European & Developing Countries Clinical Trials Partnership (EDCTP)



EDCTP

European & Developing Countries Clinical Trials Partnership





Who we are

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.

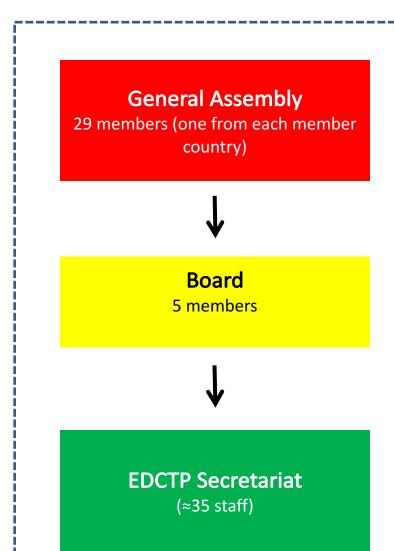
Established in 2003 in response to the Millennium Development Goals

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 <u>collaborative research</u> that accelerates the <u>clinical development</u> of new or improved interventions to prevent or treat poverty-related infectious diseases in sub-Saharan Africa

EDCTP governance: equal partnership

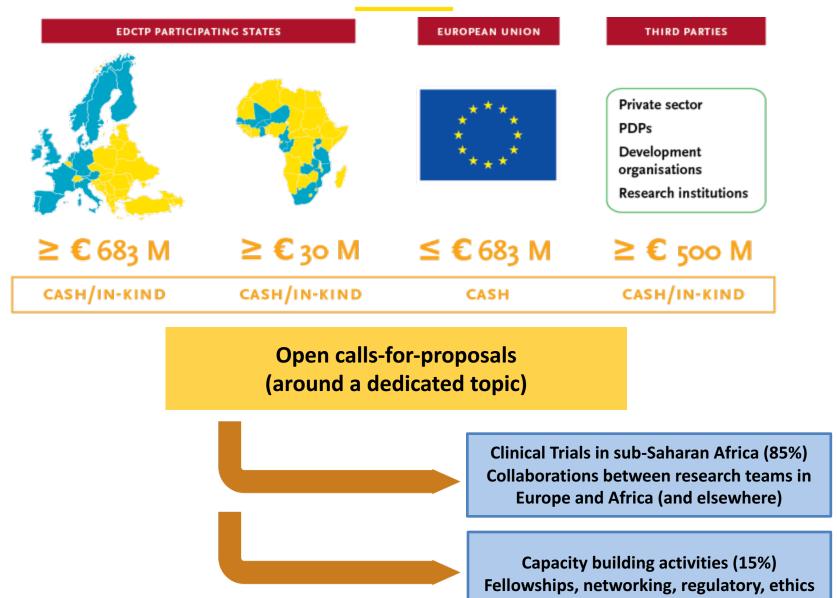


Scientific and strategic advice

EDCTP Scientific Advisory
Committee

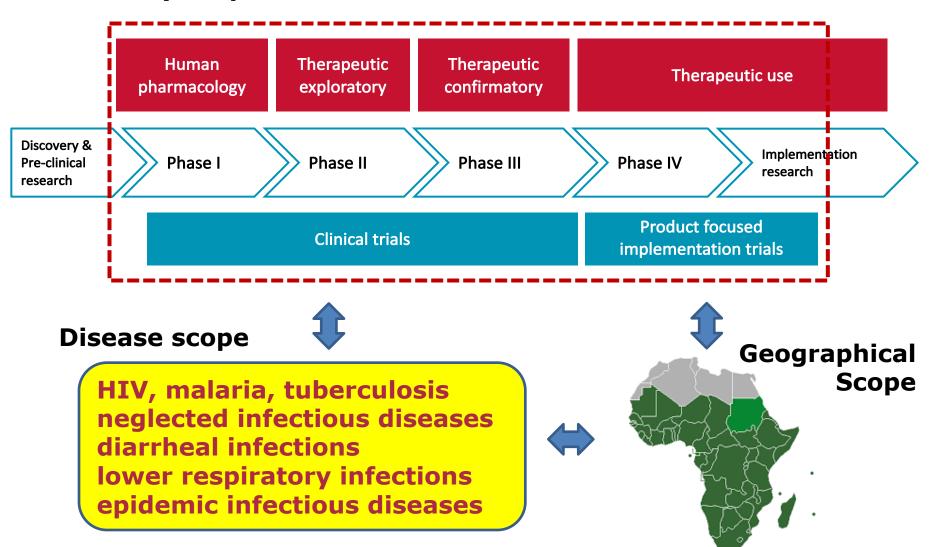
- EDCTP operates as an independent non-profit association
- EDCTP currently has 29 members (14 European + 15 African countries)

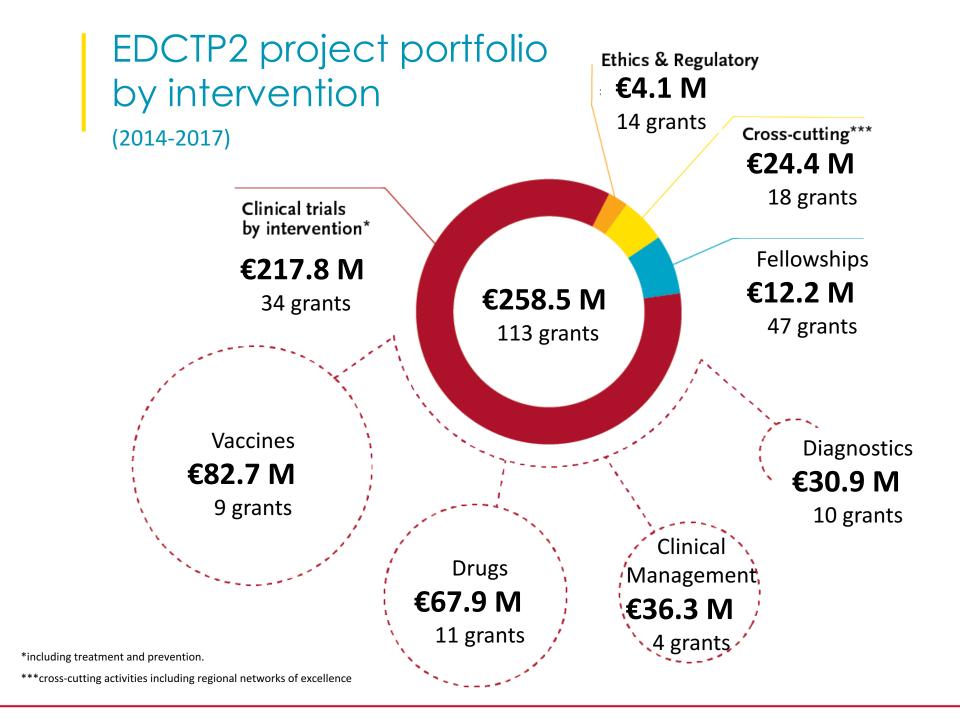
EDCTP funding streams (simplified)



What EDCTP supports

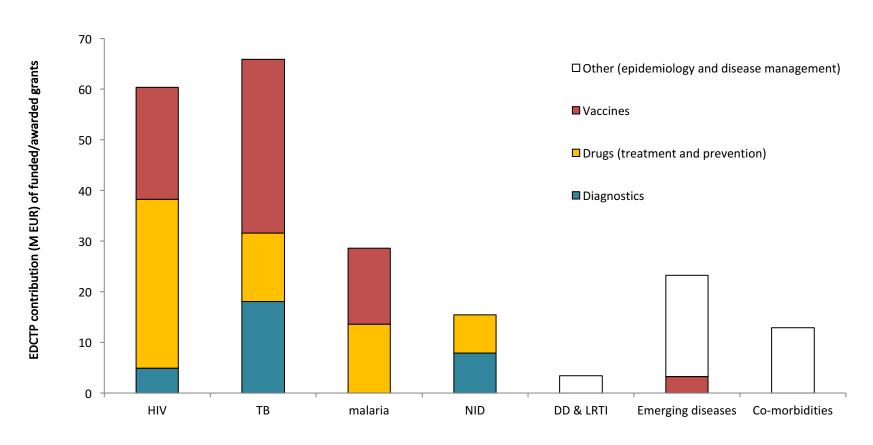
Activity scope



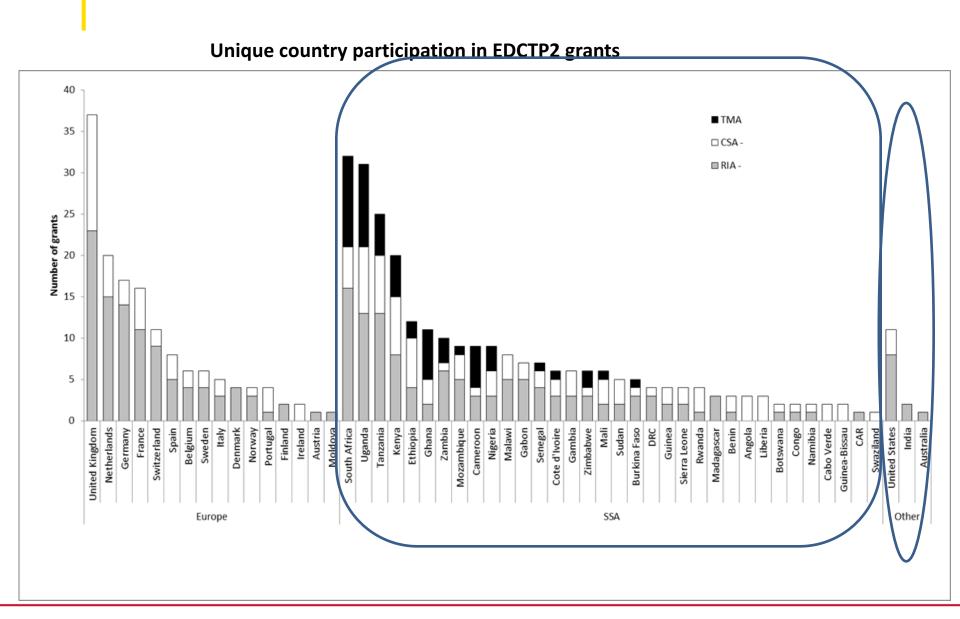


Clinical trials by disease

Intervention type by disease for clinical trials projects



EDCTP2 calls for proposals



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:

Stichting Lygature (Coordinator)

- 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

Grant Application phase

Project Implementation

Joint Call

Co-funding to specific project application

Funding to selected or ongoing project

Coordinated Call

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

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

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

















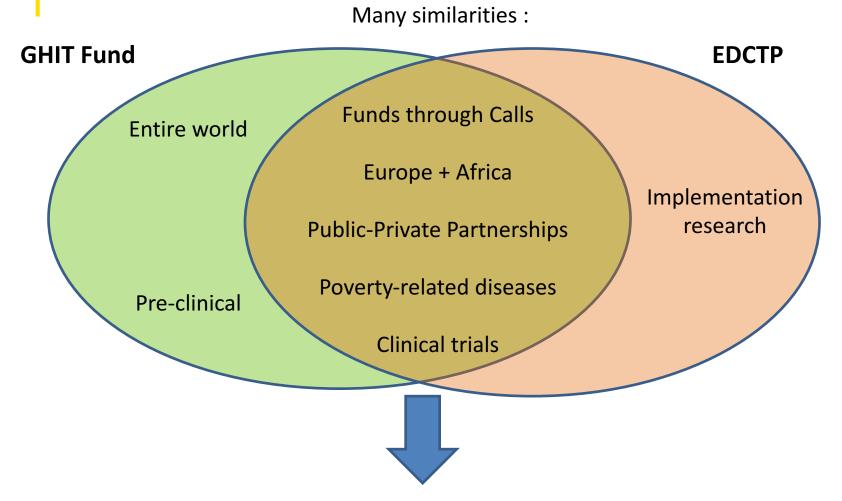




Bundesministerium für Bildung und Forschung



Collaborations between GHIT and EDCTP



Joint funding of large (global) clinical trials

Better coordination of call topics – joint or coordinated calls



THANK YOU

WWW.EDCTP.ORG

