



EDCTP

European & Developing Countries
Clinical Trials Partnership

SUMMARY OF ACHIEVEMENTS

FIRST EDCTP PROGRAMME 2003–2015



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.

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

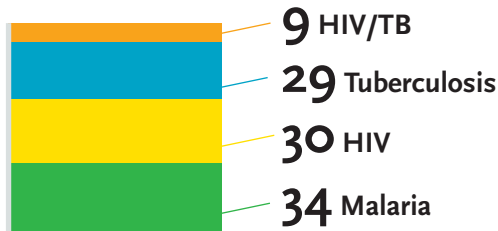


The studies **TAM-TB**, **TBDx**, & **LAM** tested new diagnostics and biomarkers. **TB-NEAT** contributed to the evidence base on the implementation and impact of Xpert MTB/RIF assay in primary health care settings (*The Lancet Global Health*, 2013).

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 coinfecting 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.

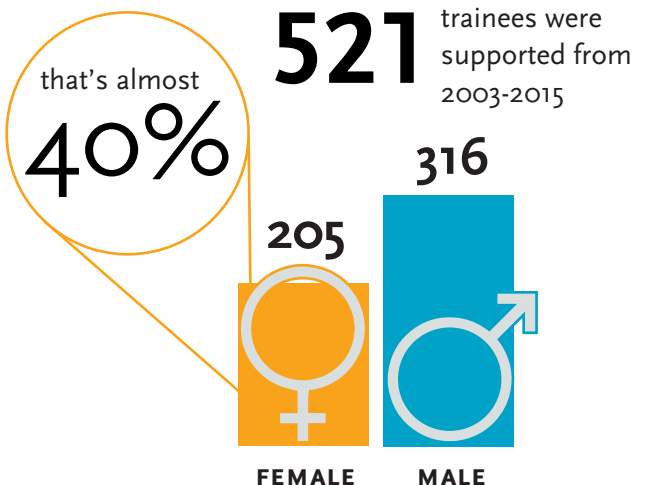
102 clinical trials were funded



over **70%** of **254** projects



were led by an **African Coordinator** by the close of the first programme.



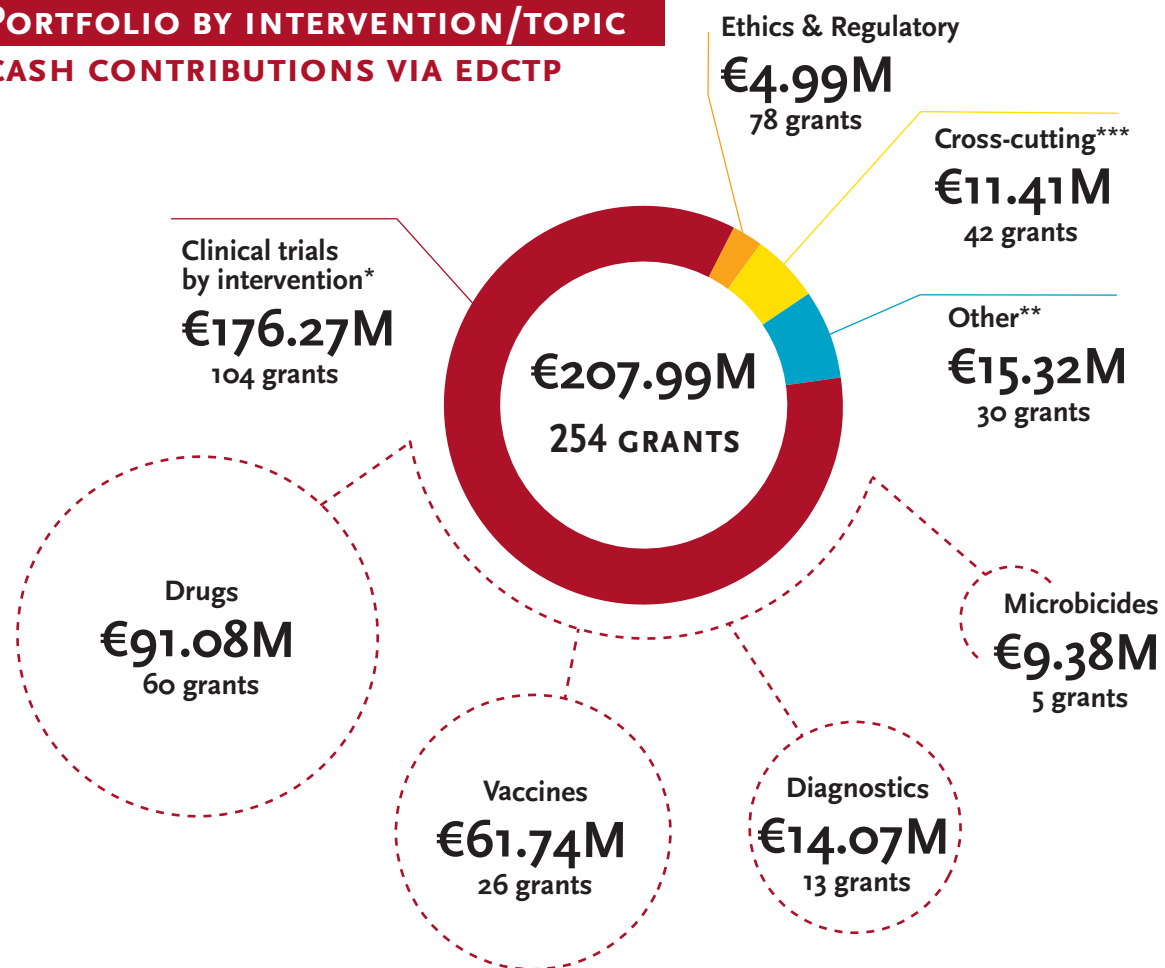
more than **700** peer-reviewed publications resulted from EDCTP projects



more than **3400** posts were supported on EDCTP grants (90% based in Africa)

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.

EDCTP NETWORKS OF EXCELLENCE FOR CLINICAL TRIALS



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



East African
Consortium for Clinical
Research (EACCR)

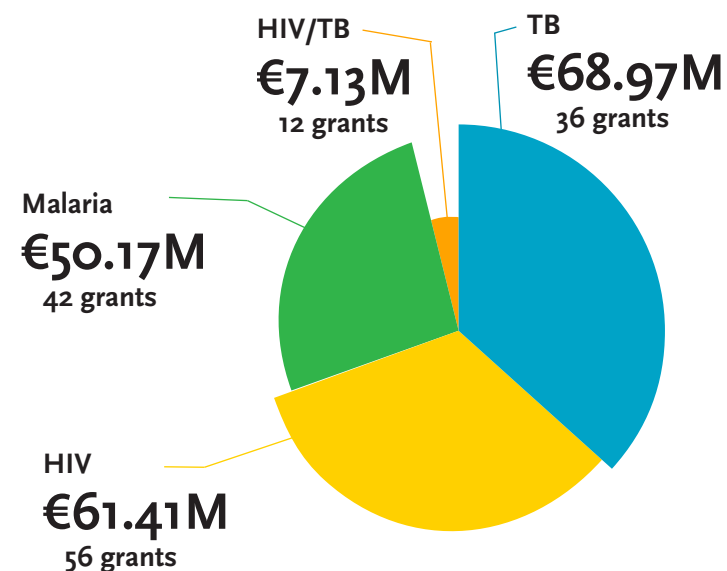


Central African
Network for TB, AIDS,
and Malaria (CANTAM)



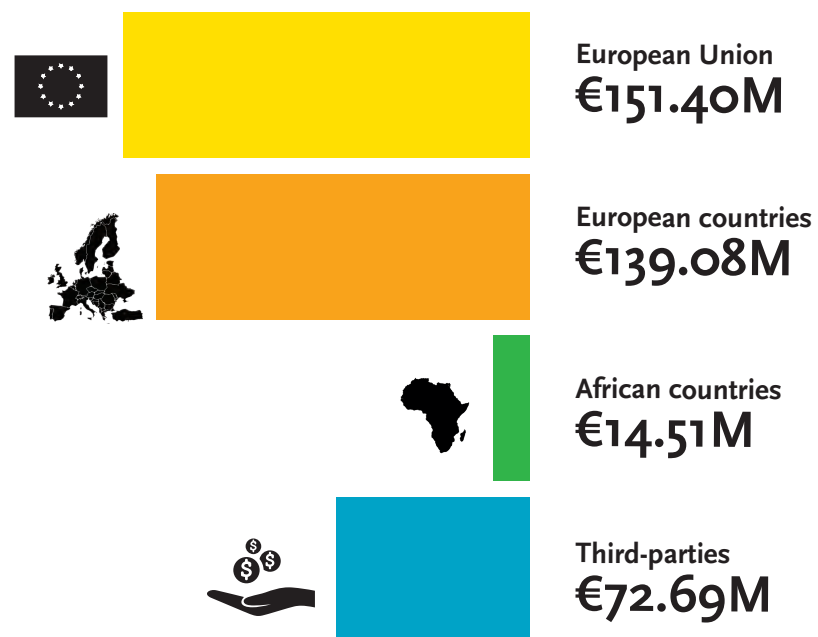
Trials of Excellence
in Southern Africa
(TESA)

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.

CASH & IN-KIND CONTRIBUTIONS FOR PROJECTS



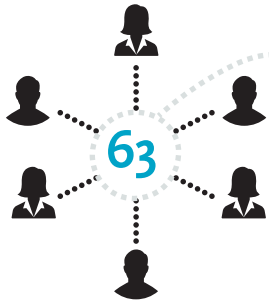
€3.50M

€3.46M

€2.80M

€2.30M

Total amount = €377.69M



institutions
united across

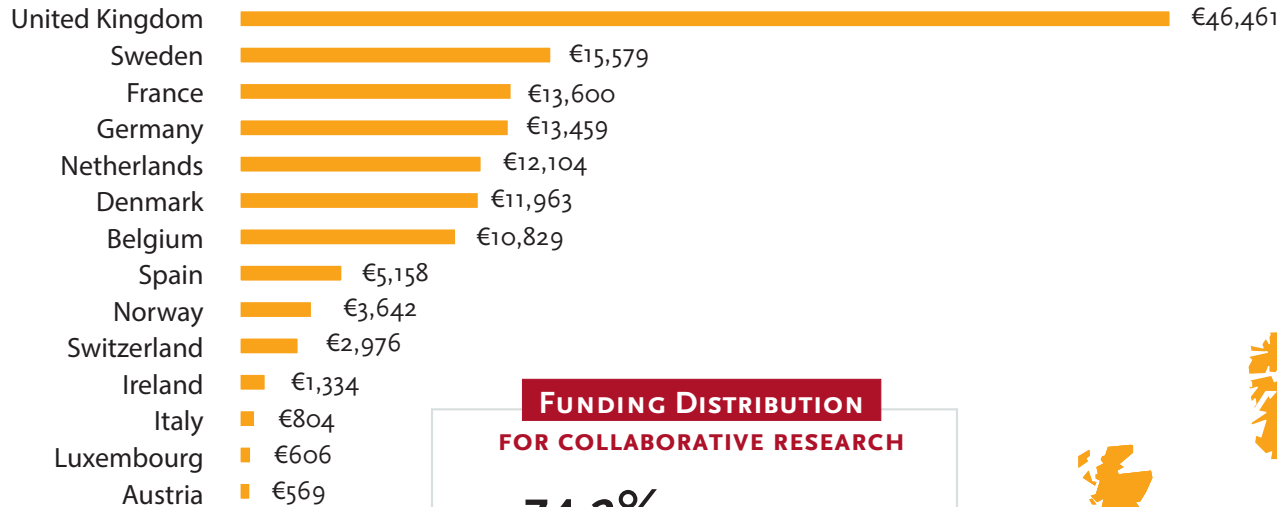
21 countries
in sub-Saharan
Africa



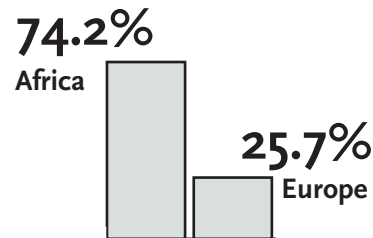
to improve trial capacity in areas such as good clinical and laboratory practice, data management, trial monitoring, and financial and project management.

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

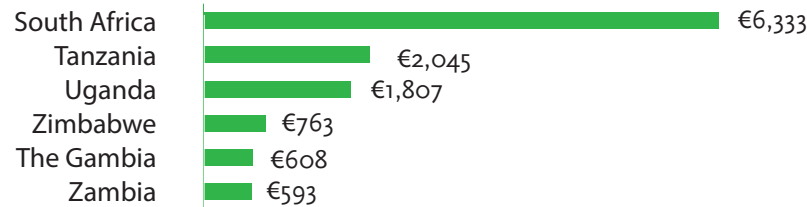
EUROPEAN CONTRIBUTIONS (€ '000)



FUNDING DISTRIBUTION FOR COLLABORATIVE RESEARCH



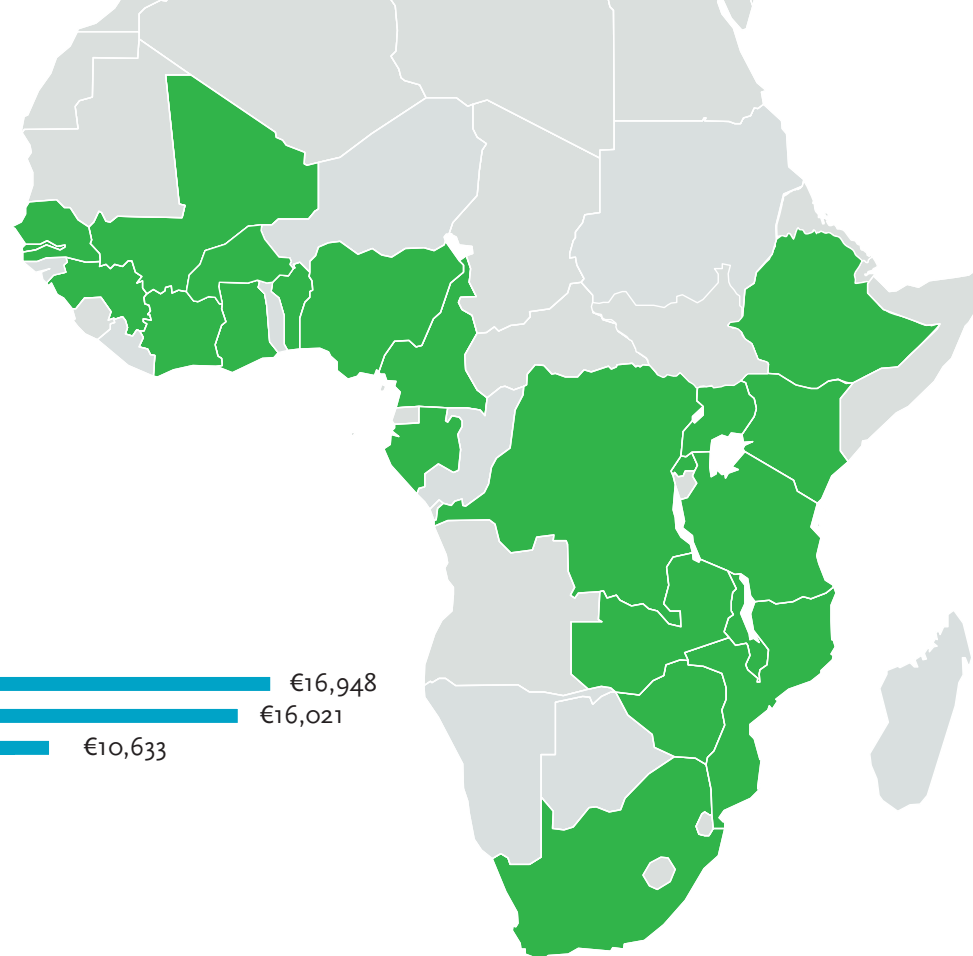
AFRICAN CONTRIBUTIONS (€ '000)



Kenya	€507
Ethiopia	€412
Burkina Faso	€207
Gabon	€202
Mali	€181
Senegal	€154
Republic of the Congo	€150
Malawi	€145
Rwanda	€103
Guinea	€90
Benin	€77
Nigeria	€43
Mozambique	€41
Cameroon	€30
Ivory Coast	€16
Ghana	€5

TOP FUNDING RECIPIENTS

South Africa
Tanzania
Uganda
Kenya
Burkina Faso
Zambia



THIRD-PARTY CONTRIBUTIONS (€ '000)

Global TB Alliance	€16,948
Bill & Melinda Gates Foundation	€16,021
Aeras Global TB Vaccine Foundation	€10,633
Medicines for Malaria Venture (MMV)	€4,513
Sequella Incorporated	€4,376
European Vaccine Initiative (EVI)	€3,923
Wellcome Trust	€2,479
Foundation for Innovative New Diagnostics (FIND)	€2,375
International Partnership for Microbicides (IPM)	€1,477
World Health Organization	€1,331
Bayer AG	€1,309
International AIDS Vaccine Initiative (IAVI)	€1,290
Family Health International (FHI360)	€1,028
Foundation for the National Institutes of Health (FNIH)	€641
Sanofi Aventis	€377
Sanaria Inc.	€369
Community HIV/AIDS Mobilisation Project (CHAMPS)	€356
Chiracon GmbH	€355
Cipla Ltd.	€350
National Institute of Allergy and Infectious Diseases (NIAID)	€308
Delft Imaging Systems	€300
Vecura Company	€200
GlaxoSmithKline	€189
Walter Reed Army Institute of Research (WRAIR)	€178
International Association of National Public Health Institutes (IANPHI)	€178
Heidelberg Pharma GmbH	€165
All Other Funders	€1,027

TOP CLINICAL TRIALS LOCATIONS

South Africa
Tanzania
Zambia
Burkina Faso
Uganda
Kenya

THE HISTORY OF EDCTP

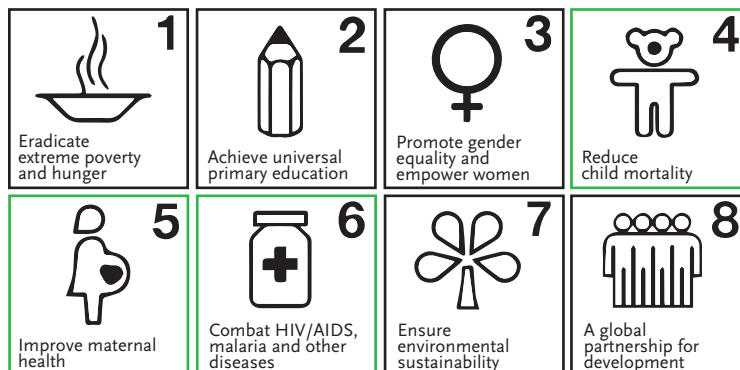


Established 2003

as the European Union's (EU's) response to the global health crisis and



as part of the EU's commitment to achieving the **Millennium Development Goals** (pictured) and under the EU's 6th Framework Programme for Research.



EDCTP was the



Article 185 initiative...



...and the largest programme on clinical trials targeted to Africa.

FROM THE FIRST PROGRAMME TO THE SECOND



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



An expanded scope: The second EDCTP Programme encompasses

neglected infectious diseases, lower respiratory tract infections, diarrhoeal diseases, and emerging infections of relevance for Africa. All stages of clinical trials (I–IV) are included.



2014–2024 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

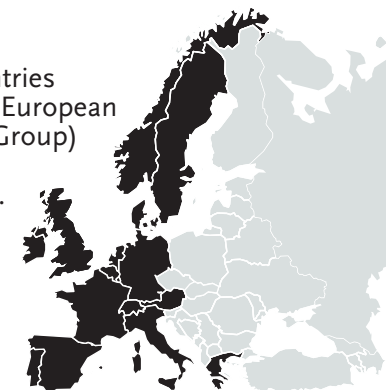
united as members of the new EDCTP Association, the legal structure for the second EDCTP programme.

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.

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



December 2015

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

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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 EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.