



EDCTP

The power of sharing science

Strengthening South-North collaboration for research on diarrhoeal diseases

12th Annual Rotavirus Symposium

Johannesburg, 30 July -1 August 2019

Shingai Machingaidze | Project Officer





Outline

- EDCTP: the organisation
- Clinical Trial Portfolio overview
- Capacity Building Strategy
- Currently funded DD projects



Who we are

The **European & Developing Countries Clinical Trials Partnership (EDCTP)** is a public-public partnership between institutions mandated by national governments in Europe and sub-Saharan Africa, and supported by the European Union.

[EDCTP in 3.30 min](#)

EDCTP public-public partnership

14 European Countries

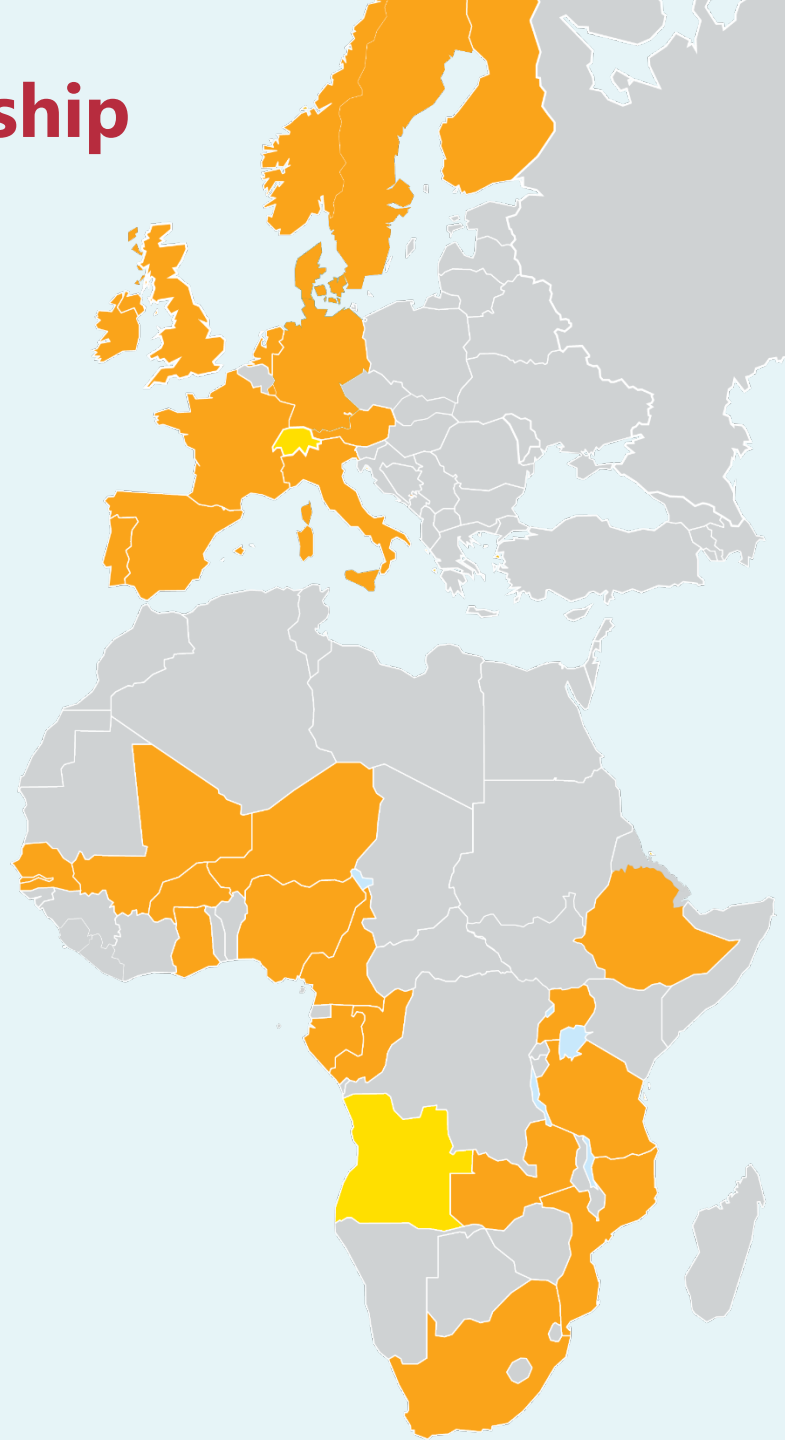
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

2 Aspirant Members

Angola, Switzerland

16 African Countries

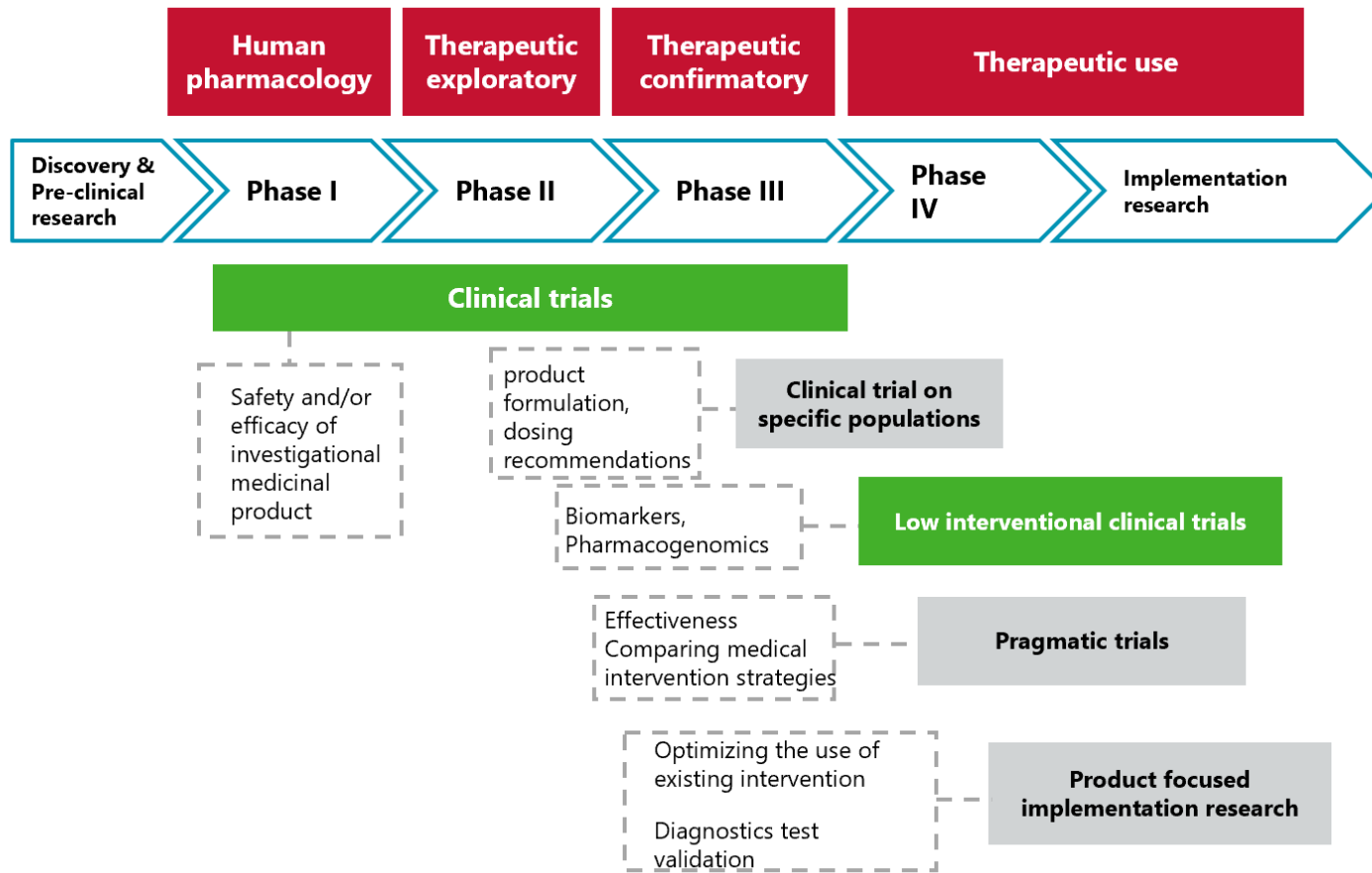
Burkina Faso, Cameroon, Rep of Congo, Ethiopia, Gabon, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia



EDCTP supported activities

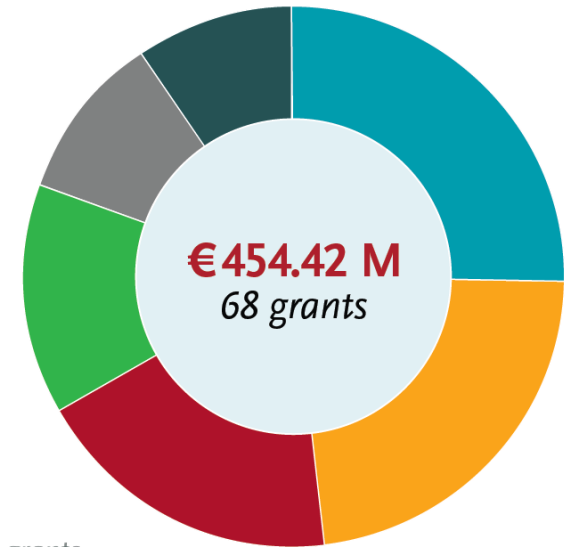
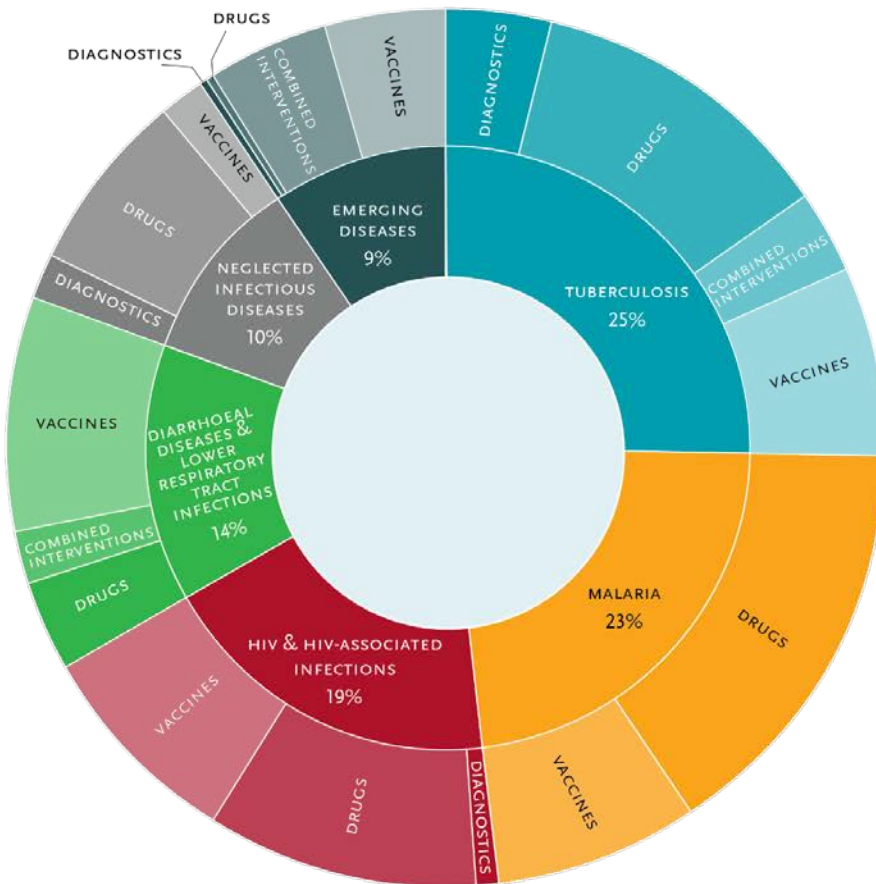
Research & Innovation Actions (RIA)	Coordination & Support Actions (CSA)	Training & Mobility Actions (TMA)	Other activities
Multi-centre clinical trials that are conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.	Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.	Fellowships that focus on the career development of individual researchers or research team members.	Non-call specific e.g. trainings, communication and dissemination, advocacy, networking and outreach activities
Either 100% EDCTP funding (RIAs) or $\leq 50\%$ EDCTP funding (Strategic RIAs; with $\geq 50\%$ cofunding from other funders)	100% EDCTP funding	100% EDCTP funding	100% EDCTP funding

Clinical studies supported by EDCTP



Portfolio of projects: collaborative clinical trials and clinical studies

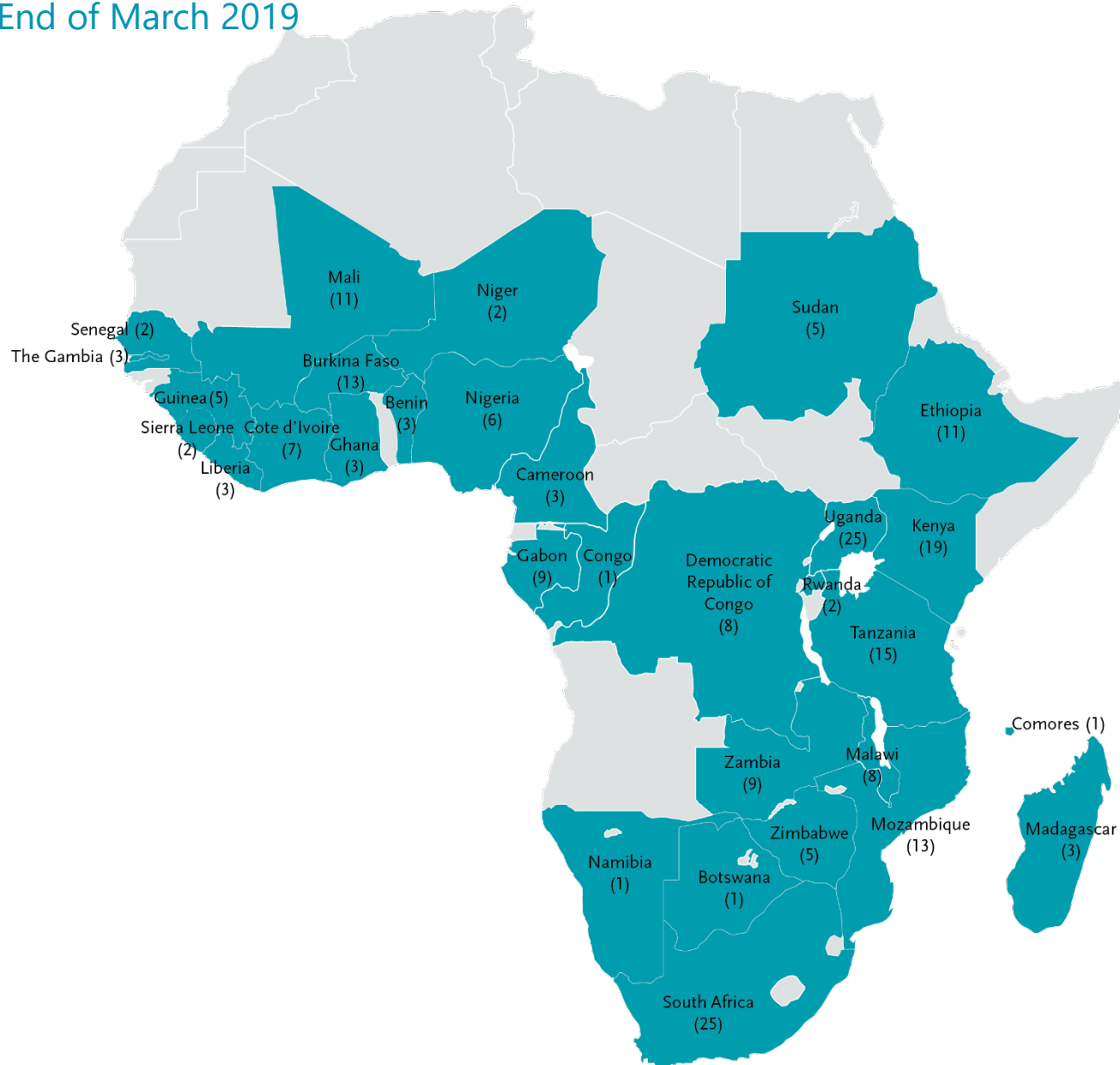
2014 - End of March 2019



- Tuberculosis, 16 grants
€115.30 M
- Malaria, 10 grants
€103.28 M
- HIV & HIV-associated infections, 13 grants
€85.10 M
- Diarrhoeal diseases and lower respiratory tract infections, 8 grants
€63.03 M
- Neglected infectious diseases, 12 grants
€46.10 M
- Emerging diseases, 9 grants
€41.61 M

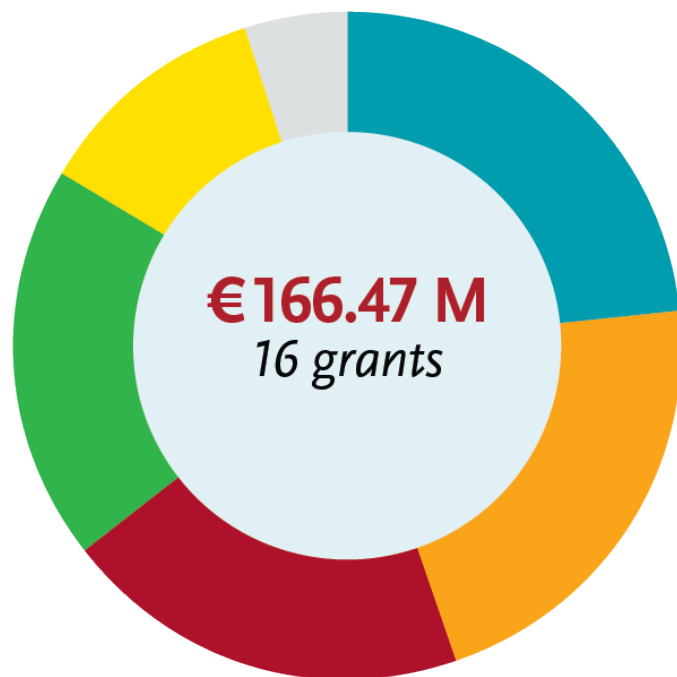
Clinical studies in sub-Saharan Africa

2014 - End of March 2019



Vaccine R&D funding

2014 - End March 2019



- Diarrhoeal diseases & lower respiratory tract infections, 4 grants
€38.95 M
- HIV & HIV-associated infections, 4 grants
€35.58 M
- Malaria, 2 grants
€33 M
- Tuberculosis, 3 grants
€31.82 M
- Emerging diseases, 2 grants
€19.12 M
- Neglected infectious diseases, 1 grant
€8 M

EDCTP Strategy for Capacity Development

Strengthening product-focused health systems research

Phase IV studies

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

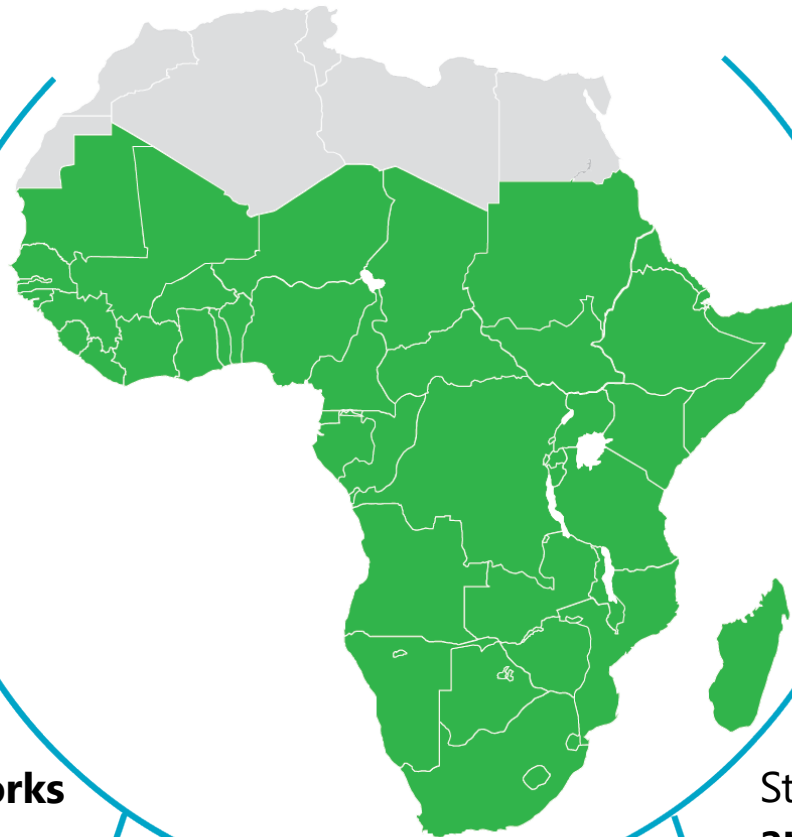
Site preparation for conducting clinical research

Comprehensive fellowship programme

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

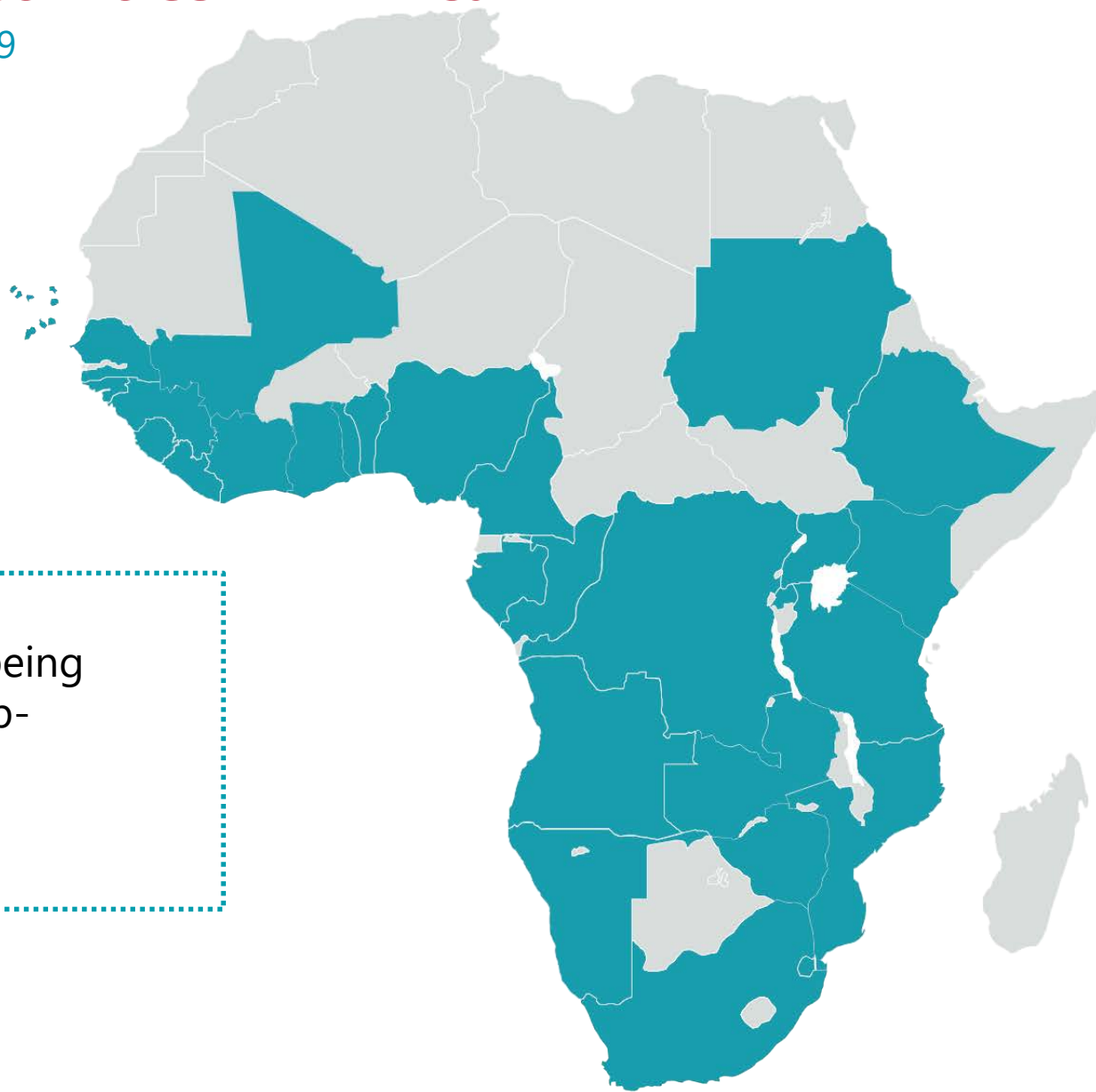
Regional Networks of Excellence

Strengthening ethics capacity and regulatory framework



EDCTP's contribution towards ethics and regulatory activities in Africa

2014- End of March 2019



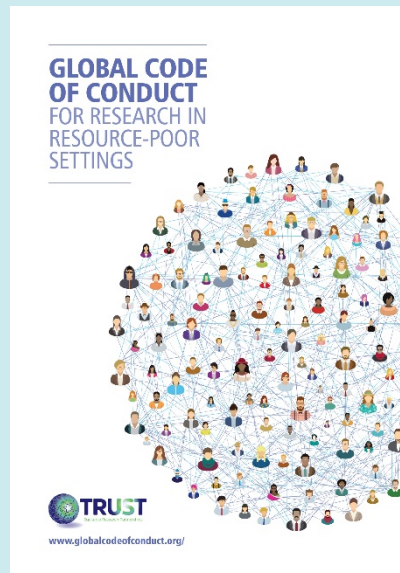
29 projects are being conducted in sub-Saharan African countries.

The TRUST Project



- A global collaborative effort to improve adherence to high ethical standards in research around the world
- 3-year project funded by the EU (2015-2018)
- 13 global multi-disciplinary partners

- Development of the Global Code of Conduct for Research in Resource-Poor Settings
- Adoption of the Code as guidance material by the European Commission.



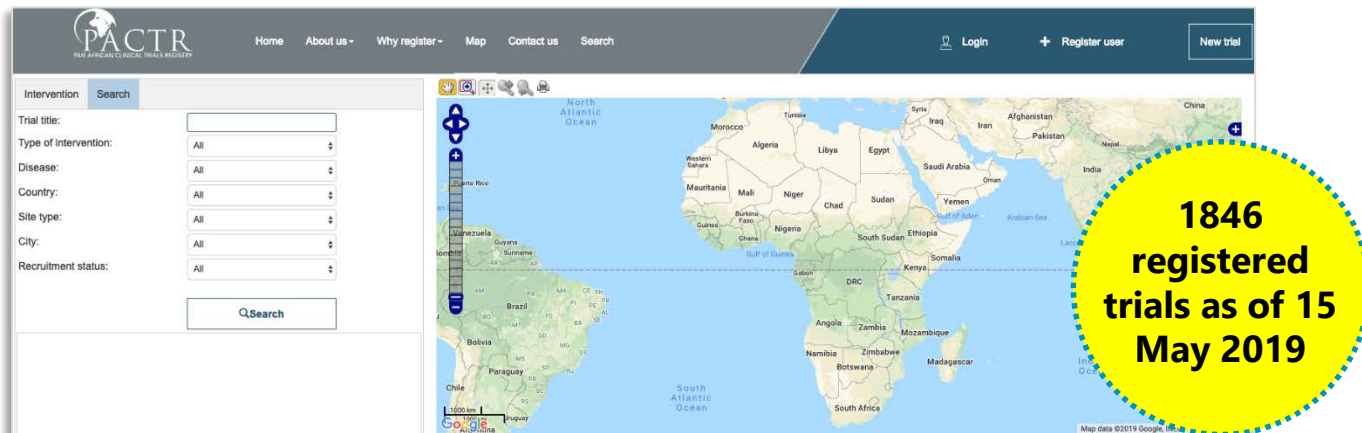
Ensuring transparency in clinical trials to inform health research

Registration of clinical trials provides policymakers, health researchers and funding agencies with comprehensive over view of clinical trials being conducted in specific countries and disease areas.

PACTR – *Pan-African Clinical Trials Registry* <https://pactr.samrc.ac.za/>

Aim: PACTR was established in 2006 as a repository tailored to the needs of researchers working on trials in Africa. In 2009, PACTR was officially recognised as a WHO primary registry, and is the only WHO-endorsed primary registry in Africa.

Impact: PACTR provides a valuable tool for exploring the current status of research in Africa in different areas of medicine, on different infections, and in different countries. PACTR also supports the work of regulatory agencies, ethics boards and systematic reviewers in Africa.



The image shows a screenshot of the PACTR website. On the left, there is a search form with the following fields: Trial title, Type of intervention (dropdown menu), Disease (dropdown menu), Country (dropdown menu), Site type (dropdown menu), City (dropdown menu), and Recruitment status (dropdown menu). A 'Search' button is located below the form. On the right, there is a world map with a callout bubble in the bottom right corner. The callout bubble is yellow with a blue border and contains the text: '1846 registered trials as of 15 May 2019'. The website header includes the PACTR logo and navigation links: Home, About us, Why register, Map, Contact us, Search, Login, Register user, and New trial.

Health Systems Strengthening

2018 Call for Proposals

Objective

- The purpose of this Call for Proposals is to support actions that will facilitate the translation of research results of medical interventions into policies and practices for national health programmes in order to strengthen health systems

Type of action: Coordination & Support Actions (CSAs)

Project budget: up to €2.25 million

Funding level: 100% of eligible costs

Stage 1 Open date: 12 June 2018, 00:00

Stage 1 Close date: 11 October 2018, 17:00

Stage 2 Open date: 21 December 2018, 00:00

Stage 2 Close date: 28 March 2019, 17:00

Call identifier: CSA2018HS

Pharmacovigilance capacities

Total investment

€6.30 M



The PAVIA consortium

- To strengthen links between NRAs, national public health programmes and local medical research institutes

The PROFORMA Consortium

- To build workforce capacity by strengthening links between NRAs and local academic institutions

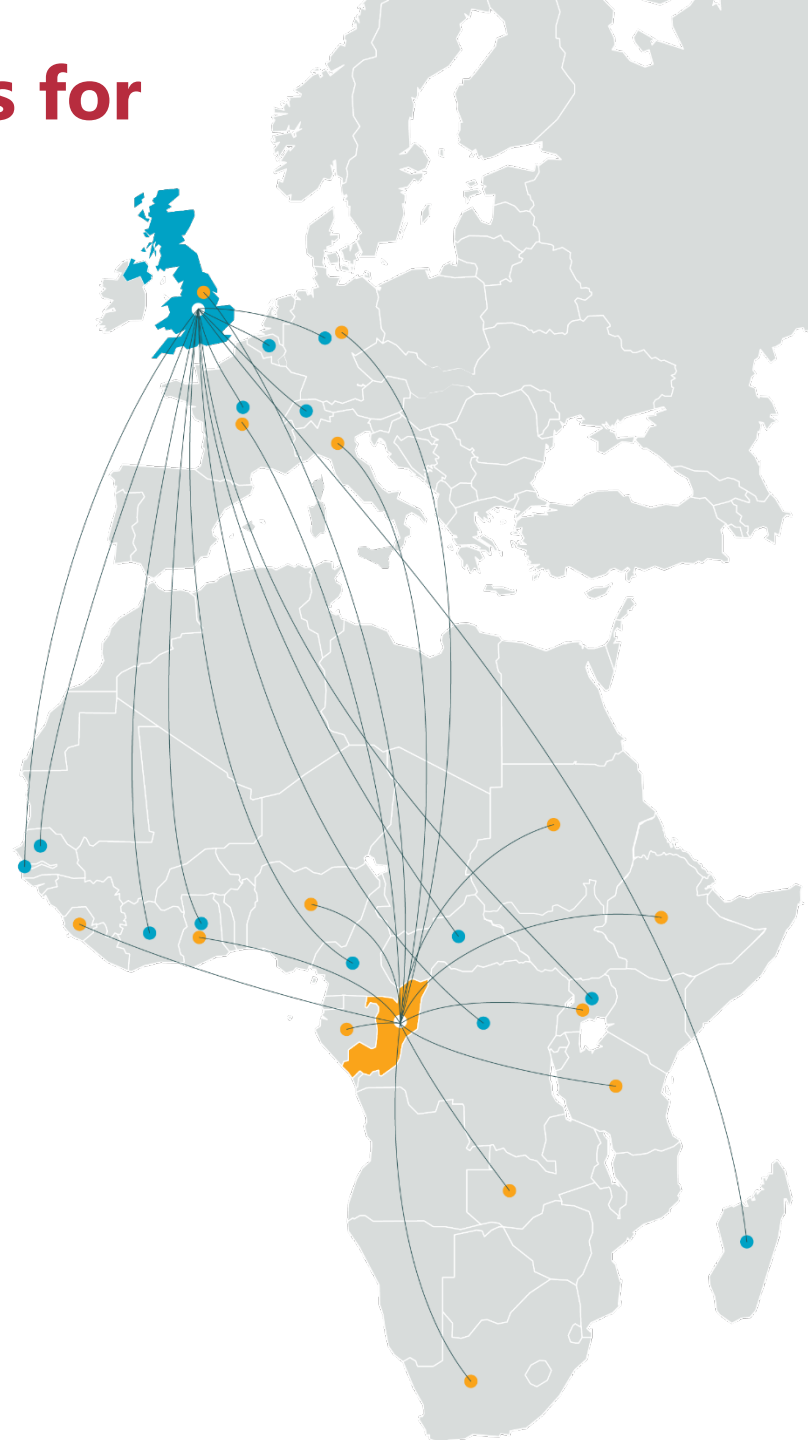
The EAPI project

- To bring together the Kenyan NRA (the Pharmacy and Poisons Board) and the University of Nairobi

Health system preparedness for outbreak response

ALERRT and PANDORA-ID-NET consortia

- Research and clinical management of patients in PRD epidemics in sub-Saharan Africa
- Aim: to establish a multidisciplinary consortium, able to provide **accelerated evidence for the optimal clinical management of patients, and for guiding the public health response to severe infectious outbreaks.**
- **18 African countries** (Cameroon, Central African Republic, Congo, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Gabon, The Gambia, Ghana, Madagascar, Nigeria, Sierra Leone, Senegal, South Africa, Sudan, Tanzania, Uganda and Zambia)
- **6 European countries** (Belgium, France, Germany, Italy, Switzerland, United Kingdom)



EDCTP2 Regional Networks of Excellence

African countries

1. Angola
2. Botswana
3. Burkina Faso
4. Cameroon
5. Congo
6. Democratic Republic of the Congo
7. Ethiopia
8. Gabon
9. Gambia
10. Ghana
11. Guinea-Bissau
12. Kenya
13. Malawi
14. Mali
15. Mozambique
16. Namibia
17. Nigeria
18. Rwanda
19. Senegal
20. South Africa
21. Sudan
22. Tanzania
23. Togo
24. Uganda
25. Zambia
26. Zimbabwe

European countries

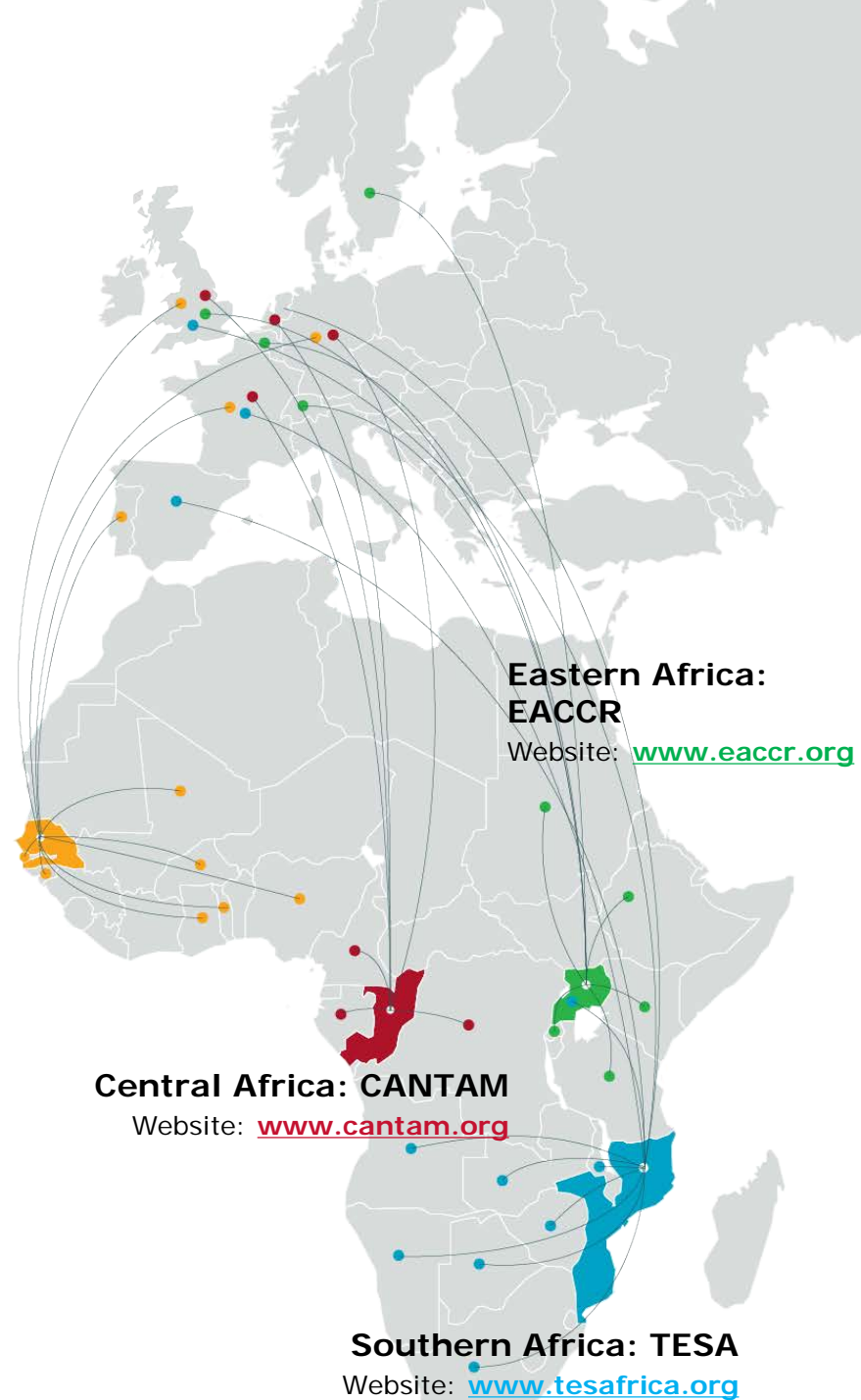
1. Belgium
2. France
3. Germany
4. Netherlands
5. Portugal
6. Spain
7. Sweden
8. Switzerland
9. United Kingdom

Western Africa: WANETAM

Website: www.wanetam.org

Outputs from EDCTP1:

- United 63 institutions in 21 African countries
- Offered short- and long-term training to 1000 researchers
- Leveraged additional € 24 M
- Published 38 peer-reviewed papers
- Strengthened laboratories to achieve international accreditation



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.



EDCTP Fellowships

2003-2018

- Geographical distribution of Fellows is skew with South Africa, Uganda, Kenya, and Tanzania having the highest number of Fellows.
- Challenge remains in Central and West Africa with many of these countries being French or Portuguese speaking.
- EDCTP needs to leverage on the strong research institutions to help strengthen and mentor those lagging behind

By gender



97

Male fellows



49

Female fellows

By country



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The EDCTP Alumni Network

Fostering excellence and collaboration in the next generation of researchers

About the EDCTP Alumni Network

The general objective of the second programme of the European and Developing Countries Clinical Trials Partnership (EDCTP2) is to contribute to the reduction of the social and economic burden of poverty-related infectious diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions. Enhanced collaborations between health research scientists and

The EDCTP Alumni Network objectives:

- To provide a mechanism by which EDCTP can profile all Fellows and keep up to date with their career progress and ongoing research projects
- To provide a tool that facilitates easier networking and collaboration among EDCTP Fellows and the extended research community
- To increase the visibility of the EDCTP comprehensive fellowship programme and demonstrate the lasting impact of investing in capacity building of African-based scientists

Currently funded DD projects

Senior Fellowship 2016

Dr Roma Chilengi

CIDRZ, Zambia

Title: A randomized controlled trial of two versus three doses of Rotarix™ vaccine for boosting and longevity of vaccine immune responses in Zambia.

Acronym: **ROVAS-2**

Duration: 48 months

Amount: €499 456.25

Career Development Fellowship 2016

Dr Caroline Chisenga

CIDRZ, Zambia

Title: Immunogenicity to cholera vaccine within a population at risk in Zambia: mapping the kinetics of immune responses over time

Acronym: **ChoVaxim**

Duration: 36 months

Amount: €149 956.25



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Diarrhoeal Diseases (DDs)



Dr Roma Chilengi
(SF) - 2016

A randomized controlled trial...



Dr Caroline Chisenga
(CDF) - 2016

Immunogenicity to cholera vacc...

www.edctpalumninetwork.org

Two additional fellowship grants under negotiation worth €300 000.

Currently funded DD projects

RIA 2017 Strategic

Dr Florian Marks

University of Cambridge

Title: Effect of a novel typhoid conjugate vaccine in Africa: a multicenter study in Ghana and the Democratic Republic of the Congo

Acronym: **THECA**

Duration: 60 months

Amount: €12 988 657.59

RIA 2017 Strategic

Mr Björn Sjöstrand

Scandinavian Biopharma Holding AB (SBH)

Title: Field studies of an oral whole cell ETEC vaccine candidate in African toddlers and children: Assess efficacy, and set parameters for pivotal Phase 3 trials

Acronym: **ETEC Vaccine Efficacy**

Duration: 48 months

Amount: €7 368 180.50

An additional phase II Shigella vaccine grant under negotiation worth €8 604 333.

THANK YOU

VISIT:

www.edctp.org

www.edctpalumninetwork.org

www.edctpgrants.org

CONTACT:

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Acknowledgements:

EDCTP Calls and Grants Team

EDCTP Finance Team