EDCTP

European & Developing Countries
Clinical Trials Partnership

Annual Report 2015

GAINING MOMENTUM

OUR MISSION

To reduce poverty in sub-Saharan Africa through improved health by funding collaborative research to accelerate the development of new or improved medical interventions against poverty-related and neglected infectious diseases.

Cover photo:
Medical staff and research volunteer at the Regional Hospital of Banfora, part of the WANECAM study led by Prof. Abdoulaye Djimdé in Banfora, Burkina Faso

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“I BELIEVE YOU WILL CONCLUDE THAT THERE ARE MANY POSITIVE ACHIEVEMENTS AND SIGNIFICANT MILESTONES IN THIS SUMMARY OF OUR YEAR’S ACTIVITIES.”

Michael Makanga, Executive Director

Foreword

MESSAGE FROM THE EXECUTIVE DIRECTOR

It is my privilege and pleasure to introduce the 2015 annual report as we take the pulse of our organisation at a time when the new programme is steadily gaining momentum. It was a very busy year with two programmes running in parallel, the first programme of EDCTP winding down and the second programme (EDCTP2) being rolled out. I believe you will conclude that there are many positive achievements and significant milestones in this summary of our year's activities.

The year 2015 was the first full year of EDCTP2, which was launched on 2 December 2014 and is being implemented by the EDCTP Association. I can say with pride that the governance structure of EDCTP2 was fully implemented in 2015. The Association registered 14 African and 14 European countries as members, the so-called Participating States. With this paradigm shift, we see European and African countries jointly take responsibility in the governance of the programme. The European Union (EU) has also maintained its commitment to EDCTP and supports the programme under its Framework Programme for Research and Innovation, Horizon 2020.

EDCTP2 has an expanded scope. Many neglected infectious diseases, lower respiratory tract infections, diarrhoeal diseases, and emerging infections such as Ebola and yellow fever were added to the programme. EDCTP received recognition for its role from the G7 Ministers of Science. In October, they met in Berlin to discuss coordination of research efforts regarding, among other topics, global issues of health. They declared their resolve to support the fight against neglected tropical and poverty-related infectious diseases by better coordination of national R&D activities building on mechanisms such as EDCTP.

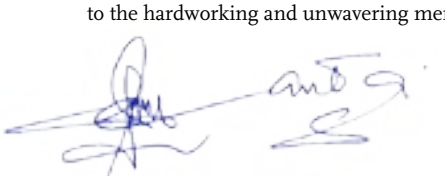
At the Science Forum South Africa 2015, the Honourable Naledi Pandor, South African Minister for Science and Technology awarded EDCTP a Science Diplomacy Award in recognition of its contribution to research capacity development.

EDCTP activities are of two kinds: the projects supported by the EU and implemented by EDCTP, and secondly, activities initiated by the Participating States (PSIAs). These are research activities within the scope of the EDCTP programme that are supported with national funding and independently executed by Participating States. The PSIAs are important as they directly contribute to achieving the EDCTP objectives. The disbursements for PSIAs also count as basis for the EU funding of EDCTP. In 2014 and 2015, European Participating States already disbursed an impressive 31% of the €683M pledged to the EDCTP programme.

In 2015, a total of 11 EDCTP calls for proposals were ongoing: 3 calls of the 2014 work plan and 8 calls of the 2015 work plan. We succeeded in completing the full process for four calls for proposals: the calls from the 2014 work plan and the 2015 call 'Research capacity development in support of the Ebola Virus Disease (EVD) response'. This last call was part of the European response to the Ebola crisis in West Africa.

In October and November 2015, five more EDCTP calls for proposals were opened for applications. Their purpose is to support research capacity development in sub-Saharan Africa through career development of African researchers, strengthening of South-South research networks and development of research ethics review capacity.

All this would not have been achieved without the commitment and effort of the broader EDCTP family. I wish to pay special homage to Professor Charles Mgone, my predecessor, who has steadily steered the ship since 2007 and stepped down at the end of 2015. He remains a very active advocate for EDCTP. I also wish to extend my appreciation to all members of the EDCTP Board, the General Assembly, Scientific Advisory Committee and EC Officers responsible for EDCTP matters. Special thanks go to the hardworking and unwavering members of the Executive Secretariat who always go the extra mile to get the work done.



Michael Makanga, MD, PhD, FRCP Edin.

Medical staff for the XACT study led by Prof. Keertan Dheda

Chapter 01

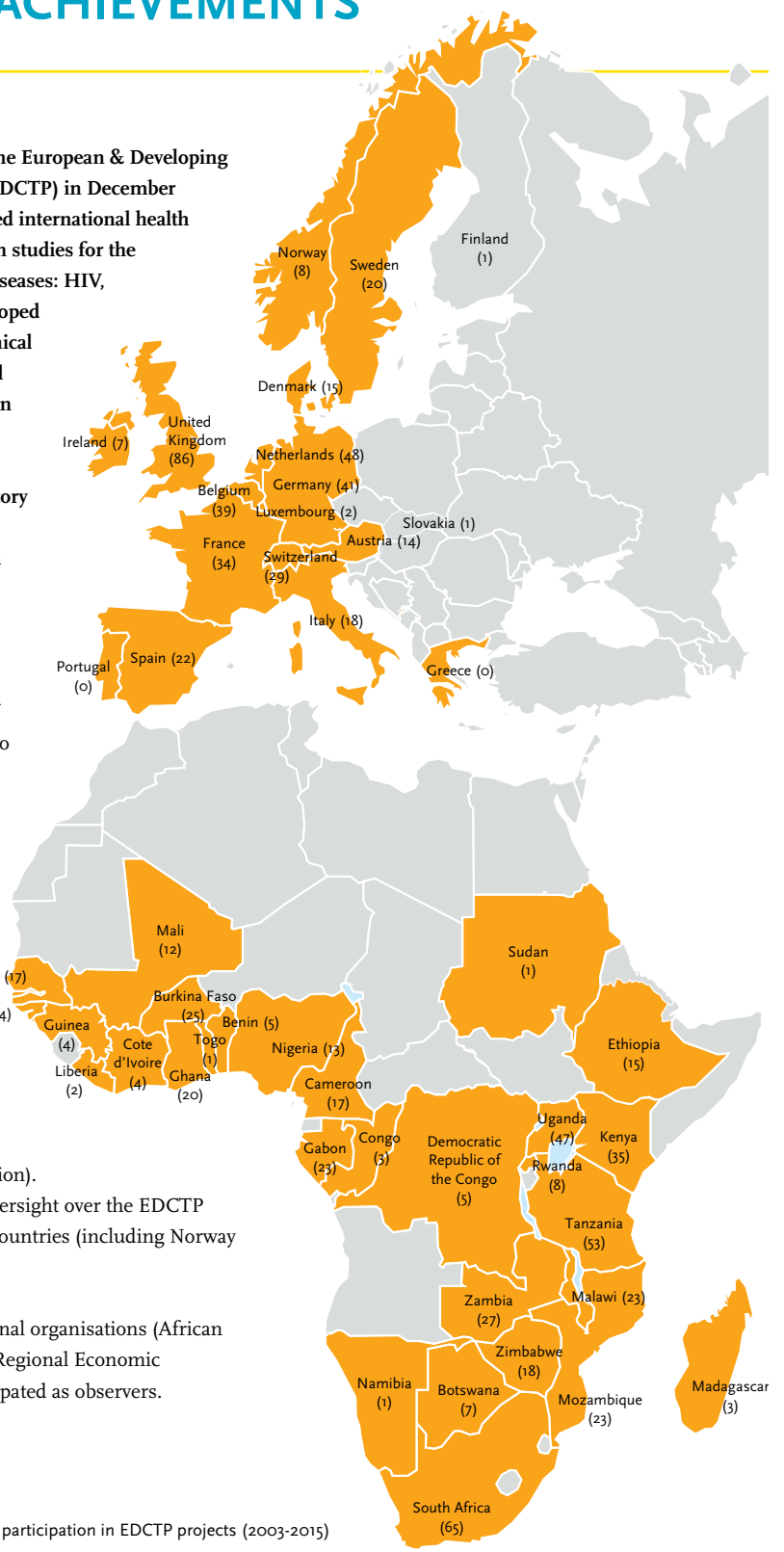
FIRST EDCTP PROGRAMME: SUMMARY OF ACHIEVEMENTS

At the close of the first programme of the European & Developing Countries Clinical Trials Partnership (EDCTP) in December 2015, EDCTP had become an established international health research funder supporting intervention studies for the three main poverty-related infectious diseases: HIV, tuberculosis and malaria. EDCTP developed a funding strategy which integrated clinical trials and the development of individual and institutional capacity in sub-Saharan Africa to conduct such trials. This capacity development also comprised strengthening of the ethical and regulatory framework for clinical trials and closely related research in sub-Saharan African countries.

EDCTP was established in 2003 as a research programme initiated by 14 European countries with the support of the European Union (EU) in response to the global health crisis caused by HIV/AIDS, tuberculosis and malaria. The programme was the largest for clinical trials targeted to Africa under the EU's 6th Framework Programme for Research.

EDCTP was constituted as a European Economic Interest Grouping (EEIG) to enable the direct participation of the European Union in the organisation (Article 185 of the Treaty on the functioning of the European Union). The General Assembly that provided oversight over the EDCTP programme consisted of 16 European countries (including Norway and Switzerland).

The European Union and African regional organisations (African Union Commission for Social Affairs, Regional Economic Communities and WHO-AFRO) participated as observers.



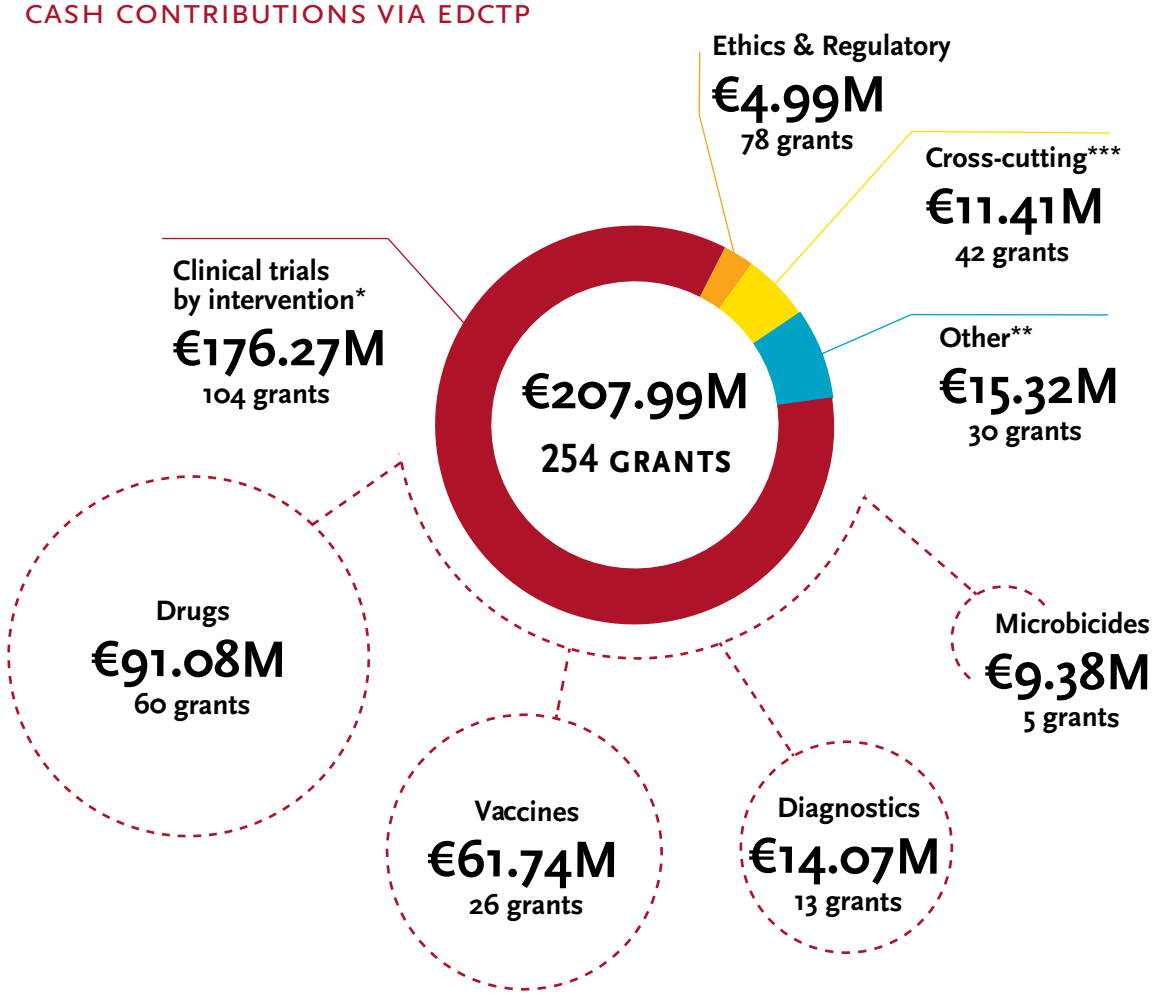
African-European participation in EDCTP projects (2003-2015)

PROJECT FUNDING AND INVOLVEMENT

- EDCTP has become an established not-for-profit funding initiative with a reputation for supporting equitable research partnerships between Europe and Africa.
- The majority of EDCTP grant funding (74.3%) was disbursed to sub-Saharan Africa.
- The promotion of African leadership in research has contributed to the training of young and mid-career investigators who have progressed in their field, whilst also supporting the careers of research and clinical personnel as well as grants administration staff. This in turn has built capacity at an organisational level.

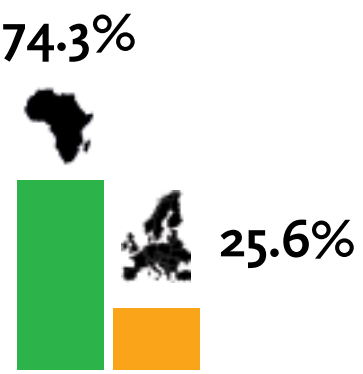
PORTFOLIO BY INTERVENTION/TOPIC

CASH CONTRIBUTIONS VIA EDCTP



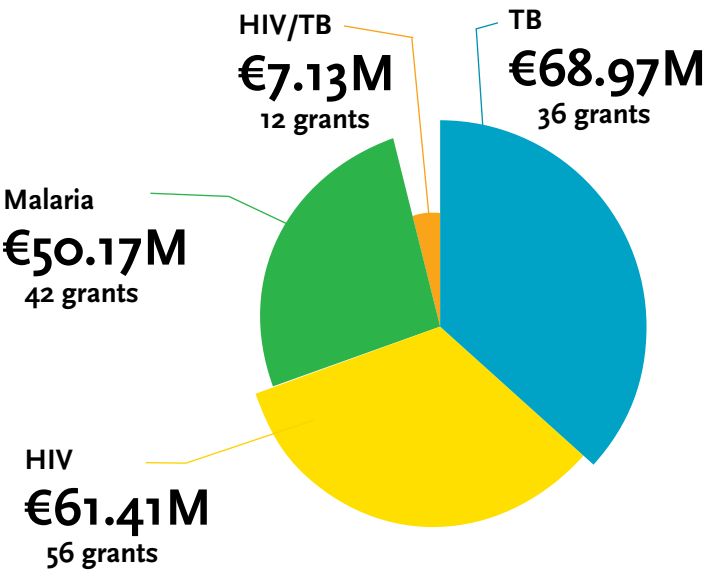
*including treatment and prevention, special populations, and laboratory investigations.
**defined as capacity development and networking activities.
***cross-cutting activities not related to a particular intervention.

Funding distribution
for collaborative research



Note: An additional 0.1% was allocated to the USA for a single supporting activity.

Portfolio by disease



Note: A further €20.31M for 108 grants was awarded to topics such as ethics & regulatory support, capacity building, support to meetings, and other non-disease specific grants, including the EDCTP Networks of Excellence.

In its first programme, EDCTP launched 65 calls for proposals, received 789 applications, and awarded 254 grants with a total value of €207.99 million.

more than **700**
peer-reviewed publications resulted from EDCTP projects

These peer-reviewed publications and supporting data influenced national and international policies and guidelines, and moved products forward through the development pipeline and to regulatory approval.

over **70%** of **254** projects
were led by an African Coordinator by the close of the first programme

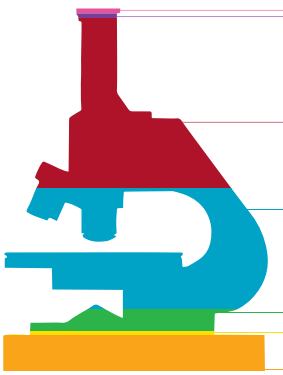
More than €154.3 million (74.3%) of EDCTP grant funding was awarded to African participants. European participants received just over €53.3 million (25.6%) of EDCTP grant funding.

An additional €0.288 million (0.1%) was allocated to a USA participant for a single supporting activity.

RESEARCH CAPACITY

516 trainees were supported from 2003-2015

Capacity development in sub-Saharan Africa has been a major part of the EDCTP programme from its inception. EDCTP aims to achieve sustainable capacity for conducting clinical trials by attracting and retaining scientific leadership in Africa, improving and upgrading research infrastructure, and strengthening the ethical and regulatory framework for conducting trials.

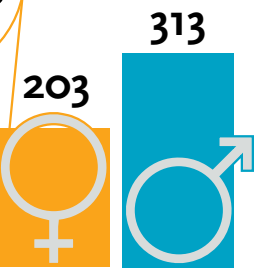


7 Medical diploma students
7 Bachelor's students
242 Master's students
172 PhD students
32 Postdoctoral researchers on EDCTP grants
5 Career Development fellows
51 Senior fellows

Through the ethics grant scheme,
75 grants were awarded to **23** sub-Saharan African countries to strengthen capacity for health research ethics review.

EDCTP support was provided for the establishment and strengthening of ethics capacity in Africa at institutional, national and sub-regional level, as well as training of ethics review board members through courses and workshops in Africa and Europe. More than half of the ethics grants awarded have supported the establishment or strengthening of Institutional Review Boards.

that's almost **40%**

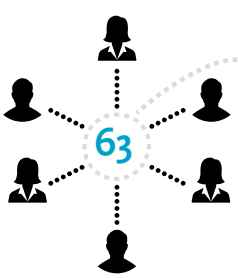


EDCTP Networks of Excellence for Clinical Trials

EDCTP established four Regional Networks of Excellence for Clinical Trials to build and maintain sufficient African capacity to design and conduct clinical research with a focus on the poverty-related diseases relevant to Africa. The Networks facilitate regional collaboration by uniting diverse institutions that bring their individual strengths in skills-based competencies and shared infrastructures for conducting clinical trials. By collaborating they learn and develop, and thereby raise the quality of clinical research and practice in sub-Saharan Africa.

West African NoE for TB, AIDS, and Malaria (WANETAM)
€3.50M

East African Consortium for Clinical Research (EACCR)
€3.46M



63 institutions united across **21 countries** in sub-Saharan Africa to improve trial capacity in areas such as good clinical and laboratory practice, data management, trial monitoring, and financial and project management.

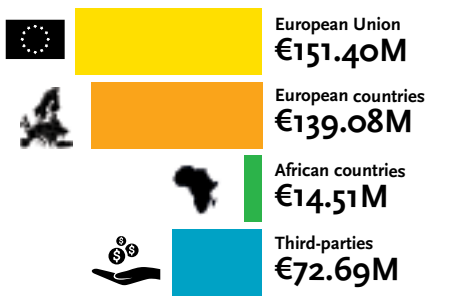
Central African Network for TB, AIDS, and Malaria (CANTAM)
€2.80M

Trials of Excellence in Southern Africa (TESA)
€2.30M

CONNECTING RESEARCH

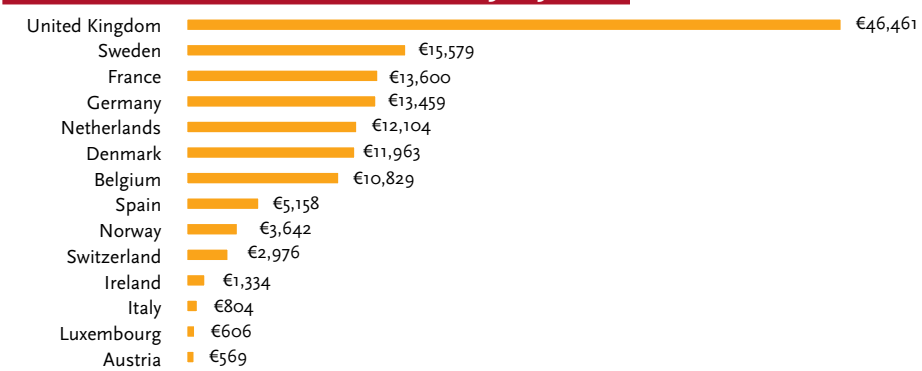
EDCTP has shown that improved coordination of European research as well as collaboration with and among African researchers is of great benefit to all partners and reinforces the impact of the European contribution. Moreover, EDCTP develops and maintains third party relations that contribute to the development of new clinical tools against HIV, tuberculosis, and malaria.

CASH & IN-KIND CONTRIBUTIONS TO EDCTP GRANTS (2003-2015)

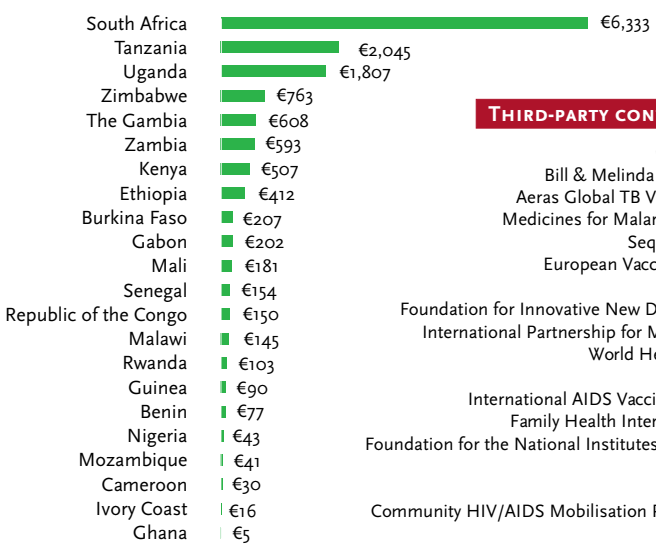


Total amount = €377.69M

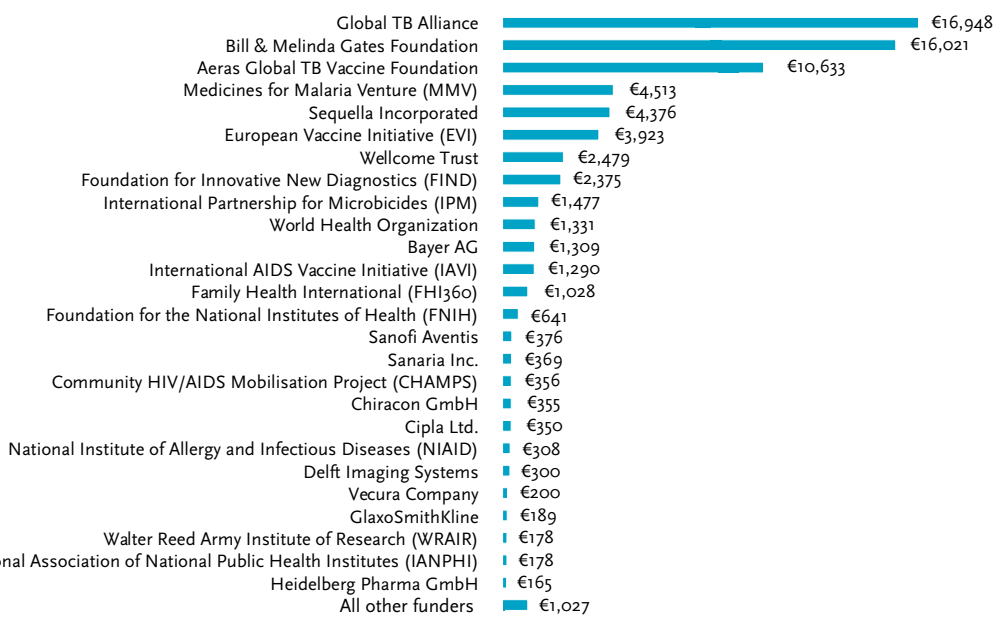
EUROPEAN CONTRIBUTIONS TO EDCTP GRANTS 2003-2015 (€ '000)



AFRICAN CONTRIBUTIONS TO EDCTP GRANTS



THIRD-PARTY CONTRIBUTIONS TO EDCTP GRANTS 2003-2015 (€ '000)



OUTPUT AND IMPACT OF KEY PROJECTS

HIV

30 CLINICAL TRIALS

Drugs	Vaccines	Microbicides	Cross-cutting*
17 trials	8 trials	3 trials	2 trials

*cross-cutting activities not related to a particular intervention.

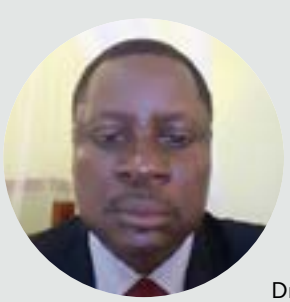
In its first programme, EDCTP supported 56 projects in HIV research and capacity building, including 30 clinical trials on HIV. Additionally, EDCTP supported research capacity development in this field:

- **The first-ever published HIV vaccine trial in Mozambique while also strengthening capacity to conduct HIV vaccine trials in The Gambia, Guinea-Bissau, Kenya, South Africa and Tanzania;**
- **Establishment and support of a network to conduct clinical trials in adolescents in South Africa;**
- **Establishment of an epidemiological cohort of high-risk individuals (fisher folk) in preparation for future clinical trials in Malawi and Uganda;**
- **HIV prevention studies in Rwanda, Mozambique and Tanzania.**

The **CHAPAS-3** (Children with HIV 1 in Africa, Pharmacokinetics and Adherence/Acceptability of Simple Antiretroviral Regimens) study, coordinated by Dr Veronica Mulenga (University Teaching Hospital, Zambia), was the first randomised controlled trial conducting a head-to-head comparison of the three most relevant nucleoside reverse transcriptase inhibitors (NRTIs) for paediatric treatment.

All regimens were shown to have low toxicity and good clinical, immunological, and virological responses. This clinical trial provided strong evidence in support of the WHO guidelines for first-line paediatric antiretroviral therapy (ART). The study allayed concerns of reduced efficacy raised by observational studies. The results, published in *The Lancet Infectious Diseases* on 6 October 2015, support clinicians and policy makers in implementing the current WHO guidelines for ART in children.
DOI: http://dx.doi.org/10.1016/S1473-3099(15)00319-9

Researchers from the **REMSTART** team – led by Dr Saidi Egwaga (Tanzanian Ministry of Health and Social Welfare) and Dr Shabbar Jaffar (Professor of Epidemiology at the London School of Hygiene & Tropical Medicine) – conducted a randomised trial of 1,999 HIV patients in Tanzania and Zambia between February 2012 and September 2014.



"SCREENING OF PATIENTS PRESENTING TO AFRICAN CLINICS WITH ADVANCED HIV DISEASE FOR CRYPTOCOCCAL MENINGITIS COMBINED WITH A SHORT PERIOD OF COMMUNITY SUPPORT FROM LAY WORKERS REDUCES MORTALITY BY 28%."

Dr Saidi Egwaga, REMSTART trial coordinator

The study enrolled patients who had advanced HIV disease and were beginning treatment. Most of the deaths in African HIV programmes occur in this group at around the time or just shortly after HIV treatment is started. All patients were first screened for tuberculosis and started quickly on HIV treatment. Patients were then given either standard care at a clinic, or standard with additional care which consisted of screening for cryptococcal meningitis as well as weekly home visits for the first four weeks by lay health care workers to support the patients with antiretroviral therapy.

The trial found that the number of deaths among patients receiving the additional care was 28% lower than among those receiving only standard care: 134 deaths and 180 deaths respectively, over a 12 month follow-up period. 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.
DOI: http://dx.doi.org/10.1016/S0140-6736(15)60164-7

Professor Philippe Van de Perre (INSERM, University of Montpellier 1, France) coordinated a randomised controlled clinical trial with research sites in Burkina Faso, South Africa, Uganda and Zambia. The trial compared two prophylactic treatment regimens to prevent transmission of HIV from mother to child during 12 months of breastfeeding. The results of the **PROMISE-PEP/ANRS12174** study, published in *The Lancet* on 18 November 2015, showed that two liquid formulations of HIV drugs are safe and highly effective at protecting infants from infection while they are breastfed by their HIV-positive mothers, including the 6-12 month period after birth which had not been studied in previous research. The study was funded by the French research agency ANRS, the Research Council of Norway/University of Bergen, and EDCTP.
DOI: http://dx.doi.org/10.1016/S0140-6736(15)00984-8

Study volunteers at the KAVI-Kenyatta National Hospital in Nairobi, Kenya, part of the HIV-CORE004 project led by Prof. Tomáš Hanke

TUBERCULOSIS

29 CLINICAL TRIALS

Drugs
11 trials

Vaccines
5 trials

Diagnostics
13 trials

The funding strategy for tuberculosis (TB) research in the first EDCTP programme focused on the key issues and challenges in sub-Saharan Africa, recognising the impact of HIV-TB coinfection in this region. Since 2003, EDCTP has supported 29 clinical trials and diagnostics studies in TB.

The **TB-NEAT** consortium reported the results of a randomised trial in four sub-Saharan African countries of the lipoarabinomannan (LAM) assay for diagnosis of HIV-associated tuberculosis TB on all-cause mortality. The investigators showed that among HIV-positive adults needing hospital admission, use of the urine-based, point-of-care LAM assay in combination with standard of care for TB, was associated with a relative risk reduction of 17% for 8-week all-cause mortality. Evidence regarding the diagnostic accuracy of the LAM assay was synthesised in a Cochrane review and assessed by a WHO expert panel in June 2015, alongside data from the trial. The data from the EDCTP-funded trial (led by Professor Keertan Dheda of the University of Cape Town, South Africa) formed an important final piece of evidence to underpin WHO's recommendations for use of this assay. As of November, 2015, WHO recommends urine-LAM testing for HIV-positive hospital inpatients with signs and symptoms of TB, who have a CD4 cell count of 100 cells per µL or fewer, and also HIV-positive inpatients who are seriously ill, irrespective of their CD4 cell count.
DOI: http://dx.doi.org/10.1016/S0140-6736(15)01092-2

The EDCTP-funded **PanACEA** consortium presented the preliminary results of the **MAMS-TB-01** clinical trial at the Conference on Retroviruses and Opportunistic Infections (CROI) from 23-26 February 2015. According to the authors (abstract number: 95LB), the results showed that high-dose (35mg/kg) rifampicin,

"A LAM-GUIDED TREATMENT STRATEGY IN HOSPITALISED AFRICAN PATIENTS WITH ADVANCED HIV SAVES LIVES, MORE PATIENTS ARE TREATED, PATIENTS ARE TREATED EARLIER, AND THOSE THAT CANNOT PRODUCE SPUTUM (THIS OCCURS OFTEN) ARE ALSO DIAGNOSED."

Prof. Keertan Dheda, TB-NEAT trial coordinator

in combination with a standard dose of isoniazid, pyrazinamide and ethambutol, may be an important component of future treatment-shortening regimens. Compared to other regimens and previous TB trials, data showed the largest reduction in time to culture conversion observed over 12 weeks of experimental treatment. Data regarding treatment up to week 26 and post-treatment follow-up will be analysed and reported together with the results mentioned above in the future main publication.

The MAMS-TB-01 trial enrolled 365 patients from 7 sites in Tanzania and South Africa in only 11 months. It is the first of several TB treatment regimen trials which will use the same innovative adaptive clinical trial design that allows several new regimens to be compared to the current standard, and incorporates interim analyses that allow for regimens that show little treatment shortening potential to be excluded from the trial at an early stage.

The PanACEA's MAMS study was coordinated by Prof. Stephen Gillespie (University College London, UK), Prof. Martin Boeree (Radboud University Nijmegen, Netherlands) and Prof. Michael Hoelscher (LudwigMaximilians Universität München, Germany).

Medical staff and patients participating in the PanACEA-MAMS project at the Kibong'oto National TB Hospital in Tanzania led by Dr Martin Boeree, Prof. Michael Hoelscher and Prof. Stephen Gillespie

OUTPUT AND IMPACT OF KEY PROJECTS

MALARIA

34 CLINICAL TRIALS

Drugs
22 trials

Vaccines
12 trials

In the first programme, EDCTP focused its strategy on key challenges in the prevention and treatment agenda, such as optimising malaria treatment in children and in HIV-infected individuals, prevention and treatment in pregnancy, as well as development and testing of malaria vaccines and drugs. Since 2003, EDCTP has supported 34 clinical trials on malaria.

The **WANECAM** consortium led by **Professor** Abdoulaye Djimde (Malaria Research & Training Centre, Mali) conducted a phase IIIb/IV clinical trial assessing the safety and efficacy of repeated administration of four artemisinin-based combination therapies (ACTs) over a two-year period in children and adults with uncomplicated malaria. At the start of the clinical trial, the approved labelling for Pyramax® (fixed dose combination of artesunate and pyronaridine, one of the four study ACTs) was limited to a single treatment, which was not useful for sub-Saharan Africa where high-risk groups, especially children, experience several episodes of malaria per season. Interim data from the trial was published online in *The Lancet Infectious Diseases* in 2015. The first results demonstrated that safety and efficacy during re-treatments was similar to the first treatment, supporting wider access to Pyramax® as an ACT option for malaria in sub-Saharan Africa.

The trial data were submitted to the European Medicines Agency (EMA) in support of an application for a label extension for the Pyramax® film coated tablets variation with repeated courses of treatment. An application for a line extension to include a paediatric formulation (Pyramax® granules for oral suspension) was also submitted to the EMA. In November 2015, the EMA approved the use of Pyramax® for treating multiple episodes of malaria after its registration in malaria-endemic countries. In parallel, the EMA approved the use of the first paediatric formulation of an antimalarial (Pyramax® granules).
DOI: http://dx.doi.org/10.1016/S1473-3099(15)00318-7

EDCTP funded three projects under the umbrella of the **Malaria in Pregnancy (MiP) consortium**, a global effort to find effective ways of preventing malaria in pregnant women and their infants. The projects supported by EDCTP focused on finding new drugs to treat and/or prevent malaria infection in pregnancy and included:

"WANECAM CREATED A NETWORK OF AFRICAN AND EUROPEAN SCIENTISTS AND A TEAM OF CLINICAL INVESTIGATORS CAPABLE OF RUNNING GCP/ICH COMPLIANT TRIALS. WE TRAINED YOUNG SCIENTISTS INCLUDING MANY WOMEN. AND WE CONTRIBUTED TO APPROVAL OF LINE EXTENSION OF PYRAMAX TABLETS® AND LABEL VARIATION OF PYRAMAX® GRANULES BY THE EUROPEAN MEDICINES AGENCY."

Prof. Abdoulay Djimdé, WANECAM consortium coordinator

- The PREGACT trial coordinated by Professor Umberto D'Alessandro (MRC Unit The Gambia). DOI: http://dx.doi.org/10.1056/NEJMoa1508606
- The Malaria in Pregnancy Preventive Alternative Drugs (MiPPAD) study coordinated by Professor Clara Menéndez (Barcelona Centre for International Health Research, Spain). DOI: http://dx.doi.org/10.1371/journal.pmed.1001964
- The IPTp-SP study coordinated by Professor Feiko ter Kuile (Liverpool School of Tropical Medicine, United Kingdom).

These trials together recruited more than 15,000 African women. They were followed through pregnancy and the outcomes regarding the children that were born were studied. The trials have created an extensive data resource on malaria in pregnancy.

On 24-26 June 2015, the MiP consortium had its sixth and final annual meeting in Sitges, Spain. The latest results from the clinical trials and cross-cutting activities of the MiP consortium were shared. Participants also reviewed the data from the projects that were to be presented to the WHO Evidence Review Group in July 2015.

Medical staff and patient in the PREGACT study in Nazoanga, Burkina Faso, project led by Prof. Umberto D'Alessandro (photo by the Institute of Tropical Medicine in Antwerp)

Clinical staff and study volunteer at the Charles de Gaulle University Hospital, in Ouagadougou, Burkina Faso, as part of the MONOD project led by Dr Valériane Leroy

Chapter 02

EDCTP-EEIG

SUMMARY FINANCIAL STATEMENTS 2015 AND AUDITOR'S REPORT

Statement of financial performance and other comprehensive income
for the year ended 31 December 2015

Expressed in thousands ('000) of Euro

	Restricted EC 2015	Restricted Donor 2015	Total 2015	Total 2014
INCOME				
Contributions	1,246	465	1,711	16,466
Finance income	40	14	54	101
Total income	**1,286**	**479**	**1,765**	**16,567**
EXPENDITURE				
Grants expenditure	2,748	(775)	1,973	(10,089)
Other expenditure	(3,680)	(260)	(3,940)	(7,835)
Governance expenditure	(192)	(30)	(222)	(273)
Total expenditure	**(1,124)**	**(1,065)**	**(2,189)**	**(18,197)**
Result of the year	**162**	**(586)**	**(424)**	**(1,630)**

EDCTP-EEIG has no other comprehensive income.

All income and expenditure relates to continuing activities.

	2015 €'000	2014 €'000
Result attributable to:		
EC	162	(470)
Donor	(586)	(1,160)
	(424)	**(1,630)**

Statement of financial position as at 31 December 2015
(after appropriation of result)

Expressed in thousands ('000) of Euro

	31 December 2015	31 December 2014
CURRENT ASSETS		
Debtors and other receivables	416	1,166
Cash and cash equivalents	10,399	19,828
Total current assets	**10,815**	**20,994**
Total assets	**10,815**	**20,994**
EQUITY		
Restricted reserve: EC	-	(162)
Restricted reserve: Donors	1,317	1,903
Total equity	**1,317**	**1,741**
NON-CURRENT LIABILITIES		
Grant payables	-	-
Total non-current liabilities	**-**	**-**
CURRENT LIABILITIES		
Grant payables	335	11,990
EC Creditor	7,751	4,640
Other payables	1,412	2,623
Total current liabilities	**9,498**	**19,253**
Total equity and liabilities	**10,815**	**20,994**

The financial statements were approved by the Executive Secretariat on behalf of the EDCTP-EEIG General Assembly by:

Dr Michael Makanga
Dated: 3 June 2016

Statement of changes in equity for the year ended 31 December 2015

Expressed in thousands ('000) of Euro

	Restricted reserve: EC	Restricted reserve: Donor	Total
BALANCE AS AT 31 DECEMBER 2013	**308**	**3,063**	**3,371**
Result of the year 2014	(470)	(1,160)	(1,630)
BALANCE AS AT 31 DECEMBER 2014	**(162)**	**1,903**	**1,741**
Result of the year 2015	162	(586)	(424)
BALANCE AS AT 31 DECEMBER 2015	**0**	**1,317**	**1,317**

EDCTP has no unrestricted reserves.

Statement of cash flows for the year ended 31 December 2015

Expressed in thousands ('000) of Euro

	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Result for the year	(424)	(1,630)
Adjustment for:		
Finance income	(54)	(101)
(Increase) decrease in debtors and other receivables	726	8,913
Increase (decrease) in grant and other payables	(9,755)	(6,376)
Net cash flows from (used in) operating activities	**(9,507)**	**806**
CASH FLOWS FROM INVESTING ACTIVITIES		
Interest received	78	108
Net cash flows from investing activities	**78**	**108**
Net cash flows from financing activities	**-**	**-**
Net increase (decrease) in cash and cash equivalents	**(9,429)**	**914**
Cash and cash equivalents at 1 January	19,828	18,914
Cash and cash equivalents at 31 December	**10,399**	**19,828**

1. Basis of preparation

The summary financial statements, including the 2014 comparative figures, comprising the statement of financial position as at 31 December 2015, the statements of comprehensive income, changes in equity and cash flows for the year then ended, have been extracted from the annual financial statements of EDCTP-EEIG for the year ended 31 December 2015. These financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (hereafter EU-IFRS).

2. Accounting policies

The summary financial statements omit the notes comprising the significant accounting policies and other explanatory information as required by EU-IFRS. Therefore, to obtain a full understanding of the financial statements, the summary financial statements should be read in conjunction with the annual financial statements from which the summary financial statements were extracted.

The annual financial statements can be obtained from the EDCTP website (www.edctp.org).

INDEPENDENT AUDITOR'S REPORT

To: the General Assembly of EDCTP-EEIG

The accompanying summary financial statements, as included on pages 17 to 20 of the Annual Report 2015, which comprise the summary statement of financial position as at 31 December 2015, the summary statements of financial performance and other comprehensive income, changes in equity and cash flows for the year then ended, and notes, comprising a summary of the significant accounting policies and other explanatory information, are derived from the audited financial statements of EDCTP-EEIG 2015. We expressed an unqualified audit opinion on those financial statements in our report dated 3 June 2016. Those financial statements, and the summary financial statements, do not reflect the effects of events that occurred subsequent to the date of our report on those financial statements.

The summary financial statements do not contain all the disclosures required by International Financial Reporting Standards as adopted by the European Union (EU-IFRS). Reading the summary financial statements, therefore, is not a substitute for reading the audited financial statements of EDCTP-EEIG.

The directors' responsibility
The directors are responsible for the preparation of a summary of the audited financial statements on the basis described in note 1. (Basis for preparation) of the summary financial statements.

Auditor's responsibility
Our responsibility is to express an opinion on the summary financial statements based on our procedures, which were conducted in accordance with Dutch law, including the Dutch Standard on Auditing 810 'Engagements to report on summary financial statements'.

Opinion
In our opinion, the summary financial statements derived from the audited financial statements of EDCTP-EEIG 2015, are consistent, in all material respects, with those financial statements, on the basis described in note 1. (Basis for preparation) of the summary financial statements.

The Hague, 21 July 2016
KPMG Accountants N.V.

C. den Besten RA

Chapter 03

2015 IN A NUTSHELL

Q1 On 28 January 2015, **two calls for proposals** under the second EDCTP programme were pre-published. The call 'Strategic actions supporting large-scale clinical trials' aimed to fund strategically important, large-scale clinical trials for rapid advances in the field of poverty-related diseases, significantly contributing to the objectives of EDCTP. The aim of the call 'Improved treatment and clinical management of poverty-related diseases' was to fund projects that evaluated new or significantly improved drugs or drug regimens in humans, or that optimised the efficacy and use of existing therapeutics for poverty-related diseases targeted through this call.

The EDCTP-funded **PanACEA** consortium released a statement on the preliminary results from the MAMS-TB-01 clinical trial which were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in February 2015. According to the authors, the results showed that high-dose (35mg/kg) rifampicin may be an important component of future treatment-shortening regimens. Compared to other regimens and previous TB trials, data for high-dose rifampicin showed the largest reduction in time to culture conversion observed over 12 weeks of experimental treatment.

The results of the **REMSTART** project, published in *The Lancet* on 10 March 2015, suggests that this low-cost intervention could be an effective approach to reducing HIV-related deaths in Africa. A new approach to caring for patients with advanced HIV, which combined community support and screening for cryptococcal meningitis, has reduced deaths by 28%.

The proceedings of the **High-level Launch Event** for the second EDCTP programme (EDCTP2) in Cape Town, South Africa on 2 December 2014 were published on 12 March 2015. Additionally, a short video report of the meeting was published on the EDCTP YouTube channel (youtube.com/edctpmedia). The proceedings summarise the contributions and discussions at the meeting, which marked the launch of the second EDCTP programme.

On 19 March 2015, EDCTP, the Medical Research Council (United Kingdom), and the Special Programme for Research and Training in Tropical Diseases (TDR) launched the **call for proposals** 'Research capacity development in support of the Ebola virus disease (EVD) response'. The call was intended to support projects that will develop and strengthen the research capacity in sub-Saharan Africa to conduct high-quality health research during infectious disease emergencies such as the EVD outbreak in West Africa. Opportunities for international synergy will be sought through collaboration with the Canadian Institutes of Health Research (CIHR) that launched a similar call in April 2015.

Q2 During its meeting on 4-5 June 2015, the General Assembly of the EDCTP Association appointed **Dr Michael Makanga** to succeed Prof. Charles Mgone as Executive Director. Prof. Mgone, who was the EDCTP Executive Director for eight years, had decided to step down at the end of the year. Dr Makanga assumed his new responsibility on 1 January 2016.

The **Malaria in Pregnancy (MiP) consortium** had its sixth and final annual meeting in Sitges, Spain on 24-26 June 2015. The latest MiP consortium's research results from the clinical trials and cross-cutting activities were shared. Participants also reviewed the data that were to be presented to the WHO Evidence Review Group in July 2015. EDCTP funded three large clinical trials under the umbrella of the MiP consortium.

Q3 On 11 August 2015 *PLOS Neglected Tropical Diseases* published the research article 'Bibliometric assessment of European and sub-Saharan African research output on poverty-related and neglected infectious diseases from 2003-2011' (DOI: http://dx.doi.org/10.1371/journal.pntd.0003997) by authors from EDCTP and Thomson Reuters. The objective of this analysis was to quantify **research output by European and African researchers** on poverty-related and neglected infectious diseases and measure its relative impact. It comprises research publications in peer-reviewed journals between 2003 and 2011, and describes patterns of research collaboration.

Q4

The EDCTP-funded **CHAPAS-3** trial was the first randomised controlled clinical trial in African children to compare three 'backbones' for antiretroviral treatment (ART) regimens involving abacavir, zidovudine, and stavudine paediatric tablets. All regimens were shown to have low toxicity and good clinical, immunological, and virological responses. This trial provides strong evidence in support of the WHO guidelines for first-line paediatric ART, allaying concerns of reduced efficacy. The results, published in *The Lancet Infectious Diseases* on 6 October 2015, support clinicians and policy makers in implementing the current WHO guidelines for ART in children.

On 8 and 9 October 2015, the **G7 Ministers of Science** met in Berlin, Germany to discuss coordination of research efforts regarding global issues of health, the (marine) environment, and clean energy. They expressed their resolve to support the fight against neglected tropical and poverty-related infectious diseases in line with the declaration of the G7 Leaders (8 June 2015) and their commitment to improve the coordination of relevant national R&D activities by building on existing mechanisms such as EDCTP.

Interim data from a clinical trial led by the West African Network for Clinical Trials of Antimalarial Drugs (**WANECAM**), published online in *The Lancet Infectious Diseases* on 23 October, support the safety and efficacy of the artemisinin-based combination therapy (ACT) Pyramax® (artesunate-pyronaridine fixed dose combination) when used for the re-treatment of adults and children (over 5 kg body weight). The WANECAM sub-study data supported an application for a label change to allow for re-treatment with the Pyramax® medicine and its use in all malaria-endemic regions including sub-Saharan Africa.

On 15 October 2015, EDCTP opened the first of the remaining **five 2015 calls for proposals**. The 'Ethics and Regulatory Capacities' call was to support countries in sub-Saharan Africa to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies in humans.

Three calls designed for individual capacity and career development were opened: the 'EDCTP-TDR Clinical Research and Development Fellowships' on 22 October 2015, followed by the 'Career Development Fellowship' and the 'Senior Fellowship' calls, both on 12 November 2015.

The purpose of the fifth call 'EDCTP Regional Networks', launched on 5 November 2015, is to support projects for networking in sub-Saharan Africa with Europe in order to build and strengthen regional, national, institutional, and individual capacities to conduct clinical trials in line with the International Conference on Harmonization Guidelines for Good Clinical Practice (ICH-GCP).

On 9 November 2015, EDCTP invited nominations for the **Dr Pascoal Mocumbi Prize**, which was created to recognise an individual for his/her outstanding achievements in advancing health research and research capacity development in Africa with significant impact on the well being of the African population.

The EDCTP-funded **PROMISE-PEP/ANRS12174** study published its results in *The Lancet* on 19 November. It showed that two liquid formulas of HIV drugs are safe and highly effective at protecting infants from infection while they are breastfed by their HIV-positive mothers, including the 6-12 month period after birth which had not been studied in previous research.

At the Science Forum South Africa on 8-9 December 2015, EDCTP received the **Science Diplomacy Award** in the category that recognises "an international science partnership which has made an outstanding contribution to human capital development."

By the end of 2015, six institutions in Africa (3) and Europe (3) had obtained funding to strengthen capacity in sub-Saharan Africa to conduct health research during emergencies and/or epidemic outbreaks. The grants were developed in response to the **Ebola virus disease (EVD)** outbreak in West Africa. EDCTP and TDR, the Special Programme for Research and Training in Tropical Diseases, are providing the €1.49 million funding.

Medical staff and volunteer at the Regional Hospital of Banfora, Burkina Faso, part of the WANECAM project led by Prof. Abdoulaye Djimdé

Chapter 04

SECOND EDCTP PROGRAMME: THE FIRST FULL YEAR

The second EDCTP programme took off with the publication of two calls for proposals shortly after the official launch of the programme on 2 December 2014. The programme gained momentum after the approval of the EDCTP2 work plan for 2015 and a new set of calls for proposals was launched. The EDCTP2 calls for proposals are open to all diseases within the scope of EDCTP, namely HIV, tuberculosis, malaria and other poverty-related and neglected infectious diseases in sub-Saharan Africa. This approach creates extended funding opportunities for clinical research. Since the start of the second programme, EDCTP has committed approximately €102 million in (indicative) contributions towards calls for proposals launched in 2014 and 2015.

THE SECOND PROGRAMME

The second EDCTP programme will run for ten years from 2014 to 2024. The partnership aims for a €2 billion budget, having already secured €1.36 billion in pledges. This includes a commitment of up to €683 million from the European Union to match the contributions from the European countries that are a member of the EDCTP Association. Additional funding will be sought from public and private parties.

The programme supports all phases of clinical trials and implementation research, with a focus on phase II and III clinical trials, for new or improved medical interventions against HIV, tuberculosis, malaria and neglected infectious diseases as well as advanced testing and field validation of new diagnostic tools.

The programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020. It is governed by the African and European Participating States through the General Assembly of the EDCTP Association, in which states from sub-Saharan Africa and Europe participate as members. Currently, 14 European countries and 14 African countries are a member of the EDCTP Association.

Poverty-related diseases covered by EDCTP

HIV, malaria, tuberculosis, neglected infectious diseases (dengue, rabies, human African trypanosomiasis, Leishmaniasis, cysticercosis/taeniasis, dracunculiasis, echinococcosis, foodborne trematodiases, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiases, Buruli ulcer, leprosy, trachoma, yaws), and diarrhoeal diseases, lower respiratory tract infections, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola and yellow fever.

CALLS AND GRANTS

In the second EDCTP programme the funding of projects is based on annual work plans and the EDCTP2 Strategic Business Plan. The EDCTP2 work plan for 2015 was developed in compliance with the objectives and provisions set out in the European Union's Decision on EDCTP, following a comprehensive consultation process involving multiple stakeholders.

The 2015 work plan provided information on EDCTP calls for proposals, including the challenge, scope and expected impact, as well as supporting information about eligibility requirements and other specific conditions for applying. It also contains an overview of the Participating States' Initiated Projects (PSIAs), i.e. activities funded and implemented directly by one or more EDCTP Participating States which are considered an integral part of the second programme. The work plan was approved by both the European Commission and the EDCTP Association.

The topics for most calls for proposals were open and broad to allow for flexibility in financing unexpected approaches and novel ideas. They were also informed by the ongoing consultation process that started in 2013-2014 with the stakeholder meetings, and continues through meetings and workshops with academic researchers, pharmaceutical industry, product development partnerships, charities and foundations, international organisations and health research funders outside Europe and Africa. The independent Scientific Advisory Committee advises the Secretariat and General Assembly on the scientific and strategic development of the programme.

Research & Innovation Actions (RIA)	Coordination & Support Actions (CSA)	Training & Mobility Actions (TMA)
Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.	Capacity support activities that strengthen the enabling environment for conducting clinical trials and clinical research.	Fellowships that focus on the career development of individual researchers or clinical staff.

CALLS FOR PROPOSALS

In 2015, a total of 11 calls for proposals were ongoing: 3 calls of the 2014 work plan and 8 calls of the 2015 work plan.

In 2015 EDCTP completed the full process for four calls for proposals. These are the three calls for proposals from the 2014 work plan: 'EDCTP-TDR Clinical Research and Development Fellowships', 'Diagnostic tools for poverty-related diseases', 'Maximising the impact of EDCTP research: translation of research results into policy and practice', and the 'Research capacity development in support of the Ebola Virus Disease (EVD) response' call from the 2015 work plan.

This last call was to support the development of the capacity to conduct health research during infectious disease outbreaks. The call was part of the European response to the Ebola crisis in West Africa and launched in March 2015 by EDCTP, the Medical Research Council (United Kingdom) and the Special Programme for Research and Training in Tropical Diseases (TDR). A similar call launched by Canadian Institutes of Health Research in April 2015 presented an opportunity for collaboration.

Five calls for proposals were published in October and November: 'Ethics and Regulatory Capacities', 'EDCTP-TDR Clinical Research and Development Fellowships', 'EDCTP Regional Networks', 'Career Development Fellowships', and 'Senior Fellowships'. For all these calls the final selection and funding decisions are expected in the second quarter of 2016.

The call for proposals for the 'EDCTP-TDR Clinical Research and Development Fellowships' was the second call of this fellowship scheme developed by EDCTP and WHO's Special Programme for Research and Training in Tropical Diseases (TDR). The scheme is based on a close collaboration with the European Federation of Pharmaceutical Industries and Associations (EFPIA) for EDCTP, and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) for TDR. Funding is provided by the European Union and the Bill & Melinda Gates Foundation respectively. The pharmaceutical companies that host the fellows provide the in-kind support needed for the placement.

The other calls reflect EDCTP's capacity development strategy: 'Ethics and Regulatory Capacities', 'EDCTP Regional Networks', 'Career Development Fellowships', and the 'Senior Fellowships'. The concept of the Career Development Fellowships was developed to address the need for career support of junior to mid-career researchers who are not yet ready to take on the responsibilities of the Senior Fellowship. This need was explicitly identified during the stakeholder meetings leading up to the second EDCTP programme. EDCTP will continue to invest in the conditions for the success of clinical research in Africa.

Call (Year)	Date opened	Date closed	Indicative call budget	Applications: 1st stage and single stage	Applications: 2nd stage (if applicable)	No. of grants
Research & Innovation Actions (RIA)						
Diagnostics (2014)	2 Dec 2014	2 March 2015	€15M	96	21	6
Treatment (2015)	28 Jan 2015	15 Oct 2015	€35M	136	40	To be confirmed
Strategic Actions (2015)	28 Jan 2015	15 Oct 2015	€25.7M	49	10	To be confirmed
Coordination & Support Action (CSA)						
Maximising Impact (2014)	17 Dec 2014	16 March 2015	€3M	14		5
EVD (2015)	19 March 2015	6 Aug 2015	€1.4M	38		6
Ethics & Regulatory (2015)	15 Oct 2015	21 Jan 2016	€1.5M	Evaluation in 2016		To be confirmed
Regional Networks (2015)	5 Nov 2015	18 Feb 2016	€12M	Evaluation in 2016		To be confirmed
Training & Mobility Actions (TMA)						
EDCTP-TDR Clinical R&D Fellowship (2014)	31 Oct 2014	30 Jan 2015	€1.5M	148	5*	3
EDCTP-TDR Clinical R&D Fellowships (2015)	22 Oct 2015	28 Jan 2016	€3M	Evaluation in 2016		To be confirmed
Senior Fellowships (2015)	12 Nov 2015	4 Feb 2016	€2.5M	Evaluation in 2016		To be confirmed
Career Development Fellowships (2015)	12 Nov 2015	4 Feb 2016	€1.5M	Evaluation in 2016		To be confirmed
Total			**€102.1M**	**481+**	**76+**	**20+**

*These are fellows supported by EDCTP only. WHO/TDR supported a total of 18 fellows.

THE PARTICIPATING STATES

The contribution of the Participating States, i.e. the European and African countries that are a member of the EDCTP Association, is an important part of the EDCTP programme. In addition to their direct contribution to EDCTP activities, these countries contribute to the objectives of EDCTP through independently conducted clinical research projects. Projects within the scope of EDCTP can be incorporated as Participating States' Initiated Activities (PSIA's) in the EDCTP work plan. In this way, PSIAs also contribute to research collaboration in Europe and sub-Saharan Africa and to the matching funds scheme of the programme by the European Union.

Financially, the PSIA's count towards the minimum contribution required for membership in the EDCTP Association. The disbursements for PSIAs also count as basis for the EU funding of EDCTP. In 2014 and 2015, European Participating States already disbursed an impressive 31% of the €683M pledged to the EDCTP programme.

DR PASCOAL MOCUMBI PRIZE

In 2015 EDCTP received nominations for the Dr Pascoal Mocumbi Prize. The prize aims to promote health research cooperation between Africa and Europe and will reward personal outstanding achievements in advancing health research and research capacity development in sub-Saharan Africa with significant impact on the well being of the African population. The prize consists of an award trophy and a cash prize of €50,000.

The prize is named after Dr Pascoal Mocumbi, EDCTP's first High Representative and former Prime Minister of Mozambique, in recognition of his outstanding contribution to fostering global partnerships in health research and his support for research capacity strengthening in Africa. This Award will be given every two years.

The cash prize shall be used by the award winner to further the capacity development and networking activities contributing to the objectives of the second EDCTP programme and promote international cooperation between Africa and Europe. The award ceremony will take place at the Eighth EDCTP Forum in Lusaka, Zambia from 6-9 November 2016.

Dr Pascoal Mocumbi

GRANT AGREEMENTS IN 2015

Four grant agreements were signed in 2015 for the following projects:

Type of grant: CSA
Acronym: WISH
Project Coordinator: Professor Janneke van de Wijgert (University of Liverpool, United Kingdom); with partners from Belgium, and Rwanda
Proposed start date: 1 Sept. 2015
Duration (months): 24
Budget: EUR 499,741

Improving HIV prevention and sexual and reproductive health care in high risk women in Rwanda using lessons learnt from previous Rinda Ubuzima projects

The purpose of this project is to take advantage of the HIV prevention and sexual and reproductive health (SRH) capacity that the non-governmental organisation Rinda Ubuzima (RU) has built during the first 10 years of its existence to: 1) formalise its role as an HIV prevention/SRH research and training centre in Rwanda; 2) demonstrate to and with stakeholders (including policymakers of the Ministry of Health, teaching staff of the College of Medicine and Health Services of the University of Rwanda, and representatives of other HIV/SRH care organisations in Rwanda) that it is feasible and affordable to improve SRH services in high-risk women using results from previous RU studies; and 3) engage the stakeholders in discussions about potential adaptations of the Rwanda STI treatment guidelines, opportunities for better integration of vertical HIV and SRH programs, and potential roll-out of novel vaginal microbicides and multipurpose prevention technologies for HIV and pregnancy prevention as soon as efficacious products become available.

Type of grant: CSA
Acronym: TWENDE
Project Coordinator: Dr Wilber Sabiiti (University of St. Andrews, United Kingdom); with partners from Kenya, Tanzania and Uganda
Proposed start date: 1 Oct. 2015
Duration (months): 24
Budget: EUR 439,047

Tuberculosis: Working to empower the nations' diagnostic effort

Tuberculosis (TB) kills more than a million people every year. Rapid and accurate diagnosis is crucial for control of TB yet around 40% of world's cases go without a laboratory test. Although much money has been spent developing novel diagnostic and treatment innovations, successful ones do not reach the people who need these most. This study aims to identify the barriers and opportunities to accelerate the uptake of successful TB diagnostics. TWENDE, a Swahili word for "let's go!" enshrines the concept of 'paving the road', i.e. to create a platform on which research innovations can be translated into policy and practice. Focus is on three countries in East Africa: Uganda, Kenya and Tanzania. The uptake of the WHO-approved Xpert MTB/Rif and Line probe assays will be used as case studies. This 'go beyond the laboratory' study will assess the extent of implementation of molecular diagnostics for TB and explore where and why the assays are unavailable. Results will be used to engage policy and decision makers on their role in ensuring uptake of effective research innovations into policy and practice. Knowledge transfer units will be created in each of the African partner institutions to maintain the channel of communication between research and policy making.

Laboratory staff at the Kibong'oto National TB Hospital in Tanzania, part of the PanACEA-MAMS project led by Dr Martin Boeree, Prof. Michael Hoelscher and Prof. Stephen Gillespie

Type of grant: CSA
Acronym: IMPACT
Project Coordinator: Dr Anja (Dianne) Terlouw (Liverpool School of Tropical Medicine, United Kingdom); with partners from Malawi, South Africa, and United Kingdom
Proposed start date: 1 Oct. 2015
Duration (months): 24
Budget: EUR 499,293

Maximising the public health impact of interventions to control malaria in pregnancy through the translation of EDCTP-funded evidence-based global policies to country level policies and plans

This project will exploit the results of previous EDCTP-funded research on the treatment and prevention of malaria in pregnancy to support countries which participated in the research, to develop clear, evidence-based policies and plans to improve practices of health providers in the countries. The primary objective is to ensure that the WHO recommendations on malaria in pregnancy control policy – resulting from the Malaria in Pregnancy (MiP) Consortium's research – will be translated into country level policy and implementation plans. The secondary objectives are: to develop and make widely available a package of methodological tools which define optimal and cost-effective interventions for malaria in pregnancy; to advance optimal uptake of the evidence through analysis of national policy decision-making and processes for control of malaria in pregnancy; and to provide expertise to support national policy change and preparation for implementation in selected countries.

Type of grant: CSA
Acronym: IMPP-ACT
Project Coordinator: Dr Jenny Hill (Liverpool School of Tropical Medicine, United Kingdom); with partners from The Gambia, Malawi, Mali and United Kingdom
Proposed start date: 1 Sept. 2015
Duration (months): 24
Budget: EUR 487,463

Improving the impact of existing malaria products - ACTs

The objective of the project is to conduct pharmacokinetic-pharmacodynamic safety analyses of dihydroartemisinin-piperaquine (DHA-PPQ) regarding cardiotoxicity and antiretroviral drug interactions pooling all patient-level data (including the EDCTP-funded targeted safety studies ADAPT and ADJusT). The analyses will use two pioneering data sharing platforms on antimalarial efficacy and safety, developed by WWARN and LSTM. Findings will be incorporated into the recent evidence review of the dosing task force for the 2015 WHO Malaria Treatment Guidelines to inform recommendations for dosing regimens. Lessons learnt and research priorities will be identified and used for targeted advocacy activities. The proposed work will guide policy decisions on DHA-PPQ dosing regimens. Beyond DHA-PPQ, it will demonstrate the importance of identifying global research priorities for targeted antimalarial safety studies and of integrating pooled patient-level safety analyses into WWARN's global efficacy data platform. Linking efficacy and safety data offers a powerful standardized process for dose optimisation that is applicable across a range of drugs.

Lab work for the WANECAM project, led by Prof. Abdoulaye Djimdé

Chapter 05

EDCTP ASSOCIATION

SUMMARY FINANCIAL STATEMENTS 2015

Statement of profit or loss and other comprehensive income
for the year ended 31 December 2015

Expressed in thousands ('000) of Euro

	EC 2015	Donor 2015	Total 2015	Total 2014
CALLS (GRANTS)				
Contributions	1,925	-	1,925	-
Grants	(1,925)	-	(1,925)	-
Results for the year	**0**		**0**	
OTHERS				
Contributions	2,365	(-)	2,365	(-)
Other	(2,365)	(-)	(2,365)	(-)
Results for the year	**0**	**(-)**	**0**	**(-)**
Total results for the year	**-**	**-**	**-**	**-**

EDCTP Association has no other comprehensive income.
All income and expenditure relates to continuing activities.

Statement of financial position as at 31 December 2015
(After appropriation of result)

Expressed in thousands ('000) of Euro

	31 December 2015	31 December 2014
CURRENT ASSETS		
Debtors and other receivables	1,599	-
Cash and cash equivalents	42,270	-
Total current assets	**43,869**	-
Total assets	**43,869**	-
NON-CURRENT LIABILITIES		
Grants and other payables	472	-
Deferred income EC	12,223	-
Deferred income Donor	-	-
Total non-current liabilities	**12,695**	-
CURRENT LIABILITIES		
Grants and other payables	35	-
Deferred income EC	15,423	-
Deferred income Donor	15,716	-
Total current liabilities	**31,174**	-
Total liabilities	**43,869**	-

The financial statements were approved by the Executive Director on behalf of the Board:

Dr Michael Makanga
Dated: 2 June 2016

Statement of changes in EC and Donor's equity

Expressed in thousands ('000) of Euro

	Reserve EC:	Reserve Donor:	Total
Balance as at 31 December 2014	-	-	-
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2015	-	-	-

EDCTP has no unrestricted reserves.

Statement of cash flows for the year ended 31 December 2015

Expressed in thousands ('000) of Euro

	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Result for the year	-	-
Adjustment for:		
(Increase) decrease in debtors and other receivables	(1,581)	-
Increase (decrease) in grants and other payables	507	
Increase in deferred income (net grant receipts)	43,304	-
Net cash flows from operating activities	**42,230**	-
CASH FLOWS FROM INVESTING ACTIVITIES		
Interest received	40	-
Net cash flows from investing activities	**40**	-
Net increase (decrease) in cash and cash equivalents	**42,270**	-
Cash and cash equivalents at 1 January	-	-
Exchange rate effects	-	-
Cash and cash equivalents at 31 December 2015	**42,270**	-

1. Basis of preparation

The summary financial statements, including the 2014 comparative figures, comprising the statement of financial position as at 31 December 2015, the statements of comprehensive income, changes in equity and cash flows for the year then ended, have been extracted from the annual financial statements of the EDCTP Association for the year ended 31 December 2015. These financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (hereafter EU-IFRS).

2. Accounting policies

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The annual financial statements can be obtained from the EDCTP website (www.edctp.org).

Researcher at the Regional Hospital of Banfora, Burkina Faso, part of the WANECAM study led by Prof. Abdoulaye Djimdé

Blood samples for the MVA85A project led by Prof. Helen McShane (photo by Aeras)

Chapter 06

EDCTP GOVERNANCE

The EDCTP-EEIG is the legal structure for the first EDCTP programme (2003-2015); the EDCTP Association is the legal structure for the second EDCTP programme (2014-2024). Both legal entities have been running in parallel since 10 April 2014.

MEMBER & OBSERVER COUNTRIES: EDCTP-EEIG

There were 16 European member countries: Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Finland and Latvia were admitted as observers.

MEMBER COUNTRIES: EDCTP ASSOCIATION

In 2015 the EDCTP Association comprised 14 African Participating States: Burkina Faso, Cameroon, Congo, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda and Zambia.

There were also 14 Participating States from Europe: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.

Additionally, Switzerland was an Aspirant member of the EDCTP Association.

EDCTP GENERAL ASSEMBLY (EEIG & ASSOCIATION)

	GA representative	Deputy GA representative
Austria (EEIG/Association)	**Dr Christiane Druml** Medical University of Vienna	**Dr Hemma Bauer** Austrian Federal Ministry of Science and Research
Belgium (EEIG)	**Prof. Bruno Gryseels** Institute for Tropical Medicine	**Ms Margarida Freire** Belgian Science Policy Office
Burkina Faso (Association)	**Dr Sodiomon Bienvenu Sirima** Centre National de Recherche et de Formation sur le Paludisme (CNRFP	**Dr Ali Sie** Centre de Recherche en Santé de Nouma (CNRST)
Cameroon (Association)	**Prof. Sinata Koulla Shiro** Ministry of Public Health	**Prof. Anne-Cécile Zoung Kanyi Bissek** Ministry of Public Health

	GA representative	Deputy GA representative
 **Congo** (Association)	**Prof. Deby Gassaye** University Marien Ngouabi	**Prof. Francine Ntoumi (Association Board member)** University Marien Ngouabi
 **Denmark** (EEIG/Association)	**Dr Mikkel Lyndrup** Statens Serum Institute	
 **Finland** (Association)	**Dr Jarmo Wahlfors** Academy of Finland	**Dr Sirpa Nuotio** Academy of Finland
 **France** (EEIG/Association)	**Prof. Jean-François Delfraissy** Agence Nationale de Recherches sur le Sida et les Hépatites Virales (ANRS); Institut de microbiologie et des maladies infectieuses (IMMI)	**Dr Bernadette Murgue** Institut national de la santé et de la recherche médicale (INSERM) **Mr Guillaume Fusai** Ministère de l'éducation nationale, de l'enseignement supérieur et de la recherche **Prof. Patrice Debré** Institut national de la santé et de la recherche médicale (INSERM)
 **Gabon** (Association)	**Dr Ayola Akim Adegnika** Centre de Recherches Médicales de Lambaréné	**Prof. Jean-Bernard Lekana Douki** Université des Sciences de la Santé
 **The Gambia** (Association)	**Hon. Omar Sey** Ministry of Health and Social Welfare	**Dr Makie Taal** Ministry of Health and Social Welfare succeeded by: **Mr Ebrima Bah** Ministry of Health and Social Welfare
 **Germany** (EEIG/Association)	**Dr Joachim Klein** Bundesministerium für Bildung und Forschung	**Dr Detlef Böcking (Vice-Chair EEIG / Association Board Member)** Deutsches Zentrum für Luft und Raumfahrt e.V.
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 **Greece** (EEIG)	**Prof. Evangelia Ntzani** University of Ioannina School of Medicine	**Mrs Eleni Stavrianoudaki** General Secretariat for Research & Technology
 **Ireland** (EEIG/Association)	**Mr Vincent Maher** Irish Aid, Department of Foreign Affairs	**Ms Lorraine Gallagher** Irish Aid, Department of Foreign Affairs succeeded by: **Mr Patrick Empey** Irish Aid, Department of Foreign Affairs
 **Italy** (EEIG/Association)	**Dr Stefano Vella (Vice-Chair EEIG/ Vice-Chair Association Board)** Istituto Superiore di Sanità (ISS)	**Dr Benedetta Mattioli** ISS
 **Luxembourg** (EEIG/Association)	**Dr Carlo Duprel** Fonds National de la Recherche	
 **Mali** (Association)	**Prof. Agrégé Abdoulaye Djimdé** University of Science, Techniques and Technology of Bamako	**Prof. Mahamadou Aly Thera** University of Science, Techniques and Technology of Bamako
 **Mozambique** (Association)	**Dr Ilesh Jani** Ministry of Health	**Dr Eusebio Macete (Vice-Chair Association Board)** Health Research Centre of Manhiça

	GA representative	Deputy GA representative
 **Netherlands** (EEIG/Association)	**Dr Eva Rijkers** NACCAP succeeded by: **Dr Gerrie Tuitert** NWO-WOTRO Science for Global Development	**Dr Marcel de Kort** Ministry of Foreign Affairs
 **Niger** (Association)	**Mrs Sakina Habou Ocquet** Ministry of Public Health	**Dr Odile Ouwe Missi Oukem** Centre de Recherche Médicale et Sanitaire (CERMES)
 **Norway** (EEIG/Association)	**Dr Sigurd Røtnes** Norwegian Directorate of Health	**Dr Wenche Dageid** The Research Council of Norway
 **Portugal** (EEIG/Association)	**Dr Ricardo Pereira** Foundation for Science and Technology (FCT)	**Dr Ana Quartin**, FCT
 **Senegal** (Association)	**Prof. Alioune Dieye** University Cheikh Anta Diop	
 **South Africa** (Association)	**Mr Mmboneni Muofhe** Department of Science and Technology Alt: **Mr Daan du Toit**, DST	**Prof. Jeffrey Mphahlele** Vice President of Research, South African Medical Research Council Alt: **Ms Vinny Pillay**, DST **Mrs Mamohloding Tlhagale**, DST
 **Spain** (EEIG/Association)	**Dr Rafael De Andrés Medina** Instituto de Salud Carlos III	**Mr Tomas López-Peña Ordoñez** Instituto de Salud Carlos III
 **Sweden** (EEIG/Association)	**Prof. Hannah Akuffo** Swedish International Development Agency (Sida)	**Assoc. Prof. Maria Teresa Bejarano**, Sida
 **Switzerland** (EEIG/Association Aspirant member)	**Dr Isabella Beretta** State Secretariat for Education and Research	
 **Tanzania** (Association)	**Dr Hassan Mshinda** Tanzania Commission for Science and Technology (COSTECH)	**Dr Flora Tibazarwa** (COSTECH)
 **Uganda** (Association)	**Dr Sam Okware** Uganda National Health Research Organisation (UNHRO)	**Prof. Pontiano Kaleebu** Uganda Virus Research Institute
 **United Kingdom** (EEIG/Association)	**Dr Mark Palmer (Chair EEIG/ Association Board)** Medical Research Council	**Dr Morven Roberts** Medical Research Council
 **Zambia** (Association)	**Dr Elizabeth Chizema-Kawesha** Ministry of Health	**Prof. Nkandu Luo** Ministry of Gender and Child Development

OBSERVERS TO THE GENERAL ASSEMBLY

Observer	GA representative	Deputy GA representative
European Commission–DG Research & Innovation (EEIG/Association)	**Dr Line Matthiessen** Head of Infectious Diseases and Public Health, DG Research & Innovation	**Dr Gianpietro van de Goor** Principal Policy Officer for International Cooperation, DG Research & Innovation
European Commission–DG Devco (EEIG/Association)	**Dr Walter Seidel** Head of Sector 'Health', Unit B4, DG DEVCO	**Dr Eric Sattin** Policy Officer for Development Cooperation on Global Health, Unit B4, DG DEVCO **Ms Veronique Lorenzo** Head of Unit B4 'Education, Health, Research, Culture', DG Development Cooperation (DEVCO
Latvia (EEIG)	**Dr Modra Murovska** Augusta Kirhensteina Microbiology and Virology Institute, Riga Stradins University	**Dr Uldis Berkis** Ministry of Science and Education **Dr Zane Kalnina** Ministry of Education and Science of the Republic of Latvia
East African Community (EAC) (EEIG/Association)	**Dr Richard Sezibera** Secretary General	**Dr Stanley Sonoiya** Principal Health Officer
WHO Regional Office for Africa (AFRO) (EEIG/Association)	**Dr Joseph Cabore** Director for Programme Management	**Dr Delanyo Dovlo** Director of Health Systems and Services

Meeting of the General Assembly, Nov. 2015

Strategic Advisory Committee Meeting, Oct. 2015

SCIENTIFIC ADVISORY COMMITTEE

The Scientific Advisory Committee (SAC) is the principal advisory group providing the General Assembly (GA) and the Executive Secretariat with strategic and scientific advice. The SAC also oversees the scientific integrity of the EDCTP programme, in order to assist EDCTP in achieving its mission and objectives. The SAC acts exclusively in the interest of the mission and objectives of EDCTP. The 2015 SAC consisted of:

Prof. Tumani Corrah (Chair)	The Gambia
Dr Salim Abdulla	Tanzania
Prof. Eleni Aklillu (vice-Chair)	Sweden
Prof. Moses Bockarie	United Kingdom
Dr Marilyn Bonnet	France
Prof. Simon Croft	United Kingdom
Prof. Knut Fylkesness	Norway
Prof. Stefan Kaufmann	Germany
Dr Maria Fraga Oliveira Martins	Portugal
Prof. Clara Menéndez Santos	Spain
Prof. Marie-Louise Newell	United Kingdom
Prof. Gita Ramjee	South Africa
Prof. Philippe Sansonetti	France
Mr Jean Marie Talom	Cameroon
Prof. Ali Zumla (vice-Chair)	United Kingdom

External observers to the Strategic Advisory Committee

Dr Line Matthiessen	European Commission, DG research & Innovation
Dr Gianpietro van de Goor	European Commission, DG Research & Innovation
Dr Vasee Moorthy	World Health Organisation, Geneva
Dr Martin O.C. Ota	World Health Organisation African Region, Brazzaville.

EDCTP SECRETARIAT IN 2015

Prof. Charles Mgone
Executive Director
(left December 2015)

Abdoulie Barry
Director of Finance and Administration

Dr Michael Makanga
Director South-South Cooperation and Head of Africa Office

Dr Ole F. Olesen
Director of North-North Cooperation

Dr Pauline Beattie
Operations Manager

Dr Gabrielle Breugelmans
North-North Networking Manager

Dr Thomas Nyirenda
South-South Networking and Capacity Development Manager

Hager Bassyouni
North-North Networking Officer
(appointed May 2015)

Dr Montserrat Blázquez Domingo
Senior Project Officer
(appointed July 2015)

Chris Bruinings
Financial Officer

Ana Lúcia Cardoso
North-North Networking Officer

Mary Jane Coloma-Egelink
Grants Financial Officer
(appointed July 2015)

Dr Christy Comeaux
Project Officer
(appointed December 2015)

Lucien de Corte
Information Technology (IT) Officer

Christopher Dixon
Financial Assistant
(appointed June 2015)

Nuraan Fakier
Project Officer

Jean Marie Vianney Habarugira
Project Officer

Dr Michelle Helinski
Project Officer
(appointed December 2015)

Suzanne Hoogervorst
Travel and Events Officer
(appointed July 2015)

Nancy Kensmil
Administrative Officer & HR Assistant

Gert Onne van de Klashorst
Communications Officer

Neli Krautsova
Grants Financial Assistant
(appointed May 2015)

Mariska Louw
Senior Administrative Officer

Shingai Machingaidze
Project Officer
(appointed September 2015)

Dr Perry Mohammed
Special Advisor
(appointed April 2015)

Pete Murphy
Grants Management System Administrator
(appointed October 2015)

Michelle Nderu
Project Officer

Lara Pandya
North-North Networking Officer

Daniela Pereira
Communications Officer
(appointed July 2015)

Emma Qi
Grants Financial Assistant
(left December 2015)

Dr Monique Rijks-Surette
Senior Project Officer
(appointed July 2015)

Sayma Siddiqui
Grants Financial Assistant
(appointed March 2015)

Dr Michelle Singh
Project Officer
(appointed October 2015)

Jennifer Stamatelos
Administrative Officer

Dr Lidwien van der Valk
Legal Officer
(left June 2015)

Jing Zhao
Grants Financial Officer
(appointed July 2015)

ANNUAL REPORT FORMATS

This Annual Report is available in the following formats:

Print

Online

http://www.edctp.org/stay-up-to-date/annual-reports/

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The Power of Sharing Science