

## EDCTP2

# New opportunities for clinical research in Poverty-Related and Neglected Infectious Diseases (PRNID)

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# Justification for EDCTP2

## Objectives

- Clinical development of affordable medical interventions for neglected diseases (PRNID) in **part**

**PRNID: HIV/AIDS, malaria, TB  
all 17 diseases on WHO's NTD list  
(minus Chagas) + diarrhoeal and  
lower respiratory infections**

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tries

## Problem

- No economic incentive for private investments in PRNID
- Public investments are sparse and fragmented
- Know-how is fragmented

## Background

- EDCTP-1: 2003-2015
- EDCTP-2: 2014-2024

# Governance

**General Assembly**  
(1 Member from each  
Participating State + EC  
as Observer)



**Steering Committee**  
(5 Members)



**EDCTP Secretariat**



**Scientific Advisory  
Committee**  
(SAC, 16 Members)

- **Public-Public Partnership between sovereign states**
- **Operates as an independent legal entity**
- **Owned by the Participating States**
- **“Membership fee” of 200,000 EUR/year**
- **EDCTP2 will operate from 2014-2024**

# Who we are

## Current Participating States (PSs)

### 14 European Countries

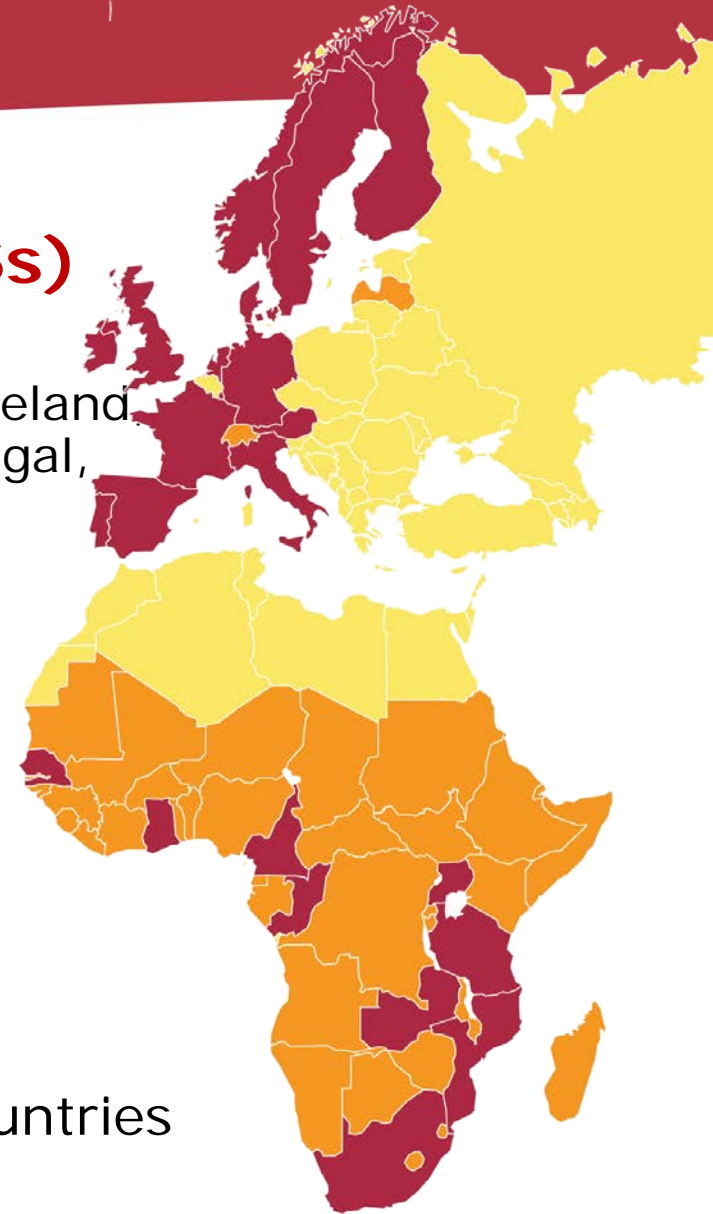
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

### 9 African Countries

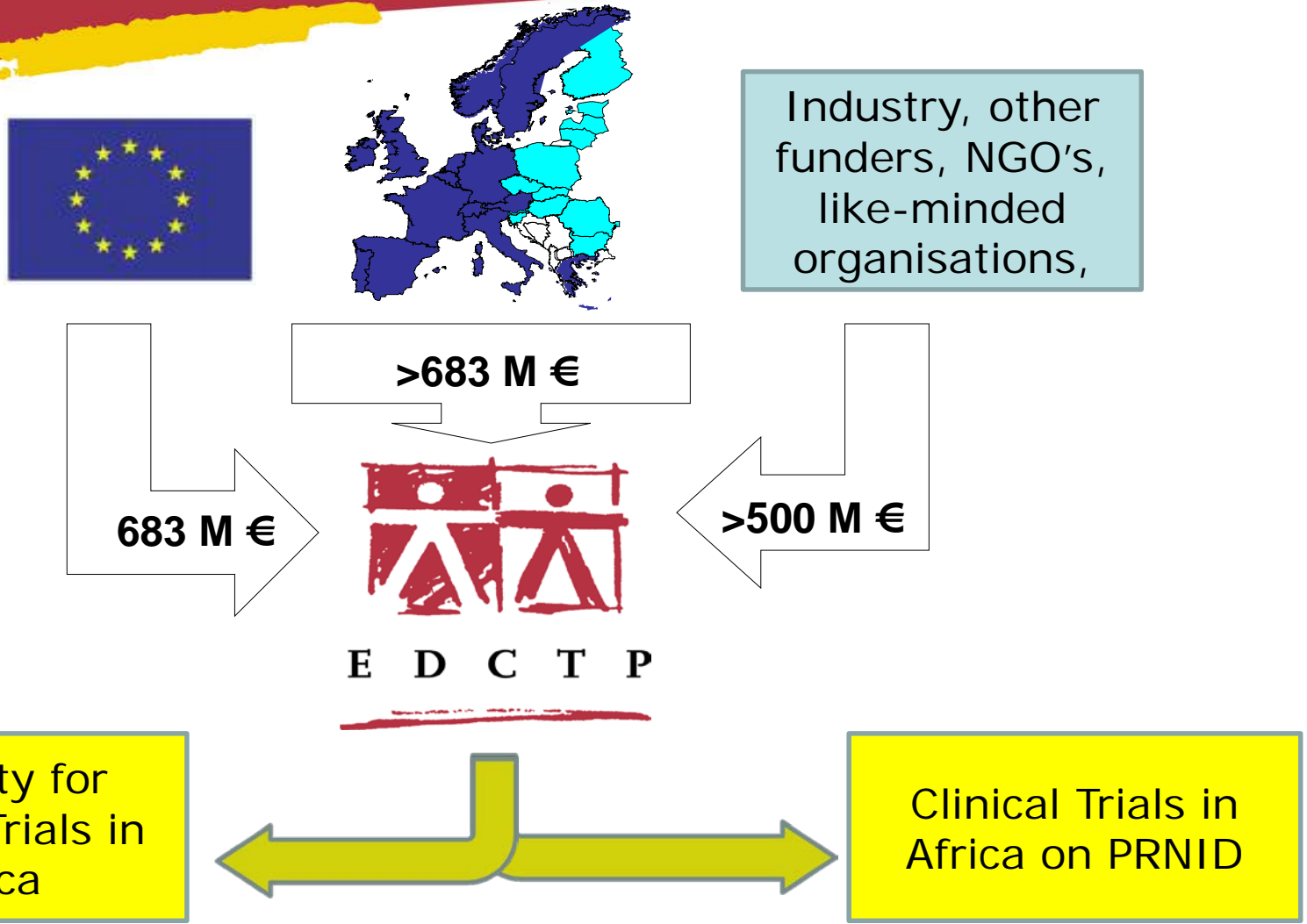
Congo, Cameroon, Ghana, Senegal, South Africa, Mozambique, Tanzania, Uganda, Zambia

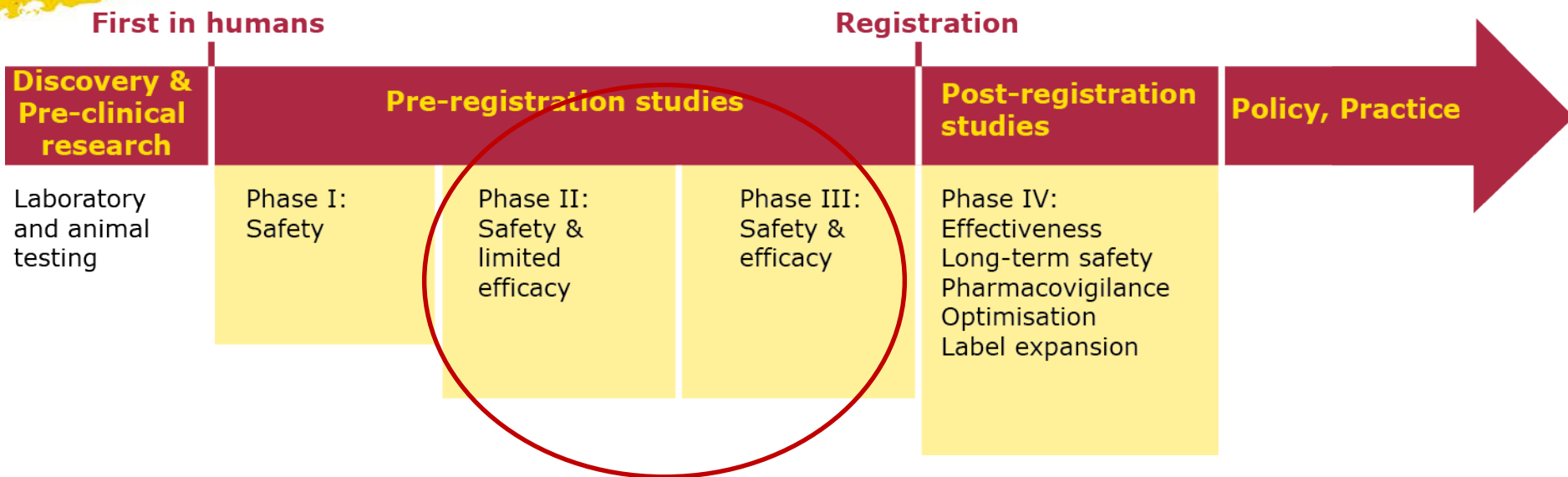
## Affiliated (“who can receive funding”)

- All sub-Saharan African countries
- All EU Member States and Associated Countries



# How it operates





**Diseases:** HIV/AIDS, TB, Malaria and NIDs

**New tools and interventions:** Diagnostics, drugs, biomarkers, vaccines and microbicides

**Capacity Development:** Fellowships, Networks, Ethics, Regulatory

# How does it work?

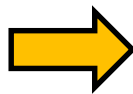
## Annual Work Plan with call topics

Thematic Stakeholder meetings (5 in 2013); Scientific advisory Committee; Commissioned studies, other input

Internal review; review by SAC; approval by GA; review by independent review panel, approval by EC

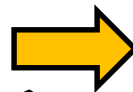
## First EDCTP2 work plan in July 2014 (tbc)

**1. Integrated Activities**



Selected, funded and managed by **EDCTP Secretariat**

**2. Participating States' Initiated Activities (PSIA)**



Selected, funded and managed by **PSs** according to national rules

# Call for proposals for Integrated Activities

## 1. Clinical Trials

Consortia of 2 European PS and 1 sub-Saharan African country (minimum)

Either full funding (100% of costs) or co-funding (25-33%) with other funders (Participating States and/or third parties)

Broad non-prescriptive topics, bottom-up

## 2. Fellowships

Grants to individuals: Career development, Senior, Industry, Regulatory, other

100% funding

## 3. Capacity Support

Individual institutions or consortia for ethics, training, networking and regulatory activities

100% funding

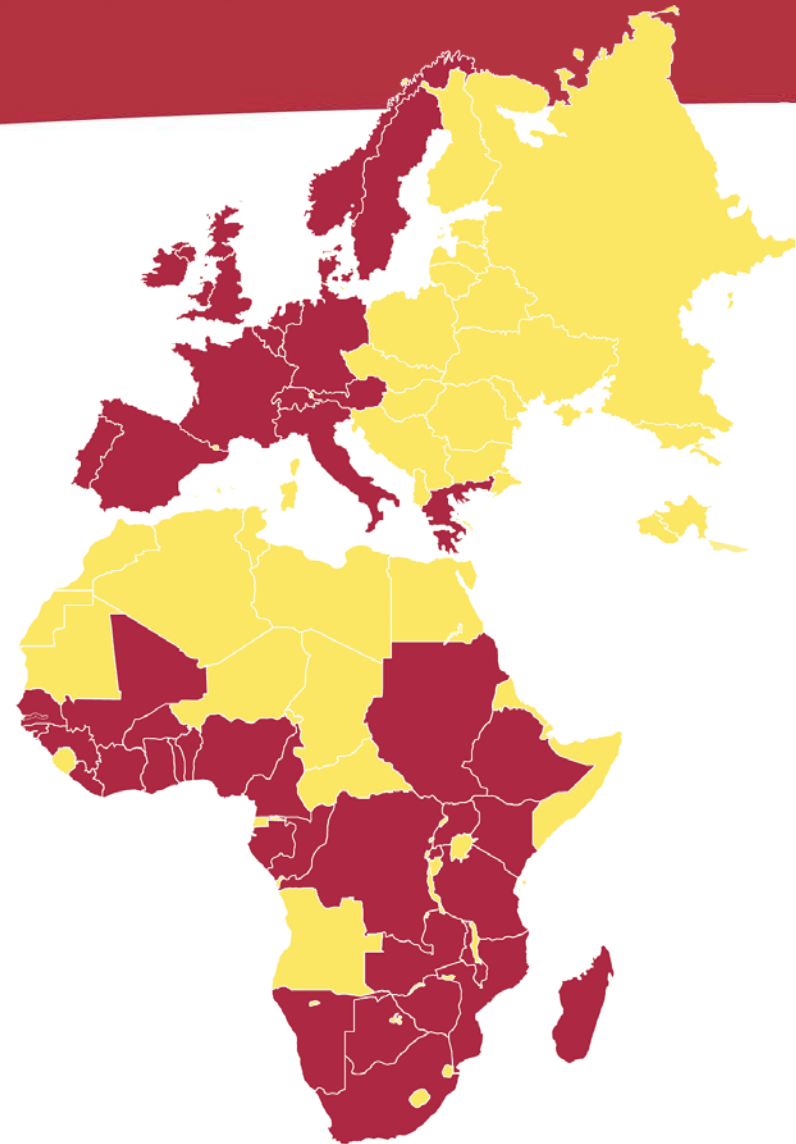




**Thank you!**

# EDCTP1 in a nutshell

- **Number of projects:** 246
- 259 institutions participate and receiving funds from EDCTP
- 3442 posts are supported on EDCTP grants (91% in Africa)
- **Clinical trials** 100  
(70% with African PI)
- **Training of scientists:** 419
- **Publications (so far):** 485



# Clinical trials (2003-2013)

	Non phase	Phase I	Phase II	Phase III	Phase IV	Total	Completed
<b>Malaria</b>	0	7	7	8	12	<b>34</b>	<b>11 (32%)</b>
<b>HIV</b>	1	7	10	9	3	<b>30</b>	<b>13 (43%)</b>
<b>TB</b>	11	1	11	3	1	<b>27</b>	<b>8 (30%)</b>
<b>HIV/TB</b>	0	0	4	2*	3	<b>9</b>	<b>4 (44%)</b>
<b>Total</b>	<b>12</b>	<b>15</b>	<b>32</b>	<b>22</b>	<b>19</b>	<b>100</b>	<b>36 (36%)</b>

1 HIV trial terminated prematurely\*

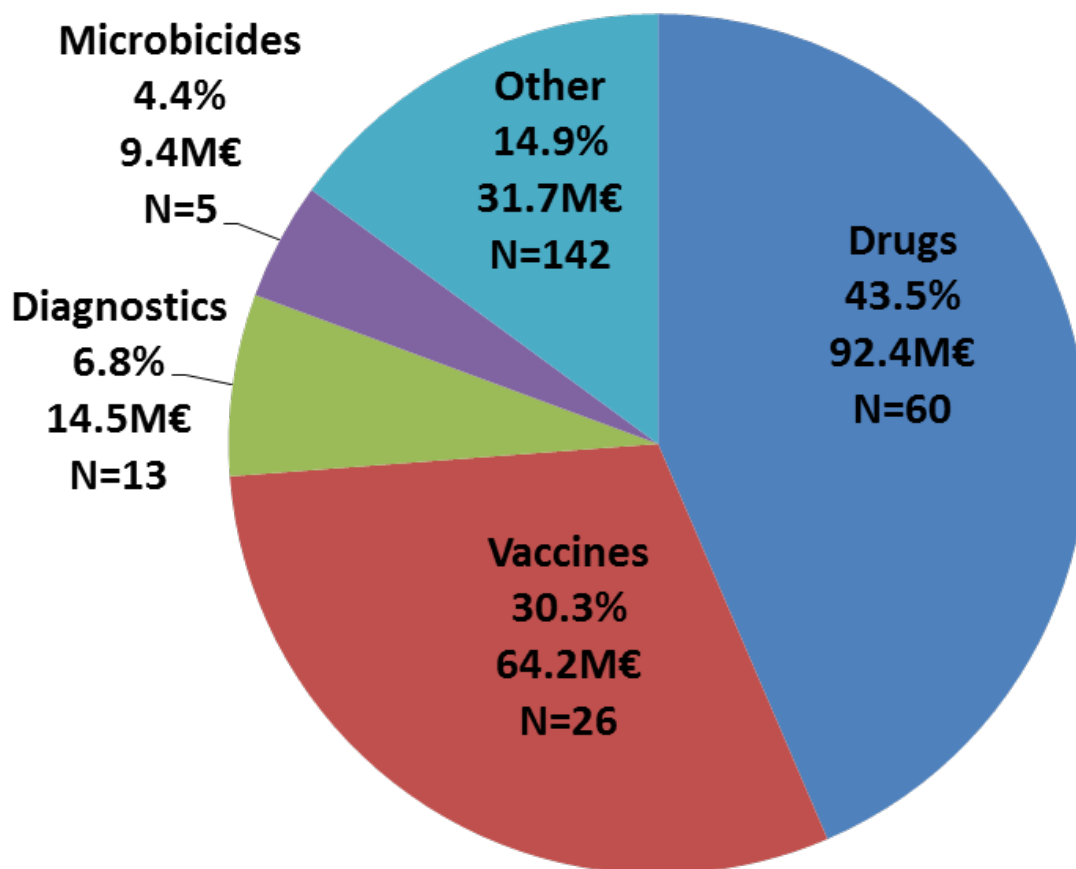
# Ethics grants

75 grants awarded (24 active)

Support for

- Establishment and strengthening of ethics capacity at national and institutional level (NECs, IRBs)
- Training (courses, online programmes)
- Coordination and networking

# EDCTP1 portfolio by intervention



# Clinical trials/country in EDCTP1



Country	Number of trials
South Africa	31
Tanzania	24
Zambia	16
Burkina Faso	14
Uganda	14
Kenya	12
Malawi	10
Mozambique	9
Gabon	8
The Gambia	8
Zimbabwe	7
Senegal	6
Ethiopia	5
Ghana	4
Côte d'Ivoire	3
Guinea, Republic of	2
Guinea-Bissau	2
Mali	2
Nigeria	2
Rwanda	2
Botswana	1
Cameroon	1
Democratic Republic of Congo	1
Namibia	1

# Example: Phase 2 trial of Malaria vaccine candidate



- GMZ2: Hybrid of glutamate-rich protein and MSP3 + Alum
- Targeting the blood stage of the malaria parasite
- 4 clinical trials sites:
  - CNRFP (Burkina Faso); Makarere (Uganda); Albert Schweitzer Hospital (Gabon); Navrongo (Ghana)
- 2 European partners:
  - SSI (Denmark); Tübingen University (Germany)
- 1747 children received 3 doses of 100 microgram or rabies vx
- Close-out: Feb 2014
- Total budget: EUR 6.6 M (from EDCTP)