European & Developing Countries Clinical Trials Partnership (EDCTP)
European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between countries in Europe and sub-Saharan Africa, and supported by the European Union.
• Established in 2003 in response to the Millennium Development Goals

The operating structure is the EDCTP Secretariat, based in The Hague, Netherlands, which implements the EDCTP programmes
• The second EDCTP programme (EDCTP2) runs from 2014-2024

EDCTP2 aims to support **collaborative research** that accelerates the **clinical development** of new or improved interventions to prevent or treat poverty-related infectious diseases in sub-Saharan Africa
EDCTP governance: equal partnership

- General Assembly
  - 29 members (one from each member country)

- Board
  - 5 members

- EDCTP Secretariat
  - (∼35 staff)

- EDCTP Scientific Advisory Committee
  - Scientific and strategic advice

- EDCTP operates as an independent non-profit association
- EDCTP currently has 29 members (14 European + 15 African countries)
EDCTP funding streams (simplified)

- Clinical Trials in sub-Saharan Africa (85%)
- Collaborations between research teams in Europe and Africa (and elsewhere)
- Capacity building activities (15%)
  - Fellowships, networking, regulatory, ethics

Open calls-for-proposals (around a dedicated topic)

EDCTP Participating States: ≥ €683 M
European Union: ≥ €30 M ≤ €683 M
Third Parties: ≥ €500 M

Cash/in-kind: EDCTP Participating States, European Union
Cash: Third Parties

What EDCTP supports

Activity scope

Human pharmacology

Therapeutic exploratory

Therapeutic confirmatory

Therapeutic use

Phase I

Phase II

Phase III

Phase IV

Implementation research

Clinical trials

Product focused implementation trials

Geographical Scope

Disease scope

HIV, malaria, tuberculosis
neglected infectious diseases
diarrheal infections
lower respiratory infections
epidemic infectious diseases
EDCTP2 project portfolio by intervention (2014-2017)

- **Clinical trials by intervention***
  - Vaccines: €82.7 M, 9 grants
  - Drugs: €67.9 M, 11 grants
  - Clinical Management: €36.3 M, 4 grants

- **Cross-cutting***
  - €24.4 M, 18 grants

- **Fellowships**
  - €12.2 M, 47 grants

- **Ethics & Regulatory**
  - €4.1 M, 14 grants

*including treatment and prevention.

***cross-cutting activities including regional networks of excellence
Clinical trials by disease

Intervention type by disease for clinical trials projects

EDCTP contribution (M EUR) of funded/awarded grants

- HIV
- TB
- malaria
- NID
- DD & LRTI
- Emerging diseases
- Co-morbidities

- Other (epidemiology and disease management)
- Vaccines
- Drugs (treatment and prevention)
- Diagnostics
EDCTP2 calls for proposals

Unique country participation in EDCTP2 grants
Example of an EDCTP supported clinical trial: PZQ4PSAC

Phase III clinical trials and registration of a new praziquantel orally disintegrating tablet formulation suitable for preschool-aged children with schistosomiasis

Funding:
EDCTP contribution: € 1,988,359.48
Total project value: € 12,103,948 (Cofunders: GHIT Fund, Merck KGaA, Swiss TPH, Lygature, ICL, Astellas and Farmanguinhos)

Consortium partners:
1. Stichting Lygature (Coordinator)
2. Université Félix Houphouët Boigny (UFHB), Cote D’Ivoire
3. Kenya Medical Research Institute (KEMRI), Kenya
4. Merck KGaA, Germany
5. Swiss Tropical and Public Health (TPH), Switzerland
6. Imperial College of Science Technology and Medicine (ICL), United Kingdom

Objectives:
• To conduct two single arm Phase III clinical trials in Kenya and Cote d’Ivoire to demonstrate the efficacy and safety of a single dose of the PZQ ODTs in children age 3 months to 6 years infected with *Schistosoma mansoni* and *Schistosoma haematobium*
• To establish the final commercial process for the Active Pharmaceutical Ingredient and the Drug Product at the respective final manufacturing sites
• To prepare the core registration dossier for EMA (Article 58) and/or WHO prequalification
• To foster awareness of the project and to further refine the Product Delivery & Access plan and seek its endorsement by key stakeholders
Partnerships in many forms and shapes

Before call is launched

Joint Call

EDCTP + Partner create “common pot” and agree on a common call topic

Coordinated Call

Grant Application phase

Co-funding to specific project application

A specific project has received funding from Partner and applies to EDCTP for co-funding

Co-funding to specific project application

Project Implementation

Funding to selected or on-going project

EDCTP funds a specific project (or shortlist project for funding). Partner provides co-funding

Sida

MERCK

Department of Health

TDR

For research on diseases of poverty

UNICEF • UNDP • World Bank • WHO

GHIT Fund

Global Health Innovative Technology Fund

NIH

International AIDS Vaccine Initiative

MRC

Medical Research Council

gsk

Mundo Sano

CALOUSTE GULBENKIAN FOUNDATION
Collaborations between GHIT and EDCTP

Many similarities:

GHIT Fund
- Entire world
- Pre-clinical

EDCTP
- Implementation research

- Funds through Calls
- Europe + Africa
- Public-Private Partnerships
- Poverty-related diseases
- Clinical trials

Joint funding of large (global) clinical trials
Better coordination of call topics – joint or coordinated calls
THANK YOU

WWW.EDCTP.ORG