Summary of Achievements

FIRST EDCTP PROGRAMME
2003–2015
Success stories

**MALARIA**

34 **CLINICAL TRIALS**

The 4ABC trial was successfully conducted at 12 trial centres in 7 sub-Saharan African countries. Three artemisinin-based combination therapies (ACTs) were found to be safe and efficacious in treating children with uncomplicated malaria. The study contributed to the evidence on dihydroartemisinin-piperaquine (DHAPQ) for addition to the list of ACTs options recommended by WHO. The results have also contributed to the registration of DHAPQ by the European Medicines Agency (EMA). (PLOS Medicine, 2011).

The trial conducted by the West African WANECAM consortium provided safety and efficacy data to guide repeated treatment of uncomplicated malaria in children. In November 2015, the EMA approved the use of Pyramax® (fixed-dose combination of artesunate and pyronaridine) for treating multiple episodes of malaria after its registration in malaria-endemic countries. In parallel, the EMA approved the use of Pyramax® granules as a paediatric formulation (The Lancet Infectious Diseases, 2016).

Five clinical trials investigated the prevention and treatment of malaria in pregnancy. The PREGACT trial (New England Journal of Medicine, 2016) showed that based on safety and efficacy DHAPQ seems the most suitable treatment for uncomplicated malaria in pregnancy, providing evidence to support the WHO treatment guidelines.

102 **clinical trials were funded**

9 HIV/TB

29 Tuberculosis

30 HIV

34 Malaria

**HIV**

30 **CLINICAL TRIALS**

EARNEST & 2LADY: two landmark studies that contributed to improved treatment strategies for patients failing first-line antiretroviral therapy (ART) in sub-Saharan Africa (New England Journal of Medicine, 2014).

Kesho Bora & PROMISE-PEP successfully found ways to prevent mother-to-child transmission of HIV. The Kesho Bora trial found that infants born to HIV-infected mothers on ART are less likely to become HIV-infected. PROMISE-PEP 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. (The Lancet Infectious Diseases, 2011 and The Lancet, 2016).

CHAPAS-1 and CHAPAS-3 provided strong evidence in support of the current WHO guidelines for first-line paediatric antiretroviral therapy (ART). Moreover, the results led to licensed fixed-dose combinations for treatment of children (Clinical Infectious Diseases, 2010 and The Lancet Infectious Diseases, 2016).

The REMSTART team showed that a low-cost community support intervention, combined with screening for cryptococcal infection, reduced the number of deaths among patients with advanced HIV disease by 28% (The Lancet, 2015).

**TUBERCULOSIS**

29 **CLINICAL TRIALS**

The studies TAM-TB, TBDx, & LAM tested new diagnostics and biomarkers. TB-NEAT contributed to the evidence base on the implementation and impact of Xpert MTB/RIF assay in primary health care settings (The Lancet Global Health, 2013).

The RIFAQUIN and REMoxTB clinical trials tested shorter, simpler TB treatment regimens. The MAMS-TB-01 study piloted an innovative trial design enabling faster selection of promising study compounds or drug combinations. The results suggested high-dose rifampicin might be an important component of shorter TB-regimens in the future (New England Journal of Medicine, 2014 and New England Journal of Medicine, 2015).

Nine clinical trials aimed to reduce high mortality and morbidity in HIV-TB coinfected patients. These included the Pharmagene trial, which optimised treatment regimens for African populations and trials to prevent TB-associated immune reconstitution inflammatory syndrome (TB-IRIS) in HIV patients.

**Did you know?**

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

- More than 3,400 posts were supported on EDCTP grants (90% based in Africa)

- Trainees were supported from 2003-2015

- That’s almost **40%** female

- More than **700** peer-reviewed publications resulted from EDCTP projects
Portfolio by intervention/topic

Cash contributions via EDCTP

Clinical trials by intervention*
€176.27M
104 grants

Vaccines
€61.74M
26 grants

Diagnostics
€14.07M
13 grants

Drugs
€91.08M
60 grants

Ethics & Regulatory
€4.99M
78 grants

Cross-cutting***
€11.41M
42 grants

Other**
€15.32M
42 grants

Microbicides
€9.38M
5 grants

42 grants

€207.99M
254 GRANTS

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.

Portfolio by disease

Malaria
€50.17M
12 grants

HIV
€61.41M
36 grants

TB
€68.97M
36 grants

HIV/TB
€7.13M
12 grants

EDCTP Networks of Excellence for Clinical Trials

West African NoE for TB, AIDS, and Malaria (WANETAM)
East African Consortium for Clinical Research (EACCR)
Central African Network for TB, AIDS, and Malaria (CANTAM)
Trials of Excellence in Southern Africa (TESA)

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.

Cash & in-kind contributions for projects

European Union
€151.40M

European countries
€139.08M

African countries
€14.51M

Third-parties
€72.69M

*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.
Total amount = €377.69M

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

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.

European contributions (€ '000)
- United Kingdom
- Sweden
- France
- Germany
- Netherlands
- Denmark
- Belgium
- Spain
- Norway
- Switzerland
- Ireland
- Italy
- Luxembourg
- Austria

Total €46,461

African contributions (€ '000)
- South Africa
- Tanzania
- Uganda
- Zimbabwe
- The Gambia
- Zambia

Total €6,333

Funding distribution for collaborative research
- 74.2% Africa
- 25.7% Europe

37 institutions united across 21 countries in sub-Saharan Africa

63 in institutions

21 countries in sub-Saharan Africa

6,333 institutions

377.69M

3.50M

3.46M

2.80M

2.30M

63

6,333

74.2%

25.7%
The European countries made up the EEIG (European Economic Interest Group) to manage the first EDCTP programme.

The first EDCTP programme closes one year after the second opens.

EDCTP is now an established international funder of clinical research on HIV, tuberculosis, and malaria.

EDCTP was the 1st initiative... and the largest programme on clinical trials targeted to Africa.

EDCTP is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union. EDCTP is governed by the African and European Participating States.

African & European countries are equal partners united as members of the new EDCTP Association, the legal structure for the second EDCTP programme.

Our mission
To reduce poverty in sub-Saharan Africa by funding collaborative health research to accelerate the development of new or improved medical interventions against poverty-related infectious diseases with a focus on phase II and III clinical trials.

The partnership aims for a €2 BILLION 10-year programme having already secured €1.36B in pledges, including €683M from the European Union.

EDCTP is committed to capacity development for an ethical research partnership between Africa and Europe.

December 2015
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