

# Collaborative clinical research between EU & sub-Saharan Africa

*European & Developing Countries Clinical Trials Partnership*

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**EDCTP**

European & Developing Countries  
Clinical Trials Partnership



# EDCTP public-public partnership

## **14 European countries**

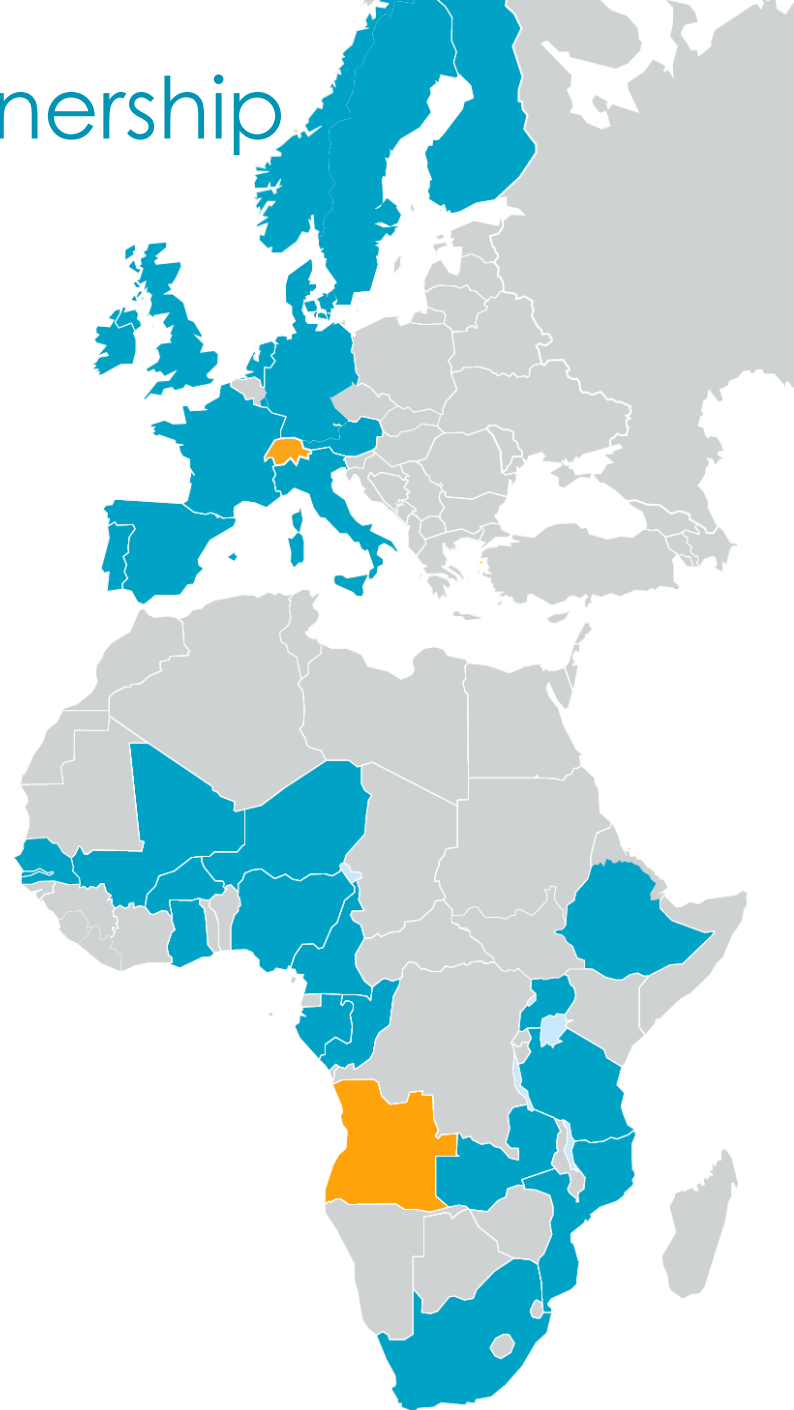
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

## **2 Aspirant members**

Angola, Switzerland

## **16 African countries**

Burkina Faso, Cameroon, Rep of Congo, Ethiopia, Gabon, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia



## Vision

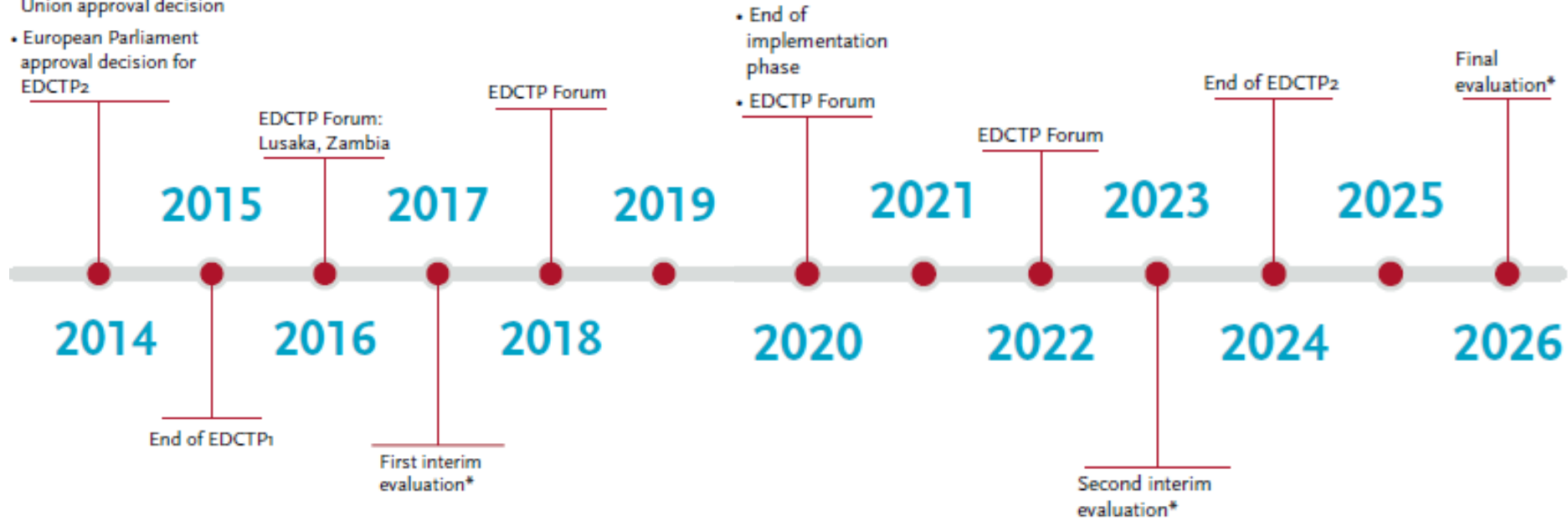
Reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa, by investing in **collaborative clinical research** to develop accessible, suitable and affordable medical interventions and investing in **research capacity development**

## Mission

To enhance research capacity and accelerate the development of new or improved medical interventions for the identification, treatment and prevention of **poverty-related infectious diseases**, including emerging and re-emerging diseases in sub-Saharan Africa, through all phases of **clinical trials, with emphasis on phase II and III trials.**

# EDCTP timeline

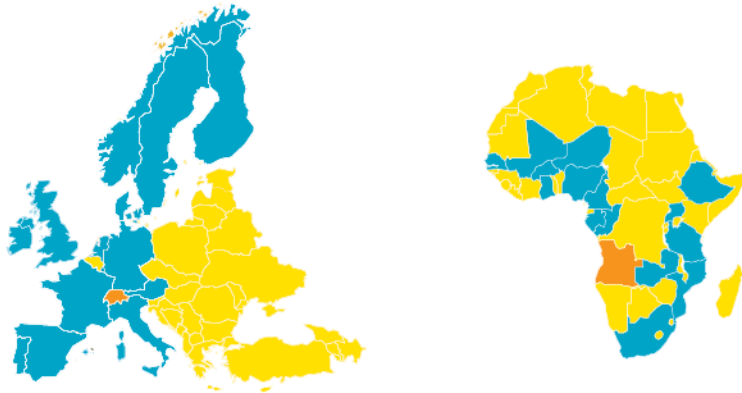
- Launch of EDCTP<sub>2</sub>
- Council of the European Union approval decision
- European Parliament approval decision for EDCTP<sub>2</sub>



\*Independent evaluations commissioned by the EC.

# The EDCTP funding programme

EDCTP Participating States



≥ € 683 M

≥ € 30 M

European Union



≤ € 683 M

Third parties

Private sector  
PDPs  
Development  
organisations  
Research institutions

≥ € 500 M

CASH/IN-KIND

CASH/IN-KIND

CASH

CASH/IN-KIND

**Participating States'  
Initiated Activities**

- Administered by Participating States
- Selected and funded by Participating States
- Application of Participating States' funding

**EDCTP Calls  
for Proposals**

- Administered by EDCTP
- Funded by the EU, Participating States and third parties
- Horizon 2020 rules for participation

# EDCTP Programme objectives



## **Medical interventions**

New or improved medical interventions against poverty-related infectious diseases



## **Collaboration and capacity development**

Improve cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards



## **European coordination**

Improve coordination, alignment and integration of European National Programmes



## **External partnerships**

Increase international cooperation with public and private partners



## **EU cooperation**

Increase interaction with other EU initiatives, including those linked to development assistance

# Target diseases

- **HIV, tuberculosis, malaria**
- **Neglected infectious diseases\***  
Dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen's disease); trachoma; yaws
- **Diarrhoeal diseases**
- **Lower respiratory tract infections**
- **Emerging and re-emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.

\* Based on the WHO list of neglected tropical diseases (excluding Chagas disease)

# Vulnerable populations



- Pregnant women
- Newborns and children
- Adolescents
- People living with co-infections and co-morbidities



# European Union R&D funding under Horizon 2020

## PRODUCT DEVELOPMENT PIPELINE

Discovery  
Proof of  
Concept

Preclinical  
research

Clinical research

Implementation  
research

H2020 collaborative translational research projects

**EDCTP2 programme**

SME-Instrument

IMI2 programme

InnoFin ID – Infectious Diseases Financing Facility (IDFF)

# EDCTP supported activities

## Research & Innovation Actions (RIA)

Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.

## Coordination & Support Actions (CSA)

Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.

## Training & Mobility Actions (TMA)

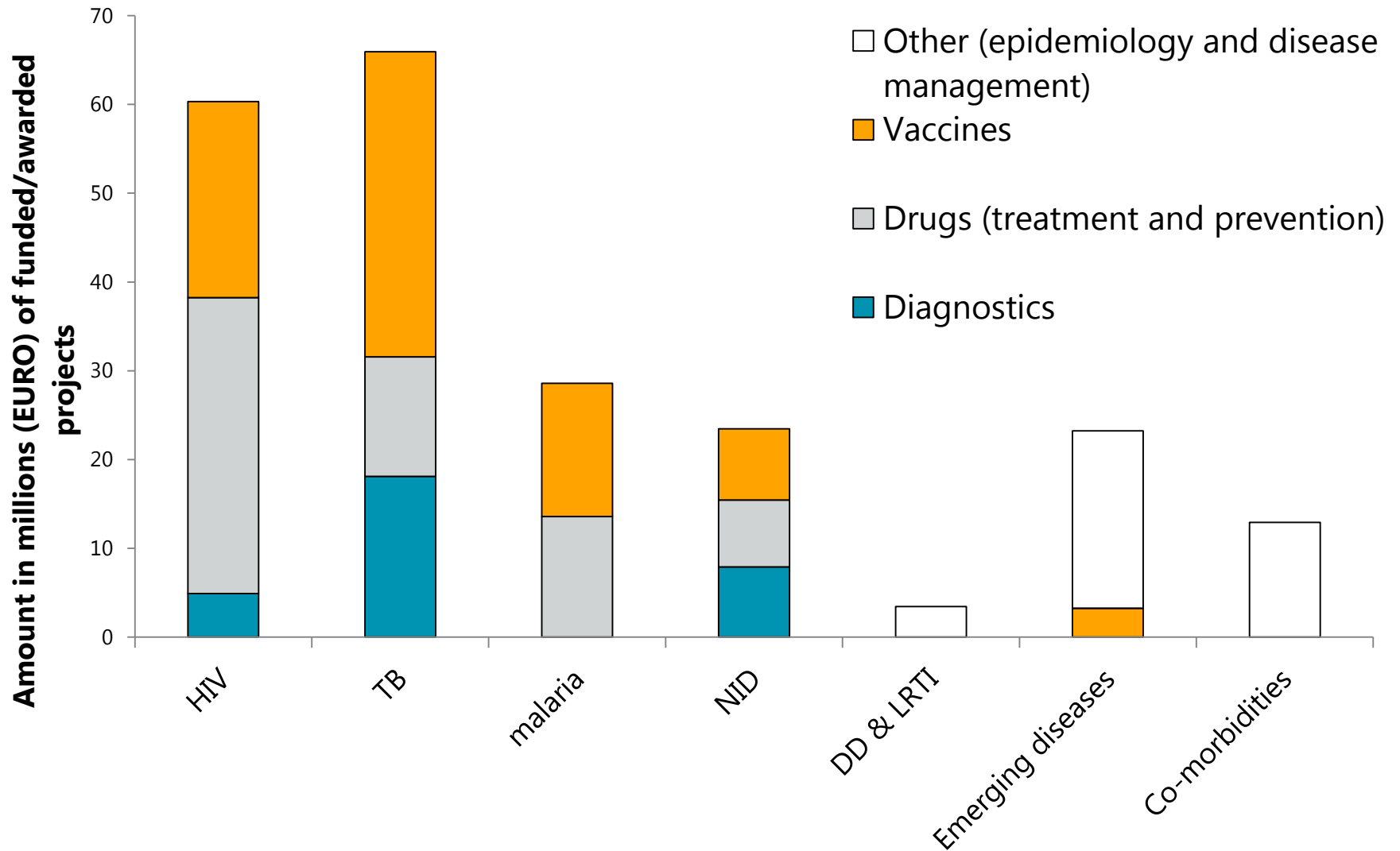
Fellowships that focus on the career development of individual researchers or research team members.

## EDCTP2 funding commitments (2014-2016)\*

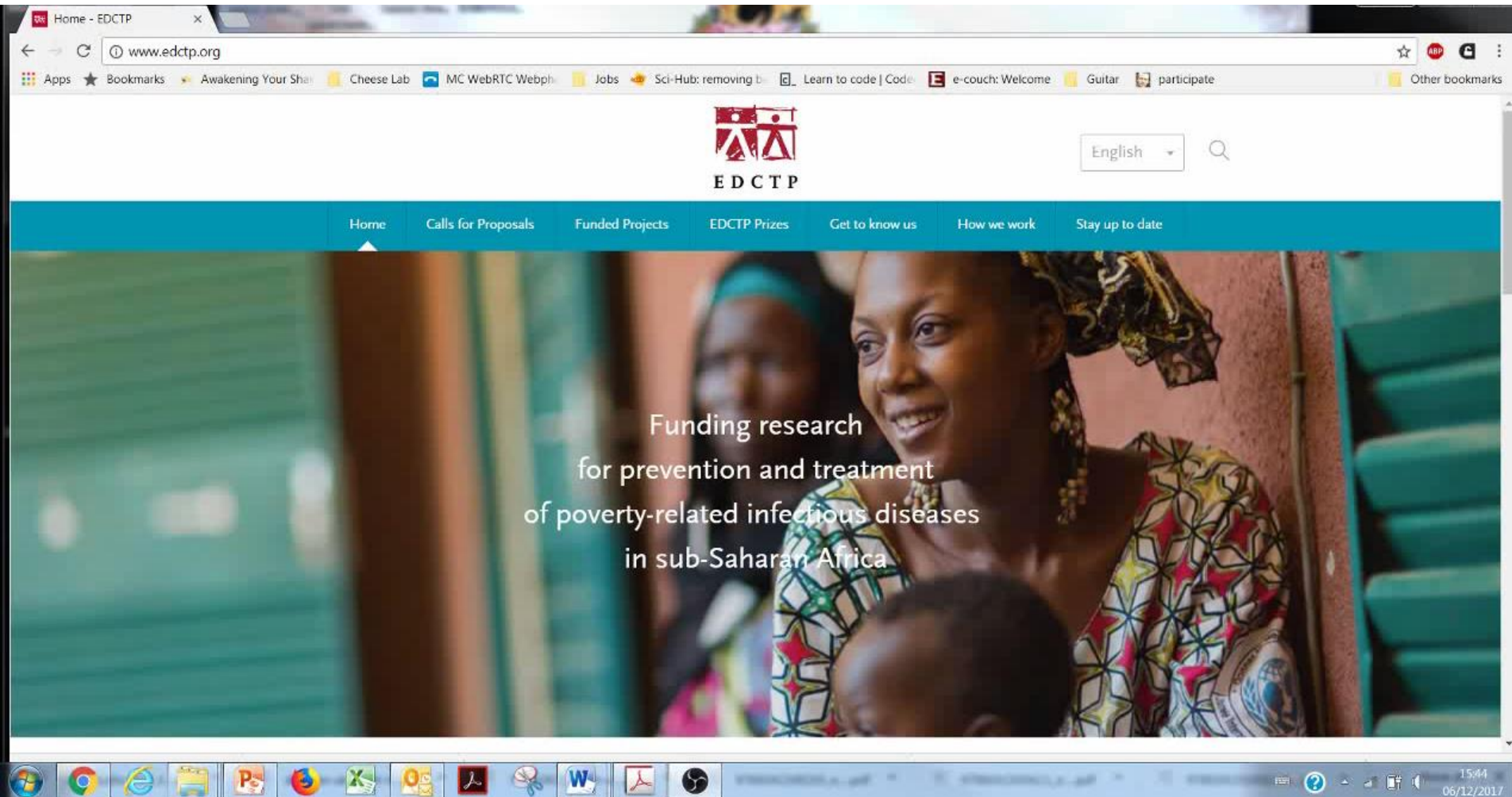
Action	No. calls	No. grants funded	Total amount awarded (M)
Research and Innovation Actions (RIA)	7	34	€217.9
Training & Mobility Actions (TMA)	7	56	€12.2
Coordination & Support Actions (CSA)	6	32	€28.4
<b>Total</b>	<b>20</b>	<b>122</b>	<b>€258.5</b>

\*as of November 2017

# Research and Innovation Actions (2014-2016)



# EDCTP2 programme so far (2014-2016)



The image is a screenshot of a web browser displaying the EDCTP website. The browser's address bar shows the URL [www.edctp.org](http://www.edctp.org). The website's header features the EDCTP logo, which consists of a red shield with white figures, and the text "EDCTP" below it. To the right of the logo is a language dropdown menu set to "English" and a search icon. A teal navigation bar contains the following menu items: Home, Calls for Proposals, Funded Projects, EDCTP Prizes, Get to know us, How we work, and Stay up to date. The main content area is a large banner image showing two women in traditional African attire, one holding a baby. Overlaid on this image is the text: "Funding research for prevention and treatment of poverty-related infectious diseases in sub-Saharan Africa". The browser's taskbar at the bottom shows various application icons and the system clock indicating 15:44 on 06/12/2017.

[www.EDCTP.org](http://www.EDCTP.org)

# EU and global context

## EDCTP involvement in broader trends

- Open access
    - Publications & data (European open science cloud)
  - Transparency
    - clinical trial registration (PACTR)
    - Reports & databases: World RePort (NIH/World Bank, TAG, G-Finder, etc.)
  - Alignment
    - Sustainable Development Goals
    - national, regional and global priorities
  - Emergency preparedness against infectious diseases
    - “Research capacity development in support of the EVD response” (2014)
    - “Research and clinical management of patients in PRD epidemics in sub-Saharan Africa” (2016)
  - Antimicrobial resistance (AMR)
-



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Thank you!  
[surette@edctp.org](mailto:surette@edctp.org)



# EDCTP2 calls for proposals

## RIA Numbers of proposals (2014-2016 Calls)

Call	LoIs	Full proposals invited (%)	Full proposals submitted	Funded (% over FP submitted)	Funded (% over LoI submitted)
RIA – 2014 - Diagnostics	88	22 (25.0%)	21	6 (28.6%)	6 (6.8%)
RIA – 2015 - Treatment	125	42 (33.6%)	40	4 (10.0%)	4 (3.2%)
RIA – 2015 - Strategic	45	10 (22.2%)	10	3 (30.0%)	3 (6.7%)
RIA – 2016- Vaccines	46	17 (37.0%)	15	6 (40.0)	6 (13.0)
RIA – 2016 - Maternal and child health	42	10 (23.8%)	10	4 (40.0)	4 (9.5)
RIA – 2016 – PRD Epidemics	10	3 (30.0%)	3	2 (66.7)	2 (20.0)
RIA – 2016 – Strategic	23	9 (39.1%)	8	5 (62.5)	5 (21.7)
<b>Total</b>	<b>379</b>	<b>113 (29.8%)</b>	<b>107</b>	<b>30 (39.7%)</b>	<b>30 (11.6%)</b>

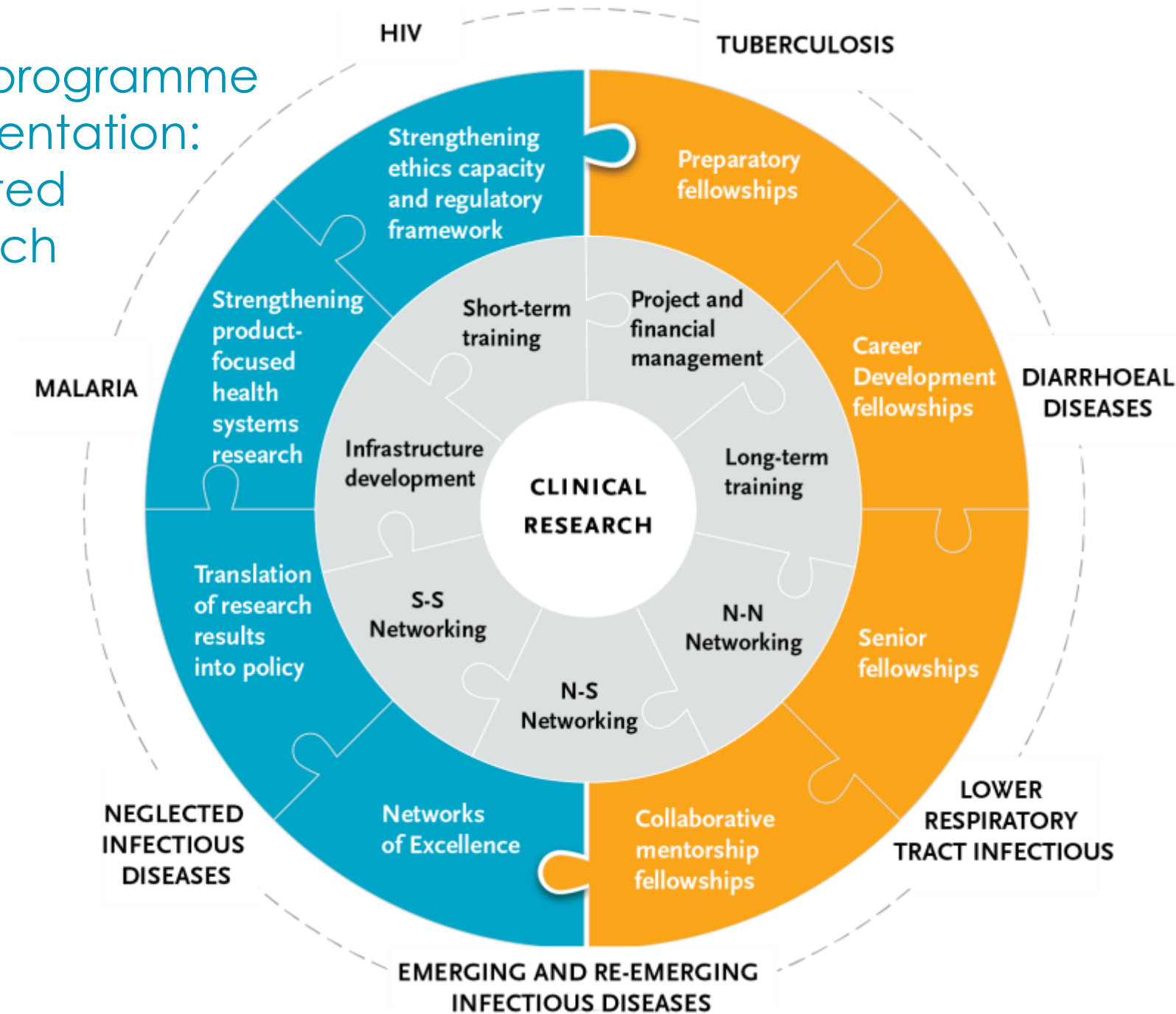


# EDCTP2 calls for proposals

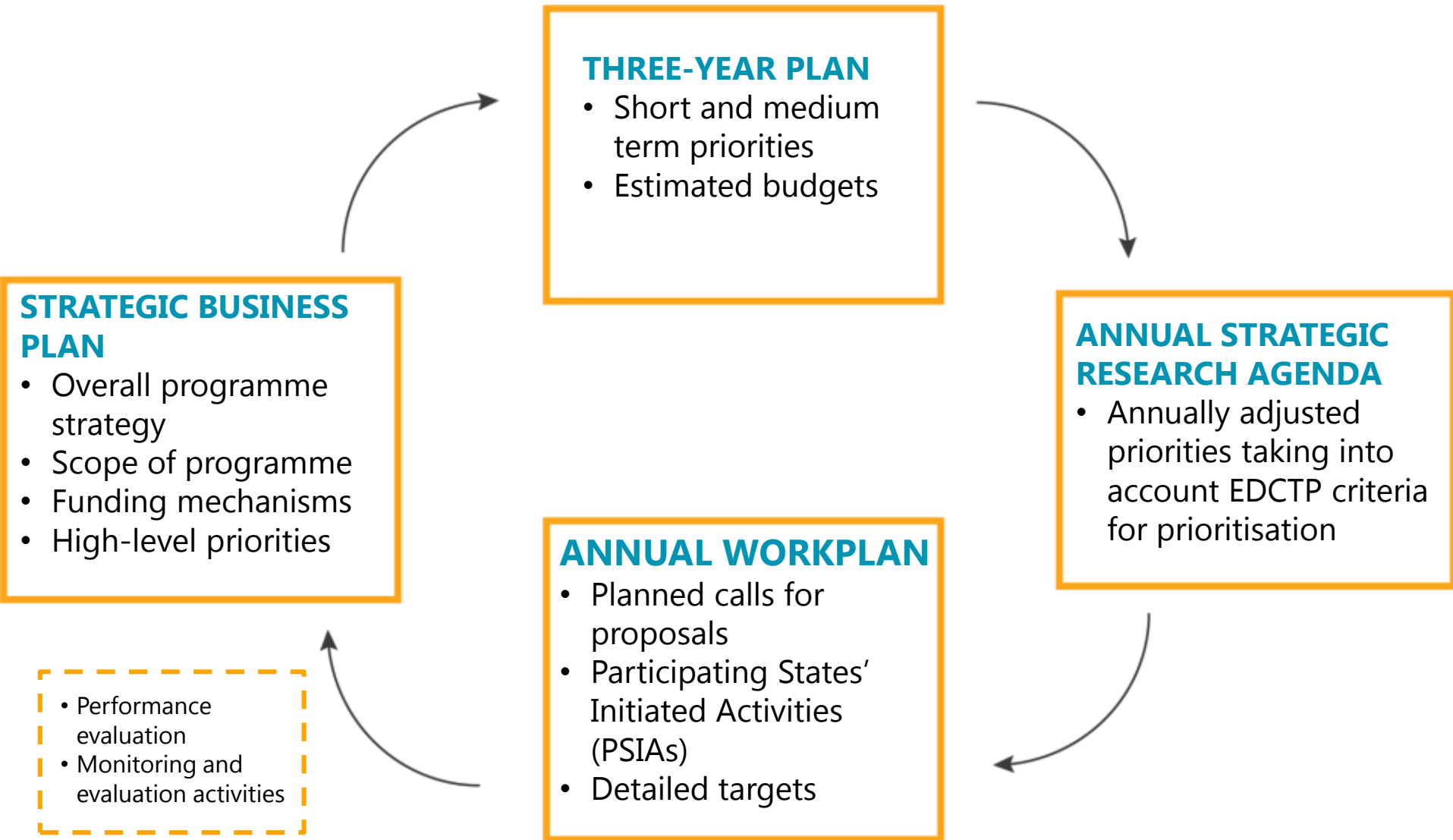
## Portfolio by disease/topic

Topic	Number of RIAs (% of total)	Number of TMAs (% of total)	Number of CSAs (% of total)	Number overall (% of total)
Malaria	3 (10.0)	6 (12.8)	2 (6.3)	<b>11 (10.1)</b>
HIV and HIV-associated infections	6 (20.0)	12 (25.5)	2 (6.3)	<b>20 (18.3)</b>
TB	9 (30.0)	9 (19.1)	2 (6.3)	<b>19 (18.3)</b>
HIV/TB	3 (10.0)	1 (2.1)	0	<b>4 (3.7)</b>
NIDs	5 (16.7)	7 (14.9)	0	<b>12 (11.0)</b>
Emerging diseases	3 (10.0)	1 (2.1)	6 (18.8)	<b>10 (9.2)</b>
Lower respiratory tract infections (LRTI)	1 (3.3)	1 (2.1)	0	<b>2 (1.8)</b>
Diarrhoeal diseases (DD)	0	2 (4.3)	0	<b>2 (1.8)</b>
Ethics and Regulatory	0	0	14 (43.8)	<b>14 (12.8)</b>
Networks	0	0	4 (12.5)	<b>4 (3.7)</b>
Capacity building and training	0	7 (14.9)	2 (6.3)	<b>10 (8.3)</b>
Other	0	1 (2.1)	0	<b>1 (0.9)</b>
<b>Total</b>	<b>30 (100.0)</b>	<b>47 (100.0)</b>	<b>32 (100.0)</b>	<b>109 (100.0)</b>

EDCTP programme implementation: integrated approach



# EDCTP priority-setting mechanisms



# Clinical studies supported by EDCTP



## Clinical trials

Safety and/or efficacy of investigational medicinal product

Product formulation  
Dosing recommendations

Clinical trial on specific populations

Biomarkers  
Pharmacogenomics

Low interventional clinical trials

Effectiveness  
Comparing medical intervention strategies

Pragmatic trials

Optimizing the use of existing intervention  
Diagnostics test validation

Product-focused implementation research

# EDCTP clinical research



Medicinal products	Drug	Human Pharmacology Therapeutic exploratory Therapeutic confirmatory Therapeutic use (Phase I to IV studies)	Clinical development progress leading to registration of new medicinal product, therapeutic regimen, indication, formulation
	Vaccine	<ul style="list-style-type: none"> <li>• Safety and efficacy</li> <li>• Optimisation of interventions for special population groups</li> </ul>	Optimised product formulations for special populations
	Microbicide	<ul style="list-style-type: none"> <li>• Active surveillance to gather product's safety data</li> </ul>	Development of pharmacovigilance platforms and product registries
	Diagnostics	<ul style="list-style-type: none"> <li>• Biomarkers</li> <li>• Pharmacogenomics</li> </ul>	New methodologies and appropriate medical devices for PRDs diagnosis
	Preventive or curative	<ul style="list-style-type: none"> <li>• Implementation research for test validation</li> <li>• Pragmatic studies on effectiveness</li> <li>• Implementation research with a product focus</li> </ul>	Optimising the delivery of existing interventions  Guidelines on benefit of medical intervention in health care  Influencing disease management policies

# Outcome from EDCTP research activities

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- Clinical development progress leading to registration of new medicinal products, therapeutic regimens, indications
- Optimised product formulations for special populations
- Development of pharmacovigilance platforms and product registries
- New methodologies and appropriate medical devices for diagnosis of PRDs
- Optimising the delivery of existing interventions to contribute to a high level of public health
- Guidelines on benefit of medical interventions in health care
- Changing disease management policies

# EDCTP strategy for capacity development

## Strengthening product-focused health systems research

Phase IV studies

- Pragmatic studies
- Implementation research with a product focus
- Pharmacovigilance

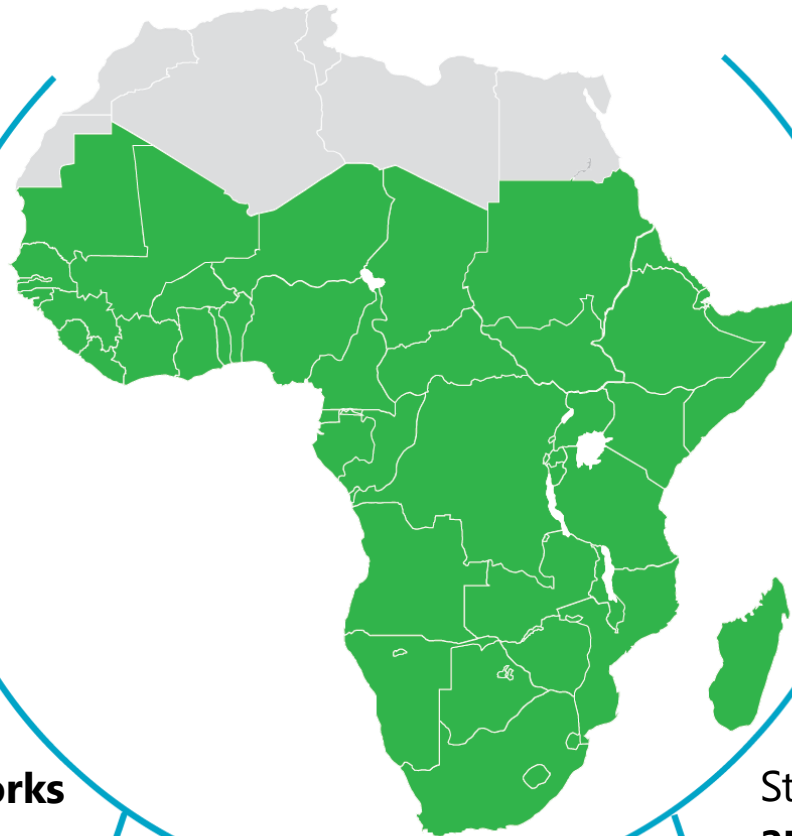
Site preparation for conducting clinical research

## Comprehensive fellowship programme

- Preparatory Fellowship
- R&D Fellowship
- Career Development Fellowship
- Senior Fellowship

Regional Networks of Excellence

Strengthening ethics capacity and regulatory framework



# EDCTP Fellowship schemes

## CLINICAL RESEARCH AND DEVELOPMENT FELLOWSHIP

**Objective:** to support researchers and key members of clinical trial research teams from low- and middle-income countries to acquire specific skills in clinical trials research through placements in pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs.

### Target individuals:

- Post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases
- Post-graduate or medical graduate degree within 15 years of submission of the application
- Researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa.

**Funding level:** 100% of eligible costs

**Max. funding:** €100,000

## EDCTP-AREF PREPARATORY FELLOWSHIP

**Objective:** to enhance the competitiveness of up-and-coming post-doctoral African scientists and clinicians aspiring to win international/regional/national fellowships or grant support through short-term placements at a host organisation in EU Member States, in countries associated to Horizon 2020 or in sub-Saharan Africa which will be contracted by the home organisation to host the fellow.

### Target individuals:

- Post-doctoral scientists
- Individuals who have been awarded their doctorate within three years before submission deadline
- PhD students or MDs who have been active researchers for up to three years following award of their doctorate
- Resident of, or willing to relocate to, a sub-Saharan African country

**Funding level:** 100% of eligible costs

**Max. funding:** €70,000

\* Joint call by EDCTP and the Africa Research Excellence Fund (AREF).

## CAREER DEVELOPMENT FELLOWSHIP

**Objective:** to support junior to mid-career researchers to train and develop their clinical research skills. The objectives are to promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa; and to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research at host organisations in sub-Saharan Africa.

### Target individuals:

- Resident of, or willing to relocate to, a sub-Saharan African country
- A graduate in a subject relevant to the EDCTP2 programme, with a PhD and up to five years' relevant postdoctoral research experience, or a medical doctor with up to five years' research experience
- At least one publication in an international peer-reviewed journal

**Funding level:** 100% of eligible costs

**Max. funding:** €150,000

## SENIOR FELLOWSHIPS

**Objective:** to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior researchers with hands-on training linked to clinical trials activities in sub-Saharan Africa.

### Target individuals:

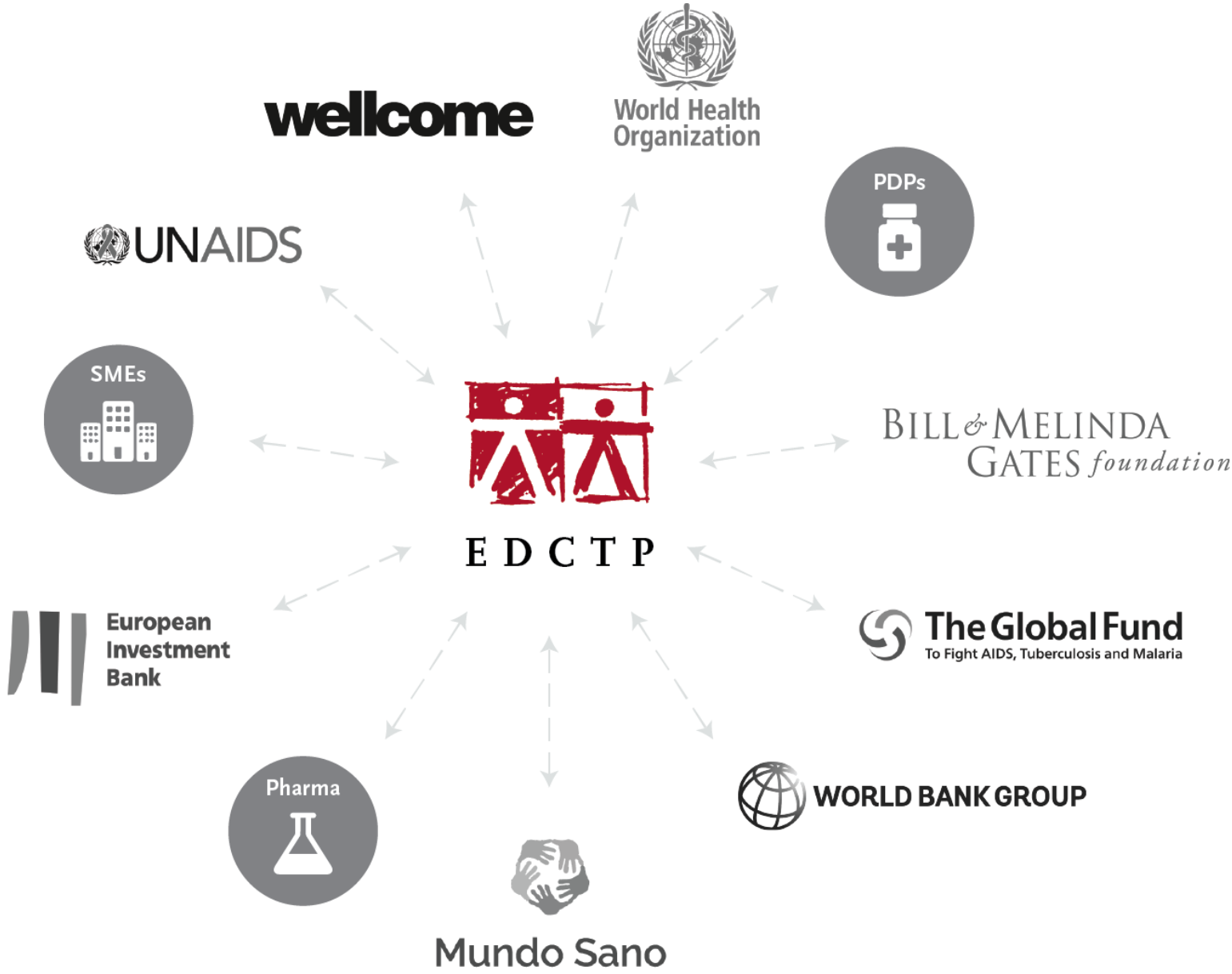
- Resident of, or willing to relocate to, a sub-Saharan African country
- A graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years' research experience after the post-graduate qualification
- A minimum of 5 first-author publications in international peer-reviewer journals

**Funding level:** 100% of eligible costs

**Max. funding:** €500,000.



# Building international collaboration



# Criteria for setting priorities

1

**State of the product development landscape**

For each disease area, these analyses identify the current state of clinical development of interventions for treatment, prevention and diagnosis.

2

**Priority infections**

Analyses of disease burdens and changing patterns of disease feed into priority setting for the poverty-related infectious diseases targeted by EDCTP.

3

**Disease burden and treatment/prevention priorities**

These analyses identify key knowledge gaps and need for new evidence.

4

**Emerging opportunities**

Our expansion into new disease areas and into post-licensing studies, including effectiveness studies, pharmacovigilance and product-focused implementation research, provides new opportunities for EDCTP to achieve impact.

5

**Balanced portfolio**

We aim to develop and sustain a balanced portfolio, across disease areas, types of intervention and type of study, balancing short-term and long-term priorities; this will help to ensure steady flows through product development pipelines.

# Key features of EDCTP



We were established as a flagship European–African partnership and are recognised as an international funder of clinical research for poverty-related infectious diseases.



We are enhancing the research capacity of sub-Saharan African countries to conduct clinical studies in compliance with ethical and regulatory standards.



We operate as a true 'partnership of equals' between North and South, with input from African countries at all levels.

# Key features of EDCTP

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We support studies encompassing populations often excluded from clinical studies but with major unmet medical needs.



Our expansion to cover product-focused implementation research on delivery and uptake of medical research outputs makes our work more relevant to health services in sub-Saharan Africa. It also provides new opportunities for partnership with development assistance initiatives.

# Key features of EDCTP

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We focus on clinical challenges and policy-relevant questions, ensuring results of funded research feed directly into national and international policy-making.



We are committed to working with like-minded partners to promote wider use of the opportunities established for collaborative research.

# EDCTP supported activities

## Research & Innovation Actions (RIA)

Multicentre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.

## Coordination & Support Actions (CSA)

Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.

## Training & Mobility Actions (TMA)

Fellowships that focus on the career development of individual researchers or research team members.

# Eligibility criteria for EDCTP calls for proposals

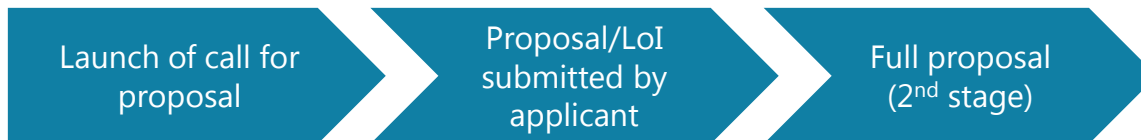
Research & Innovation Actions (RIA)	Coordination & Support Actions (CSA)	Training & Mobility Actions (TMA)
Consortia of $\geq 2$ European countries and $\geq 1$ sub-Saharan African country	Individual institutions or consortia for ethics, training, networking and regulatory activities	Grants to individuals: Career development, Senior, other
Either full funding (RIA) (100% of costs) or cofunding (SRIA) ( $\leq 50\%$ ) with other funders (PSs and/or third parties)	100% funding	100% funding
Broad non-prescriptive topics, bottom-up		

# Competitive process for grants

## Annual work plan with call topics



## Proposal preparation and submission



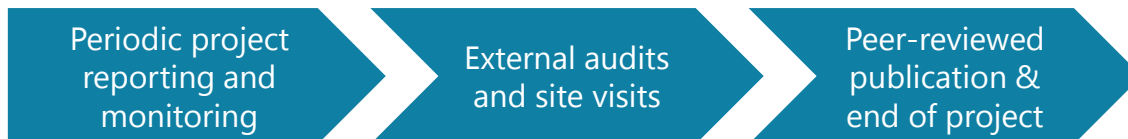
## Proposal review and approval



## Project award

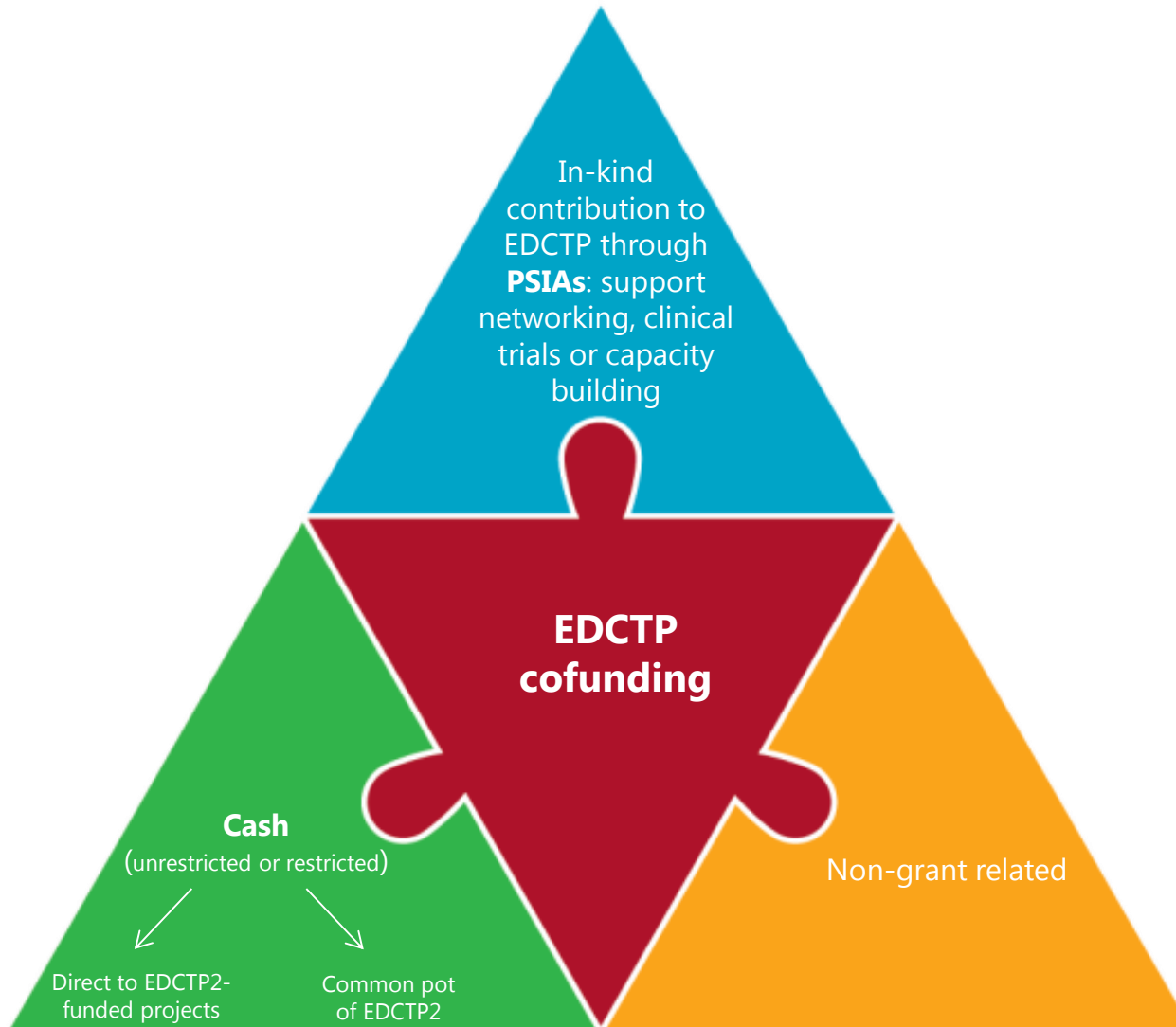


## Monitoring and grant closure





# Types of co-funding by EDCTP Participating States



# What are the Participating States' Initiated Activities (PSIAs)

**Activities funded and managed by a single or several Participating States (independently or jointly) that fall within the scope of the EDCTP programme, based on common principles.**

Equal treatment

Transparency

Independent peer review evaluation

Ethics and scientific integrity

Functional appeal system

Exploitation and dissemination of results

# What are eligible PSIA's?

## Activities within the EDCTP scope

Clinical development of new or improved medicinal products for treatment and prevention of diseases covered by EDCTP

Product focused:  
diagnostics, drugs,  
vaccines and  
microbicides

Networking, coordination,  
alignment, cooperation and  
integration activities on EDCTP  
disease areas

Capacity development for  
clinical research

Implementation research  
with a product focus

All phases of clinical trials  
from human pharmacology  
to therapeutic use

