



EDCTP NEWSLETTER

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EDCTP

European & Developing Countries Clinical Trials Partnership



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CALLS TO PARTNERSHIP



The objectives of the EDCTP programme can only be achieved through the contribution and cooperation of our many stakeholders in the fight against poverty-related and neglected infectious diseases (PRNIDs). This call to partnership is reflected in many forms in this issue of our Newsletter.

EDCTP2 2014-2016: public consultation

A public consultation regarding ‘the implementation of the Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) during the period 2014-2016’ was opened by the European Commission (EC) on 29 June 2016. It will close on 15 October 2016. The consultation is open to all. Contributions from stakeholders and experts active in the field of clinical trials are particularly invited. An analysis of results will be published in February 2017.

The views and opinions of stakeholders, experts active in the field and the wider public will contribute to the interim evaluation of the EDCTP2 programme. The interim evaluation is carried out by the EC with the assistance of independent experts. Interim evaluations are part of the monitoring of the programmes the European Union decided to support.

The objective of this interim evaluation is “to assess the implementation of the EDCTP2 programme up to the present moment; to judge how recommendations from previous evaluations have been implemented; and to provide an outlook on what can be expected from EDCTP2 in the future”. All information is on the website of the European Commission: http://ec.europa.eu/research/consultations/edctp-2-2014-2016/consultation_en.html

Esteemed stakeholders, the EDCTP work plan for 2016 is available on our website. I invite you to view the activities funded and implemented directly by the member countries of the EDCTP Association. These so-called Participating States’ Initiated Projects (PSIAs) are an integral part of the second programme and contribute directly to achieving our overall objectives. Moreover, a total of nine calls for proposals - funded by the European Union and EDCTP member countries and managed by EDCTP - are available in 2016. The 2016 calls represent an investment of approximately €138.6 million of which €70 million is earmarked for vaccines studies against poverty-related and neglected infectious diseases.

It is with great pleasure that I highlight our renewed collaboration with the Calouste Gulbenkian Foundation, a Portuguese international charitable organisation. Our agreement aims to contribute to the important objective of developing research capacity in sub-Saharan Africa. Currently, EDCTP supports three fellowship schemes aimed at developing African scientific leadership capacity. The Gulbenkian Foundation will contribute towards funding of successful applications of researchers from Portuguese-speaking countries in sub-Saharan Africa.

Other initiatives mentioned in this issue are equally calls to partnership. EDCTP welcomes and seeks the advice, support

and collaboration from many stakeholders. We call for applications from high-level experts in various fields and sectors for membership of the EDCTP Scientific Advisory Committee starting in January 2017. Two stakeholder meetings were held in July 2016, with representatives from academic and research institutions, funding agencies, product development partnerships and pharmaceutical industry and others. The participants discussed possible priorities in new fields added to our scope: diarrhoeal diseases and lower respiratory tract infections. In preparation for the Eighth Forum, we have received a great response from various stakeholders to our call for scientific symposia and many abstracts from the scientific community. Finally, the European Commission launched a public consultation on our programme covering the period 2014-2016.

On behalf of EDCTP I take this opportunity to extend our thanks to all who invest their time and expertise to support the efforts of EDCTP. In concluding, I wish to express a warm welcome to the new Director of South-South Cooperation and Head of Africa Office, Professor Moses John Bockarie. He brings considerable expertise and experience to our organisation, especially in the field of neglected infectious diseases.

Dr Michael Makanga
Executive Director

Newly signed grants

Call: EDCTP-TDR Research & Development Fellowship (2014)

Fellow: Dr Solomon Mequanente Abay

Addis Ababa University (Ethiopia)

Starting date: 1 May 2016

Duration: 18 months

Grant budget: EUR 72,087

Grant agreement: TMA2014-434

Fellow: Dr Alice Matimba

University of Zimbabwe University College of Health Sciences (Zimbabwe)

Starting date: 1 May 2016

Duration: 22 months

Grant budget: EUR 106,000

Grant agreement: TMA2014-431

Fellow: Dr Isidore Traore

Centre Muraz (Burkina Faso)

Starting date: 1 May 2016

Duration: 21 months

Grant budget: EUR 97,875

Grant agreement: TMA2014-433

Call: Diagnostic tools for poverty-related diseases

Culture-free diagnosis and follow-up of multidrug-resistant tuberculosis patients

Centre national hospitalier de pneumo-phtisiologie (Benin) with partners from Belgium, Cameroon, Democratic Republic of Congo, Ethiopia, France, Guinea, Mali, Rwanda, Senegal, Switzerland, and United Kingdom

Starting date: 1 June 2016

Duration: 60 months

Grant budget: EUR 2,967,202

Grant agreement: DR1A-2014-326



Dr Myron Levine (Univ. of Maryland, USA) delivering the keynote speech on diarrhoeal diseases

Stakeholder meetings: diarrhoeal diseases and lower respiratory tract infections

EDCTP held two stakeholder meetings for new fields added to our scope under the second programme: diarrhoeal diseases and lower respiratory tract infections. The meetings took place in Amsterdam, The Netherlands on 5 and 6 July 2016 to inform EDCTP's funding strategy. Representatives from academic and research institutions, funding agencies, product development partnerships among others were invited to participate.

On 5 July, Prof. Philippe Sansonetti (Institut Pasteur and Collège de France, France) and Dr Jeffrey Mphahlele (South African MRC, South Africa) chaired the meeting on diarrhoeal diseases which featured three speakers and sessions with focus groups. On 6 July, Prof. Jeremy Brown (University College London, United Kingdom) steered

the discussions on lower respiratory tract infections in response to six speakers. The objectives of both meetings were to review the research landscape, available interventions and products in development, and to identify short and medium term priorities for EDCTP in terms of disease, research and intervention. Reports of the meetings will be published.

EDCTP regularly organises thematic stakeholder meetings. The purpose of thematic stakeholder meetings is to contribute to shaping the programme's strategic research agenda, funding approach and strategic alignment with work of other partners involved in clinical development of interventions against poverty-related and neglected infectious diseases. More information on www.edctp.org.

EDCTP work plan 2016 available online

The EDCTP work plan 2016, approved in June 2016, is available on the website. It provides information on all our calls for proposals, including the challenge, scope, expected impact, and supporting information about eligibility requirements and other specific conditions for applying. Additionally, the other activities which support our programme are also described.

Importantly, the work plan contains an overview of the activities funded and implemented directly by the countries that are a member of the EDCTP Association, the Participating States. These Participating States' Initiated Projects (PSIAs) are considered an integral part of the second programme and contribute to achieving the objectives of the programme.

Under the second EDCTP programme the funding of projects is based on EDCTP2 Strategic Business Plan and annual work plans which are developed following a comprehensive consultation process involving many stakeholders. The annual work plans are approved by both the European Commission and the EDCTP Association.

New projects! Cryptococcal meningitis and HIV

HIV-associated central nervous system (CNS) infections cause significant disease burden and mortality in sub-Saharan Africa. Cohort studies of patients accessing antiretroviral programmes estimate that CNS infections cause up to 25% of HIV-related deaths. Of these, approximately 20% are caused by cryptococcal meningitis, the most common life-threatening meningitis for HIV-infected patients. Successful interventions for diagnosis, treatment, care and innovative home support are essential to reduce this burden.

TRIP: treating cryptococcal meningitis in HIV patients

The REMSTART study, funded under the first EDCTP programme, suggested a new approach to caring for patients with advanced HIV. A randomised trial involved 1,999 patients in Tanzania and Zambia with advanced HIV disease and beginning ARV treatment. The trial found that combining community support with screening for prevention of cryptococcal meningitis reduced deaths by 28%. The results, published in *The Lancet* in 2015, suggest that this low-cost intervention could be an effective approach to reducing HIV-related deaths in Africa.

Based on these positive results, a follow up project received funding under the second EDCTP programme. The TRIP study, led by Dr Sayoki Godfrey Mfinanga (National Institute for Medical Research, Tanzania), aims to

assess the REMSTART approach on a larger scale trial in urban and rural settings in Tanzania. The objective is to determine the feasibility and cost-effectiveness of scaling up the intervention to routine health care systems, and to inform guidelines for services to patients with advanced HIV.

DREAMM: diagnosing cryptococcal meningitis in HIV patients

Clinical outcomes of HIV patients with cryptococcal meningitis are often aggravated by delayed diagnosis of the infection and an inability to stratify patients based on infection severity in addition to limited treatment options and capacity to administer the gold standard treatment for cryptococcal meningitis treatment in low-resource settings.

The DREAMM project, led by Dr Angela Loyse (St. George's University of London, UK), is a multi-centre study that aims to evaluate a new diagnostic tool, a semi-quantitative cryptococcal antigen lateral flow assay (CrAG LFA) developed by the Pasteur Institute (France). This test will diagnose HIV patients with cryptococcal meningitis with high CrAg titres. These patients may benefit from a more aggressive or prolonged antifungal therapy. The test also aims to reduce time to diagnosis as well as time to start of effective treatment. The DREAMM project will be conducted in collaboration with Pasteur International and the Centre for Disease Prevention (CDC) in sites in Cameroon, Malawi and Tanzania.



Nomination deadlines extended

Nominations are still being accepted for the following awards:

- **Scientific Leadership Award** is given to excellent world-class scientists in Africa up to 50 years of age.
- **Outstanding Female Scientist Award** is given to excellent world-class female scientists residing in sub-Saharan Africa and working in research activities within the scope of the second EDCTP programme.
- **Outstanding Research Teams Award** is given to outstanding research teams in Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in the scope of the second EDCTP programme.

The nominations deadline is 8 August 2016. The award ceremonies will take place at the Eighth EDCTP Forum in Lusaka, Zambia 6-9 November 2016.

For more information on the awards and submission, please visit www.edctp.org/edctp-awards-2016

Gulbenkian Foundation co-funds Fellowships

The Calouste Gulbenkian Foundation (Lisbon, Portugal) and EDCTP have renewed their collaboration agreement in order to develop research capacity in Portuguese-speaking African countries. The foundation will contribute to EDCTP's fellowship programmes by providing grants to successful applicants from Portuguese-speaking African countries.

Currently, three fellowship schemes are supported under the second EDCTP programme: Senior Fellowships, Career Development Fellowships, and Clinical Research and Development Fellowships, the latter in collaboration with WHO-TDR. Calls for proposals are opened each year. The Gulbenkian Foundation pledges to contribute up to €265,000 to support successful applications of researchers from Portuguese-speaking countries in sub-Saharan Africa.

Funds from the Gulbenkian Foundation will be granted through EDCTP. All fellowships schemes are eligible to receive this support, starting from the calls launched in 2016 or 2017. Applications are reviewed by a Scientific Review Committee (SRC) composed of independent experts. If applications from researchers from Portuguese-speaking countries are successful, the Gulbenkian Foundation will be requested to contribute.

The Calouste Gulbenkian Foundation is a Portuguese private institution of public utility and supports both individuals and organisations. It promotes a wide range of programmes and projects within its four areas of action: arts, charity, education and science. Since 2003, the programme 'Partnerships for development' aims to develop the capacities of Portuguese-speaking African countries and East Timor.

Call for experts: Scientific Advisory Committee

EDCTP invites high-level experts from various fields and sectors to become members of its Scientific Advisory Committee (SAC) as of January 2017. The SAC is the principal independent advisory group for EDCTP, providing strategic and scientific advice to the EDCTP General Assembly and the Executive Secretariat. It also advises regarding the scientific integrity of the EDCTP programme. The SAC is not involved in the review of applications submitted to EDCTP calls for proposals.

Applicants should have skills, knowledge, expertise and standing in one or more of the following fields:

- Poverty-related and neglected infectious diseases in the scope of the EDCTP2 programme
- Clinical trials and clinical research, especially in sub-Saharan Africa
- Research capacity strengthening and training
- Public health (including epidemiology, biostatistics, health economics, global health, maternal and child health and implementation research)
- Product development, especially in an industry setting
- Post-registration safety and effectiveness programmes
- Social and behavioural sciences within the disease scope of EDCTP2
- Clinical research ethics and regulatory affairs.

The deadline for applications is 12 September 2016. For more information and how to apply, please visit www.edctp.org.

Secretariat



Professor Moses John Bockarie joined EDCTP as Director of South-South Cooperation and Head of Africa Office on 1 July 2016. Prof. Bockarie, a Fellow of the Royal College of Physicians of Edinburgh, is a specialist in the field of neglected infectious diseases and an internationally experienced researcher. He has worked in many countries in Africa, Europe and the Pacific region, and in the United States of America.

The Director of South-South Cooperation is responsible, in addition to the management of the EDCTP office in Cape Town South Africa, for coordinating and executing all tasks of the EDCTP programme that are most effectively and efficiently conducted from Africa.

“On behalf of the greater EDCTP family, I warmly welcome Professor Bockarie as our newly appointed Director of South-South Cooperation. This is a timely appointment to strengthen our cooperation with sub-Saharan African countries and to bolster their commitment and active participation in the second programme of EDCTP.”

-Michael Makanga, Executive Director

Prof. Bockarie is the 2016 recipient of the Royal Society of Tropical Medicine and Hygiene Mackay Medal for outstanding work in tropical health. Professor Bockarie is also Chair of the WHO/TDR Scientific Working Group for Vectors, Environment and Society and a member of the WHO Regional Programme Review Group for Neglected Tropical Diseases in the African Region. Before joining EDCTP as a Director,

Moses Bockarie was a member of the independent EDCTP Scientific Advisory Board. He was Director of the Centre for Neglected Tropical Diseases and Professor of Tropical Health Sciences at the Liverpool School of Tropical Medicine (LSTM), United Kingdom from 2008 to 2015. He obtained his Bachelor's degree in Zoology from the University of Sierra Leone and a Masters and PhD in tropical health sciences from the Liverpool School of Tropical Medicine.

Prof. Bockarie worked on various research programmes on malaria and other neglected diseases in Sierra Leone, before taking up an appointment at the Papua New Guinea Institute of Medical Research, becoming Principal Research Fellow in Medical Entomology and Head of the Vector Borne Disease Unit in 1996. In 2005 he joined the Centre for Global Health and Diseases, Case Western Reserve University, Cleveland Ohio, USA as Visiting Professor, where he continued his research on neglected diseases until his appointment in Liverpool in 2008.

Alumni meeting for clinical research & development fellows

The alumni meetings for the EDCTP-TDR Clinical Research and Development Fellowship scheme were established to further South-South and North-South cooperation and African scientific leadership through collaborative research. The Fourth Alumni meeting for Clinical research and Development Fellows was held in Geneva from 8-10 June 2016. The meeting brought together current fellows of the EDCTP-TDR Clinical Research and Development Fellowship programme and of its precursor, the TDR Career Development Fellowship programme.

A total of 52 fellows (previous and current) attended this meeting together with representatives of several home institutions,

pharmaceutical organisations and companies, representatives of product development partnerships that host fellows as well representatives of the Gates Foundation and EDCTP. The participants reviewed the programme and identified needs and opportunities at the home institutions.

The first call for proposals of the EDCTP-TDR fellowship scheme was launched in October 2014. To date, 21 fellows have been placed in countries worldwide to work in areas that include data management, research design, and project management in the context of diagnostic studies or clinical trials. A new call for proposals will open on 20 October 2016. Read more on www.edctp.org.

2016 Calls for proposals

In total EDCTP will publish nine calls for proposals in 2016 to support clinical research and related activities against poverty-related and neglected infectious diseases (PRNIDs). Of these, five calls for proposals opened in July. The calls are worth approximately €138.6 million. Proposals are invited for the following topics:

Vaccines for poverty-related diseases (PRDs)

Purpose: to support large-scale collaborative projects which include one or more clinical trials (phase I to IV) aiming to accelerate the clinical development of new vaccines (preventive or therapeutic) against one of the PRNIDs. Proposals must include at least one clinical trial which will be carried out in sub-Saharan Africa to test the safety, immunogenicity and/or efficacy of the vaccine(s).

Call budget: EUR 70M

Maximum funding: EUR 15M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 7 July 2016, 17:00

Close date: 13 October 2016

Research and clinical management of patients in PRD-epidemics in sub-Saharan Africa

Purpose: to support the establishment of a multidisciplinary consortium able to provide accelerated evidence for the optimal clinical management of patients and for guiding the public health response to any severe infectious outbreak caused by pathogens within the scope of the EDCTP programme with pandemic potential or that may cause significant damage to health and the socio-economic situations in Africa (including antimicrobial-resistant pathogens).

Call budget: EUR 10M

Maximum funding: EUR 10M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 7 July 2016

Close date: 29 September 2016

Clinical trials and operational research studies to optimise the use of products for PRDs in mothers, newborns, children and/or adolescents

Purpose: to support projects on preventive and therapeutic clinical interventions regarding post-registration products, as well as related behavioural studies. The projects should aim to optimise the use of new or improved products or combination of products for mothers, newborns, children and/or adolescents. The scope of this call is limited to clinical trials and operational studies with a product focus.

Call budget: EUR 10M

Maximum funding: EUR 3M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 7 July 2016

Close date: 29 September 2016

Strategic actions supporting large-scale clinical trials

Purpose: to support distinct, strategic clinical research activities which are part of a large-scale clinical trial that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRNIDs. Applications for a strategic action should focus on clinical trials in sub-Saharan Africa and may address any disease within the scope of the EDCTP programme. Proposals that include phase III trials are encouraged.

Call budget: EUR 28M

Maximum funding: EUR 15M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 14 July 2016

Close date: 13 October 2016

Strategic actions supporting health systems/ services optimisation research capacities in cooperation with development assistance initiatives

Purpose: to support distinct strategic actions to strengthen the capacity of health systems in sub-Saharan Africa to effectively deliver new products and to monitor their post-market safety. This will be achieved through effective cooperation with relevant European Union initiatives including development assistance.

Call budget: EUR 10M

Maximum funding: EUR 3M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 14 July 2016

Close date: 29 September 2016

Ethics and regulatory capacities

Purpose: to provide funding to actions that aim 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. This scheme targets both National Ethics Committees and National Regulatory Authorities.

Call budget: EUR 2M

Maximum funding: EUR 300,000

Funding level: 100% of eligible costs

Procedure: One-stage application

Open date: 4 August 2016

Close date: 22 November 2016

EDCTP-WHO/TDR Clinical Research and Development Fellowships

Purpose: to support junior to mid-career researchers and key members of clinical trial research teams from low- and middle-income countries to acquire specific skills in clinical research and development through placements in pharmaceutical companies and product development partnerships. The call is a joint initiative with WHO-TDR. EDCTP funding will support fellows from sub-Saharan Africa placed at pharmaceutical companies in Europe.

Call budget: EUR 3.5M

Funding level: 100% of eligible costs

Procedure: Two-stage application

Open date: 20 October 2016

Close date: 2 February 2017

Senior Fellowships

Purpose: This call for proposals aims to support the development of potential African research leaders (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. Moreover, it aims to support senior researchers to establish themselves as research leaders in product development through clinical trials and related activities.

Call budget: EUR 3M

Maximum funding: 500,000

Funding level: 100% of eligible costs

Procedure: One-stage application

Open date: 3 October 2016

Close date: 1 February 2017

Career Development Fellowships

Purpose: This call aims to support junior to mid-career researchers ("fellows") to train and develop their clinical research skills. The objectives are to promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa, and to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research and team at host organisations in sub-Saharan Africa.

Call budget: EUR 2.1M

Maximum funding: EUR 150,000

Funding level: 100% of eligible costs

Procedure: One-stage application

Open date: 3 October 2016

Close date: 28 February 2017

Eighth EDCTP Forum

Preparations are underway for the Eighth EDCTP Forum that will take place in Lusaka, Zambia, from 6-9 November 2016. This Eighth Forum, which is organised in partnership with the Ministry of Health of the Republic of Zambia, provides an opportunity to share experiences and discuss key research findings, lessons learnt and best practices under the Forum's theme "Defeating poverty-related and neglected infectious diseases (PRNIDs) in Africa: harnessing research for evidence-informed policies."

The **Forum programme** will comprise a wide range of topics of clinical research covering PRNIDs within the scope of the EDCTP programme. The Forum will feature invited speakers who are leaders in their respective areas of research, as well as abstract-driven oral and poster presentations. A number of these presenters will be early career investigators and scientists who will participate through our scholarship programme. The programme also offers:

- Informal 'Meet the experts' sessions that will give young researchers the possibility to attend group meetings with leading experts in the field of PRNIDs.
- Special seminars such as the 'Session on laboratory accreditation', and the seminar 'From research to publication', moderated by Dr Trish Groves from the British Medical Journal Global Health to provide an editor's perspective and tips to help researchers publish their studies.
- Scientific symposia organised by research groups or organisation with EDCTP. One of these symposia will highlight research in Zambia. Local researchers will showcase their work and present research findings.
- Four award ceremonies, i.e. for the Scientific Leadership Award, Outstanding Female Scientist Award, Outstanding Research Team Award, and the Dr Pascoal Mocumbi Prize. These awards aim to promote African-European scientific research collaboration, and will reward outstanding individual researchers and research teams especially from Africa and Europe.

As part of the Forum, a **high-level meeting** will take place on 7 November 2016. It will bring together invited representatives and policy makers from existing and aspiring EDCTP member countries in Africa and Europe, African regional bodies, health and research councils, and funding agencies.

The objective of the meeting is to increase African participation in EDCTP and discuss how EDCTP can build on the recent experience from the Ebola virus disease epidemics in West Africa. During that emergency situation in the Mano River Union countries (Côte d'Ivoire, Guinea, Liberia, and Sierra Leone), it was shown possible to translate research results into clinical and public health practice in less than two years, much quicker than is typically the case. Similar rapid improvements in research capacity and laboratory capabilities were also seen.

Our **sponsorship packages** offer various ways to profile organisations and to engage with conference participants. Importantly, sponsor contributions to the Forum ensure broad participation of young African researchers through the Forum's scholarship programme.

Please visit the Forum website (www.edctpforum.org) for more information about the programme, our sponsorship packages, and registration and fees.



EDCTP Secretariat at the International AIDS Conference 2016 in Durban, South Africa

EDCTP at AIDS 2016

The 21st International AIDS Conference (AIDS 2016) was held at the Durban International Convention Centre from 18 to 22 July 2016. EDCTP participated in several activities at the AIDS 2016, and was represented at the conference by Dr Gabrielle Breugelmans (North-North Networking Manager), Dr Christy Comeaux (Project Officer), Ms Mariska Louw (Senior Administrative Officer), Ms Shingai Machingaidze (Project Officer), and Ms Lara Pandya (Networking Officer). An information booth shared by EDCTP and the EC welcomed visitors throughout the conference.

At the conference, Lara Pandya presented the poster 'EDCTP as a model for Europe-Africa partnership on HIV/AIDS research: achievements and future directions' (pictured below). The poster presentation included the contributions from the first EDCTP programme towards the fight against HIV and HIV/TB co-infection and the funding priorities for the second EDCTP programme.

The symposium was chaired by Gita Ramjee (HIV Prevention Research Unit, MRC-South Africa) and Ilesh Jani (Instituto Nacional de Saúde Maputo, Mozambique). The programme also included presentations from Alessandra Martini (EC), Dr Gabrielle Breugelmans (EDCTP), Claire Thorne (University College London, UK), Rebecca Hodes (University of Cape Town, South Africa), and Philippe Van de Perre (University Montpellier, France), pictured below.



On 20 July, the symposium 'Every mother, every child: closing the caps in HIV management' took place. The symposium was jointly organised by the European Commission (EC) and EDCTP. It highlighted prominent advances in maternal and child health, including the accomplishments of recent EU and EDCTP-funded projects, and the future plans in this area through the Horizon 2020 and research funding strategies of the second EDCTP programme.



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HAVE A QUESTION OR COMMENT?
info@edctp.org

EDCTP EUROPE
PO Box 93015
2509 AA The Hague
The Netherlands
T: +31 70 344 0880
F: +31 70 344 0899

EDCTP AFRICA
PO Box 19070
Tygerberg 7505 Cape Town
South Africa
T: +27 21 938 0690
F: +27 21 938 0569

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