The challenge

Poverty-related infectious diseases have huge negative impacts on health, society and the economy. They particularly affect the world’s poorest and most marginalised communities. More than 1 billion people, including 400 million children, are suffering from the three major poverty-related diseases — HIV/AIDS, malaria and tuberculosis — and the neglected infectious diseases combined. Malaria and tuberculosis alone lead to the death of an estimated 2.1 million people annually. The poverty-related diseases increase infirmity and insecurity, undermine productivity, and thus perpetuate the cycle of poverty. Sub-Saharan Africa is disproportionately affected; approximately 90% of all malaria-related deaths occur in this region which also accounts for 68% of all people living with HIV and 72% of AIDS-related deaths.

The European & Developing Countries Clinical Trials Partnership (EDCTP) was created as a European response to the global health crisis related to poverty-related infectious diseases. This research funding partnership aims to accelerate the clinical development of new or improved medicinal products while also strengthening African clinical research capacity. EDCTP is a partnership between countries in Europe and sub-Saharan Africa, and the European Union.

EDCTP programmes

The first EDCTP programme (EDCTP1, 2003-2015) was launched in 2003 by 16 European countries and the European Union to support clinical trials and research capacity development to fight HIV/AIDS, malaria and tuberculosis in Africa. EDCTP1 supported 254 projects with EUR 378 million, involving 194 African and 72 European research institutions. African researchers led more than 70% of the projects.

The EU’s commitment to EDCTP resulted in an increased H2020 budget for the second programme (EDCTP2, 2014-2024), of up to EUR 683 million. This enabled an expanded scope and targeted investments in the neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections,
and (re-)emerging infectious diseases with pandemic potential. The EDCTP Association implements EDCTP2 and currently has 30 member countries: 14 European and 16 African countries. Between 2014-2017, EDCTP2 has already awarded EUR 255 million in grant funding: 50 projects including at least one clinical trial, 58 fellowships for researchers from sub-Saharan Africa, and 13 grants to strengthening the regulatory and ethics review capacities in Africa. The grants involve altogether 206 sub-Saharan institutions and 95 European institutions.

EDCTP2 contributes to the European Union as strong global player in health research and complements other EU initiatives with third countries, such as GLoPID-R. The Global Research Collaboration for Infectious Diseases is a network of funders, chaired by the EU that facilitates an effective research response within 48 hours of a significant outbreak of a new or re-emerging infectious disease with pandemic potential. EDCTP2 also supports EU initiatives on open access to clinical trials results and open clinical data, research ethics and anti-microbial resistance.

**EDCTP success stories**

**TB diagnostics** | The TB-NEAT Consortium tested the GeneXpert© TB diagnostic system for use in community-based clinics (XACT study). The first part of the trial enrolled 1502 patients in South Africa, Zambia and Zimbabwe. The study (published in The Lancet) showed that the Xpert MTB/RIF test can be accurately administered by a nurse in primary-care clinics, resulting in more patients starting same-day treatment, more culture-positive patients starting therapy, and a shorter time to treatment.

**Malaria treatment** | The 4ABC study was successfully conducted in 7 sub-Saharan African countries at 12 trial centres. The study screened more than 10,000 children between 6 and 59 months old; a total of 4,116 children were included in the study and treated. Three novel artemisinin-based drug regimens were found to be safe and efficacious in treating children with uncomplicated malaria. AL, ASAQ, and DHAPQ had excellent efficacy up to day 63 post-treatment while risk of recurrent infections was significantly lower, even in areas of high transmission, for DHAPQ (followed by ASAQ, and then AL). A fourth treatment regimen (CDA) was withdrawn for safety reasons (high risk of severe anaemia in certain individuals).

**HIV treatment** | Developing paediatric formulations that are palatable, simple once-daily treatments is a priority to improve adherence and tolerability whilst maintaining efficacy. The CHAPAS-1 trial investigated the appropriate dose and adherence to a fixed-dose combination of stavudine (d4T), lamivudine (3TC) and nevirapine (NVP) in a new formulation specifically developed for children (Triomune Baby/Junior). The results of the study contributed to the evidence base that led the Food and Drug Authority (USA) to approve this formulation. The drug then received WHO prequalification status and could be supplied through the President’s Emergency Plan for AIDS Relief (PEPFAR) and the Clinton Foundation programmes. Pharmacokinetics data from the trial contributed to the WHO Formulation and Pharmacology Group’s recommendation on the optimal drug ratios in fixed-drug combinations and on weight band dosage for ARVs drugs in children worldwide.

**More information:** [www.edctp.org](http://www.edctp.org)