deployed in Conakry towards the end of 2014, will be used in the current project to assess performance and operational characteristics of the differential RPA, using material from EVD-suspected cases, archived and prospective EBOV-negative samples, and selected routine diagnostic samples. Training is being provided to the teams using the suitcase lab in DRC, and the project is directly contributing to the response capacity by increasing the mobile laboratory capacity for the current and future outbreaks.

A big thank you to the reviewers

As a funder, we must rely on independent experts with a high workload. In the case of our seven-day call, the task was challenging, because we had promised to finalise the review in ten days after call closure. The difficult part was to ensure a selection of reviewers from among the best in the field who would not have a conflict of interest, and get their agreement on short notice to take part in an expedited review. Our warm thanks goes to all those who considered, and especially to those who would and could commit to this and accepted to review up to 8 proposals within the short period of four days (11-14 September). On 18 September, they participated in a final consensus review meeting by teleconference. Thanks to the reviewers, we had a ranked list ready for approval by our Board on 20 September. We had kept the promise of a ten-day review process following closure of the seven-day call.

* *EDCTP. Mobilisation of research funds in case of Public Health Emergencies.*
<http://www.edctp.org/call/mobilisation-of-research-funds-in-case-of-public-health-emergencies>



The **2018 Emergency Funding Initiative** supports **24 institutions** in Africa, Europe and North America in response to **Ebola outbreaks** in the Democratic Republic of the Congo.

From Accra to Dakar to Lisbon: national health research systems and the next EDCTP programme

By Lara Pandya (EDCTP Strategic Partnership Officer) and Dr Thomas Nyirenda (EDCTP Strategic Partnerships and Capacity Development Manager)

Participation of the member countries of EDCTP (also known as the Participating States) in the design and implementation of its programme is key to its success. Fully functional national health research systems (NHRS) contribute to active involvement in and increase ownership of the EDCTP programme. In Africa, previous surveys have indicated several weaknesses in NHRS. Therefore, in 2018, EDCTP developed a strategy to support the development and strengthening of these systems in its African member countries. Two high-level meetings in Africa focused on the NHRS in Africa, followed by a high-level meeting in Europe on the design of an EDCTP successor programme, organised to invite ideas from the African and European Participating States.

From 9-10 July 2018, EDCTP and the WHO Regional Office for Africa (WHO-AFRO), in partnership with the Ghanaian Health Service, held a high-level meeting of over 50 delegates from the 17 African EDCTP member countries and international stakeholders in Accra, Ghana. Its objective was to collaboratively initiate assessment and strengthening of NHRS in sub-Saharan Africa with the aim of supporting greater involvement of the African Participating States in the EDCTP programme. The largest gathering to date of representatives from the African Participating States engaged heads of government research units and secured a commitment from the heads of the delegations of the 17 African Participating States to strengthen the NHRS in their respective countries.

In July 2018, NHRS in 47 WHO-AFRO member states were surveyed. The results were presented on 30 August 2018 in Dakar, Senegal, at a second EDCTP high-level meeting. As a side event at the 68th session of the WHO-AFRO Regional Committee meeting, it focused on 'Engaging African governments to strengthen national health research systems with complementary international cooperation'. Representatives from governments, including African ministers of health, regional bodies, regulators, policy makers, and strategic partners committed to health research and strengthening national health research systems in Africa. Strong NHRS would facilitate more country ownership and alignment of the EDCTP programme regarding specific national health research needs.

The proceedings from this meeting informed a subsequent EDCTP high-level meeting in Lisbon, Portugal, on 17 September 2018. At this side event of the Ninth EDCTP Forum, approximately 100 representatives from African and European Participating States and strategic partners convened on the theme of 'Moving forward and consolidating gains for an EDCTP successor programme'. Held just two days after the 15th anniversary of the establishment of EDCTP, the meeting celebrated this unique partnership between Europe and Africa. Acknowledging achievements and challenges, it looked ahead at how best to build on the investments and gains made to date. Feedback was solicited on how to maximise this partnership for research and innovation under a future EDCTP programme. There was acknowledgement of the need for African governments to increase their investments in health research, establish their own national research agendas and meet the existing commitments to direct a part of their health budget to health research. Building on the political commitments made by the African EDCTP member countries in the preceding two high-level events, statements of support for a future EDCTP programme were made by several European member countries, including the Portuguese host, the United Kingdom, France, Germany and Sweden.



Photo: Dr Michael Makanga; Dr Mark Palmer, Chairman of the Board and General Assembly of EDCTP; Irène Norsted, Acting Director of the Health Directorate, Directorate General for Research and Innovation, European Commission; and Helena Pereira, Vice President, Foundation for Science & Technology, Portugal at the opening session of the high-level meeting in Lisbon.



Photo: Professor Stanley Okolo, Director General of WAHO; Hon. Prof. Dr João Leopoldo da Costa, Vice-Minister of Health of Mozambique; Cécile Tassin-Pelzer, Head of Cooperation of the EU Delegation to Senegal; and Dr Prosper Tumusiime, WHO AFRO, at the high-level meeting in Dakar, Senegal.

This series of meetings has contributed to the development of a draft EDCTP Strategic Business Plan for 2021-2031, currently studied by the EDCTP General Assembly. 2019 is expected to bring more clarity on how the EDCTP partnership can be organised under Horizon Europe through continued political engagement with the European Commission, the EDCTP member countries and other key stakeholders in the future of EDCTP. With strengthened national research systems, political and financial commitment from the Participating States and the EU, and working with other public and private partners globally, EDCTP has the potential to contribute substantially towards achieving the Sustainable Development Goals in sub-Saharan Africa.

EDCTP welcomes new SAC members

Seven new members have joined the EDCTP Strategic Advisory Committee (SAC) as of 1 January 2019:



Professor Richard Adegbola is an independent consultant in Immunisation & Global Health at RAMBICON, Lagos, Nigeria. He worked with GlaxoSmithKline Vaccines as Global Director, Scientific Affairs & Public Health until 31 March 2018. Prior to that, he worked for the Gates Foundation as a Senior Programme Officer & Lead for Pneumonia Clinical Studies. Professor Adegbola obtained a PhD in Medical Microbiology (Univ. of Dundee, UK), did postdoctoral work at Biomedicum (Uppsala, Sweden), and became a Fellow of the Royal College of Pathologists (London UK). He was awarded honorary Fellowship of the Royal College of Physicians, London in 2008, elected as a Fellow of the Nigerian Academy of Science in 2016, and he serves on several international scientific advisory boards.



Professor Christine Stabell Benn is an MD (1996), PhD (2003) and Doctor of Medical Science (2011) from the University of Copenhagen. She has worked at the Bandim Health Project in Guinea-Bissau since 1993. In 2012, she was selected by the Danish National Research Foundation to establish and lead a Centre of Excellence on research for vitamins and vaccines. Since 2013, Dr Benn is Professor in Global Health at University of Southern Denmark. She participates in a large-scale vaccine initiative within the Indepth Network (www.indepth-network.org). Through this initiative, she has studied vaccination programs and their implementation in many different African settings. The vaccine initiative trained PhD students in Guinea-Bissau and from Burkina Faso, Ghana, Kenya and Bangladesh.



Professor Eric Delaporte is Professor of Infectious and Tropical Diseases at the University and University Hospital of Montpellier, France and Director of an international research unit on AIDS and associated diseases with the University of Montpellier, INSERM and IRD. He has 25 years of experience in conducting research and intervention programs in Africa in close collaboration with the national AIDS programmes and African universities. His main focus in HIV concerns the evaluation of different treatment strategies, the co-morbidities, and the emergence of HIV resistance to antiretroviral drugs. Another important field of his research concerns the response to epidemics, in particular due to the Ebola virus. Prof. Delaporte is the author of more than 400 publications.



Professor Paulo Ferrinho is Full Professor of International Health at the Institute of Hygiene and Tropical Medicine (Universidade NOVA, Lisbon, Portugal) and its Director since 2009. Moreover, he manages a research centre of excellence on Global Health and Tropical Medicine and coordinates the WHO Collaborating Centre on Health Workforce Policy and Planning. His areas of expertise include public health, epidemiology, human resources for health (human resources planning and health workers training), maternal and child health, travel medicine, and capacity development of academic institutions. Prof. Ferrinho has been involved in collaborative international work in Europe, Africa (all Lusophone countries and Eritrea, South Africa, and Zambia) South America (Brazil) and Asia (Thailand and East Timor).



Professor Harleen Grewal is Professor of Microbiology (2002) and Global Health (2013) (University of Bergen, Norway) and Consultant Physician at the Haukeland University Hospital, also in Bergen. As MD (1987, University of Maharashtra, India), she trained in medical microbiology at the All India Institute of Medical Sciences (1991) and the Haukeland University Hospital (2000). In 1995, she obtained a PhD in molecular microbiology (University of Bergen). Professor Grewal conducted research on the molecular pathogenesis of diarrhoeal and respiratory pathogens. Since 2002, she focused on tuberculosis-related research: e.g. building site capacity for TB vaccine efficacy testing, antimicrobial resistance and rapid point-of-care diagnostics to improve personalised therapy. She received the Schering-Plough prize (microbiology) and the Søren and Sigurd Falch award (medical research).



Professor Collen Masimirembwa has founded and leads the African Institute of Biomedical Science and Technology (AiBST). Currently, he is the President of the African Pharmacogenomics Consortium (APC). His research focuses on pharmacogenetics and clinical pharmacology. He demonstrated the clinical relevance of Africa's genomic diversity, especially with respect to the safe use of anti-retroviral drugs. He is a Distinguished Professor of Health Sciences (Witwatersrand University, South Africa), and a Fellow of the Zimbabwe Academy of Sciences and the African Academy of Sciences. He received many awards including the HUGO Africa Award (2018). Prof. Masimirembwa studied at the University of Zimbabwe and the Karolinska Institute, Sweden (PhD). After having worked for AstraZeneca Pharmaceutical Company as a Principal Scientist for about 10 years, he returned to Africa.



Professor Michael Ramharter trained at the Medical University of Vienna (Austria), and specialised in Internal Medicine, Infectious Diseases & Tropical Medicine. He was also affiliated to the Institut Pasteur, (Paris, France), and the Institute of Tropical Medicine (University of Tübingen (Germany)). Since 2008, he heads the group "Infectious Disease Control" at the Centre de Recherches Médicales de Lambaréné (Gabon). In 2018, he was appointed Professor in Tropical Medicine - heading also the Department of Clinical Research at the Bernhard Nocht Institute for Tropical Medicine - in Hamburg (Germany). Prof. Ramharter worked in South-East Asia and Africa on improving the diagnosis and management of infectious diseases. His work focuses on clinical development of antimalarial drugs and vaccines in Africa (phase I-IV) as well as on neglected tropical diseases and emerging infectious diseases.

About the SAC

The Scientific Advisory Committee (SAC) consists of independent scientific experts from Europe and Africa. Working with the Secretariat, the SAC develops the strategic framework for EDCTP and advises the General Assembly on technical and scientific matters relating to the EDCTP programme. The SAC is not involved in the review of applications submitted to EDCTP calls for proposals. For more information about the SAC and its members, please visit www.edctp.org.

Meet the team behind financial management at EDCTP

By Abdoulie Barry (EDCTP Director of Finance and Administration)

Another year has come to an end and as usual the talented financial team has ensured that financial transactions for the year ended on 31 December 2018 have all been accurately posted into the accounting system, including carrying year-end adjustment and reconciliations. The EDCTP finance team comprising two Finance Officers (Chris Bruinings and Christopher Dixon) and three Grant Finance Officers (Mary Jane Coloma-Egelink, Sayma Siddiqui and Neodia Flores-Mensing) is responsible for the financial management of all funds received by EDCTP. These include timely disbursement of funds to beneficiaries, reviewing of financial reports received from beneficiaries, preparation of donor financial reports, and providing guidance and training to beneficiaries to ensure they fully comply with the Grant Agreement for article 185 initiatives.

Mr Abdoulie Barry, the EDCTP Director of Finance and Administration, is proud of the varied and complementary skills set of the finance team, quality of work produced by them, and their unflagging commitment to exceed the expectation of stakeholders, particularly EDCTP beneficiaries and donors. Before the commencement of EDCTP, an extensive ex-ante assessment of EDCTP systems, policies and procedures by a consulting firm appointed by the European Commission reported no findings for the accounting system pillar. Similarly, from inception of EDCTP, all our independent audit reports are unmodified meaning that auditors had concluded for all the years up to year ended 31 December 2017 that our financial statements had been prepared, in all material aspects in accordance with financial framework applicable to EDCTP.

These are the people who are behind these successes:



Mary Jane Coloma-Egelink
Grants Finance Officer



Neodia Flores-Mensing
Grants Finance Officer



Sayma Siddiqui
Grants Finance Officer



Abdoulie Barry
Director of Finance & Administration



Chris Bruinings
Finance Officer



Chris Dixon
Finance Officer

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