



EDCTP

The power of sharing science

EDCTP Strategic Business Plan for 2014–2024



Supported by the
European Union



About EDCTP

EDCTP's mission is to contribute to the reduction of the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa.

We support collaborative clinical research to accelerate the development of accessible, suitable and affordable medical interventions to identify, prevent or treat these diseases. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.



Photo:
Researchers at KAVI-Kenyatta National Hospital in
Nairobi, Kenya
*part of the HIV-CORE004 project (led by Prof.
Thomáš Hanke)*

Foreword

It is my pleasure to introduce the new concise version of the original Strategic Business Plan that underpinned the elaboration and initial implementation of the second EDCTP programme. As the programme is now being rolled out and up to speed, a concise strategy will help us to stay focused and reach out to potential partners with a clear message.

The practical purpose of this publication is therefore twofold. It will assist the members of the EDCTP Association to keep the Partnership on a purposeful course amidst the many choices inherent in the broad scope of EDCTP. The Strategic Business plan identifies clear priorities for our funding strategy in order to achieve the EDCTP objectives. Likewise, it will assist the African and European member states of EDCTP to align their national research efforts towards a joint programmatic effort. In this way they will provide the necessary counterpart to EDCTP-funded research mainly supported by the European Union. Our programme needs both these contributions to get the results we all pursue.

Secondly, this publication will be of considerable help in reaching out to new partners. In its concise form it clearly conveys who we are, what we want to achieve, how we operate and what our specific priorities are. This is necessary to gain the trust of other stakeholders, be they academic researchers, product development partnerships, national authorities considering a full membership of the Partnership, international

agencies, philanthropic organisations, or pharmaceutical and biomedical companies.

Our calls for proposals will reflect our strategy, values, objectives and priorities. Their competitive nature, independent review, and yes sometimes detailed procedures should keep no one from participating. Researchers and companies alike thrive on competition; international collaboration contributes to better results. Competitiveness and collaboration will help us invest in the best international research projects available.

I fully expect that the Strategic Business Plan in this ready-to-hand format will assist the Partnership in staying focused on its mission. I am equally confident that it will show other stakeholders clear ways to collaborate with EDCTP in our common fight against infectious diseases of poverty.

Dr Mark Palmer

*Representative for the United Kingdom
Chair of the EDCTP Board and the EDCTP
General Assembly*

The European & Developing Countries Clinical Trials Partnership (EDCTP) is an innovative public–public partnership through which countries in Europe and sub-Saharan Africa are working together to alleviate the health and economic burden of infectious disease in Africa. Founded in 2003, it has united clinical researchers, health professionals, policy-makers and other public and private partners spanning the North and South, advancing the development of drugs, vaccines and other medicinal products to control key infectious diseases affecting people in sub-Saharan Africa and strengthening the capacity of African medical research to address these challenges in the future.

This document summarises the strategy for the second EDCTP programme (EDCTP2) covering the ten-year period 2014–2024. It summarises the scope, objectives and key features of EDCTP2, and its implementation by the EDCTP Association, the legal entity established to deliver the programme.

An earlier version of the Strategic Business Plan for EDCTP2 was approved in May 2013 on behalf of the national authorities with political responsibility for each country's participation in EDCTP. It supported the European Commission proposal for EDCTP2 that was approved by the European Parliament and by the Council of the European Union in their Decision No 556/2014/EU of 15 May 2014. The objectives of the EDCTP2 programme are described in full in Annex 1 of this document. The updated Strategic Business Plan summarised here was approved by the EDCTP General Assembly in June 2016.

In its first 10 years, EDCTP established a reputation for supporting high-quality studies that influenced national and international health policy and practice. We aim to achieve yet more in the coming decade and – through this new programme and in partnership with like-minded organisations – ultimately to improve the health and wellbeing of the people living in sub-Saharan Africa.

Dr Michael Makanga

Executive Director, EDCTP



Photo:
Clinic staff and study volunteer at the Charles De Gaulle
University Hospital, in Ouagadougou, Burkina Faso
part of the MONOD project (led by Dr Valériane Leroy)

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Executive summary

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. It was set up to support high-quality collaborative research to accelerate the development of new or improved medical interventions for poverty-related as well as emerging and re-emerging infectious diseases affecting sub-Saharan Africa.

EDCTP was established by the EU in 2003. The first EDCTP programme ran until 2015 and focused on HIV, tuberculosis (TB) and malaria. It supported numerous trials that aimed to have a significant impact on the diagnosis, treatment and prevention of these diseases. In light of significant unmet medical needs, the scope of the second programme (EDCTP2) was extended, covering neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections affecting sub-Saharan Africa (such as Ebola and yellow fever), in addition to HIV, TB, and malaria.

We fund all phases of clinical trials (I–IV), with a particular focus on phase II and phase III studies. Our post-licensing (phase IV) studies encompass pharmacovigilance and effectiveness studies (pragmatic trials) as well as medicinal product-focused implementation research. We support research on the full range of medical interventions, including diagnostics, drug treatments, and vaccines and other preventive measures such as microbicides.

Our second important goal is to strengthen the capacity of institutions in sub-Saharan Africa to carry out clinical research. EDCTP funds the development of laboratory and clinical facilities and other infrastructure required for clinical research and associated studies. We are also developing local expertise and scientific leadership, through training, mentoring and by providing career development opportunities for African researchers, from master's and PhD training through to senior fellowships.

We are also working to establish an enabling environment for research, particularly by helping sub-Saharan Africa countries to strengthen their ethical, regulatory and legal frameworks for research, ensuring they are able to host clinical studies consistent with international standards and respecting local regulations.

Our research and capacity-building activities are underpinned by a strong commitment to international networking. North–South collaboration promotes the exchange of knowledge and expertise between researchers and institutions in Europe and in Africa. North–North networking is encouraging coordinated activities in Europe, to maximise the impact of investments in health research. South–South collaboration, which includes regional Networks of Excellence, supports sharing of local expertise and is enabling proven capacity for multicentre international studies. We engage with African governments to promote a better alignment of research and development agendas within our areas of interest.

We work with a wide range of partners beyond the European and African Participating States. Other countries in Europe and Africa can work with the programme, while researchers outside Europe and Africa can join EDCTP-funded collaborations. We engage with national and international development agencies for collaboration and alignment in view of common goals. We also work with international organisations, industry, private non-profit organisations and public–private product development partnerships, which can take advantage of the funding offered by EDCTP.

EDCTP2 is a ten-year programme, running from 2014 to 2024, due to receive up to €683M funding from the EU through its Horizon 2020 initiative matching the investments provided by European Participating States. The EDCTP Association, registered in The Netherlands, is the legal structure established to deliver the programme. Its key decision-making body is the EDCTP General Assembly, which includes representatives from all mandated institutions from Participating States (currently 14 European and 14 African countries). The EDCTP Executive Secretariat, responsible for the day-to-day management of the programme, has offices in The Hague, The Netherlands, and in Cape Town, South Africa.



Photo:
Laboratory staff at the Kilimanjaro Clinical Research Institute (KCRI)-Kilimanjaro Christian Medical Centre (KCMC) part of the PanACEA-MAMS project (led by Dr Martin Boeree, Prof. Michael Hoelscher and Prof. Stephen Gillespie)

EDCTP: international partnership against infectious diseases

EDCTP is a public–public partnership funding concerted and coordinated action against poverty-related infectious diseases affecting sub-Saharan Africa.

Tackling the questions that matter

We support North–South collaborations undertaking major clinical trials of drugs and other medicinal products – such as vaccines and diagnostics – needed to control infectious diseases. Our ultimate aim is to reduce the health and economic impact of poverty-related infectious diseases in sub-Saharan Africa – HIV, TB, malaria, the neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging diseases.

Driven by the needs of the South and a genuine 'partnership of equals', we are committed to supporting high-quality clinical research that accelerates the development of medical interventions that have the potential to make a real difference to the lives of millions of people across sub-Saharan Africa.

A lasting legacy

As well as generating valuable data on new and improved medical interventions, we are also building the capacity of countries in sub-Saharan Africa to undertake clinical research, so they can continue to support live-saving research into the future. Within the scope of EDCTP2, we fund new research facilities and equipment, and are supporting the intellectual development and training of the next generation of African researchers and scientific leaders.

Working together to achieve more

Partnerships lie at the heart of our work. As well as scientific collaborations spanning North and South, we encourage greater coordination of funding and research activities to focus resources on key questions and to maximise impact. Regional networks in Africa are helping to share resources, expertise and knowledge, and enable more countries to participate in clinical research. Strong links with policy-makers increase the likelihood that new evidence generated by EDCTP-funded studies feeds into national and international policy and practice.

Lowering the hurdle to participation

As well as working closely with Participating States (Box 1), we are committed to establishing productive relationships with other partners – including additional countries in Europe and in sub-Saharan Africa, national and international development agencies, intergovernmental organisations, other funding agencies and charitable organisations, WHO initiatives, for-profit organisations, and product development partnerships. EDCTP funding enables high-quality collaborative multisite clinical trials, with the potential to accelerate the development of medical interventions and ensure that populations benefit more rapidly from potentially life-saving treatments and preventive interventions.

Box 1: Membership of the EDCTP Association

Membership of the EDCTP Association is open to:

- Sovereign states from the European Union (EU)
- Other sovereign states associated to the EU's Framework programme for research, technological development and demonstration activities (Horizon2020)
- Sovereign states from sub-Saharan Africa
- (Groups of) institutions specifically mandated for this purpose by the aforementioned states
- Alliances of sovereign states and/or mandated institutions from the EU, and
- Alliances of sovereign states and/or mandated institutions from sub-Saharan Africa.

EDCTP Participating States

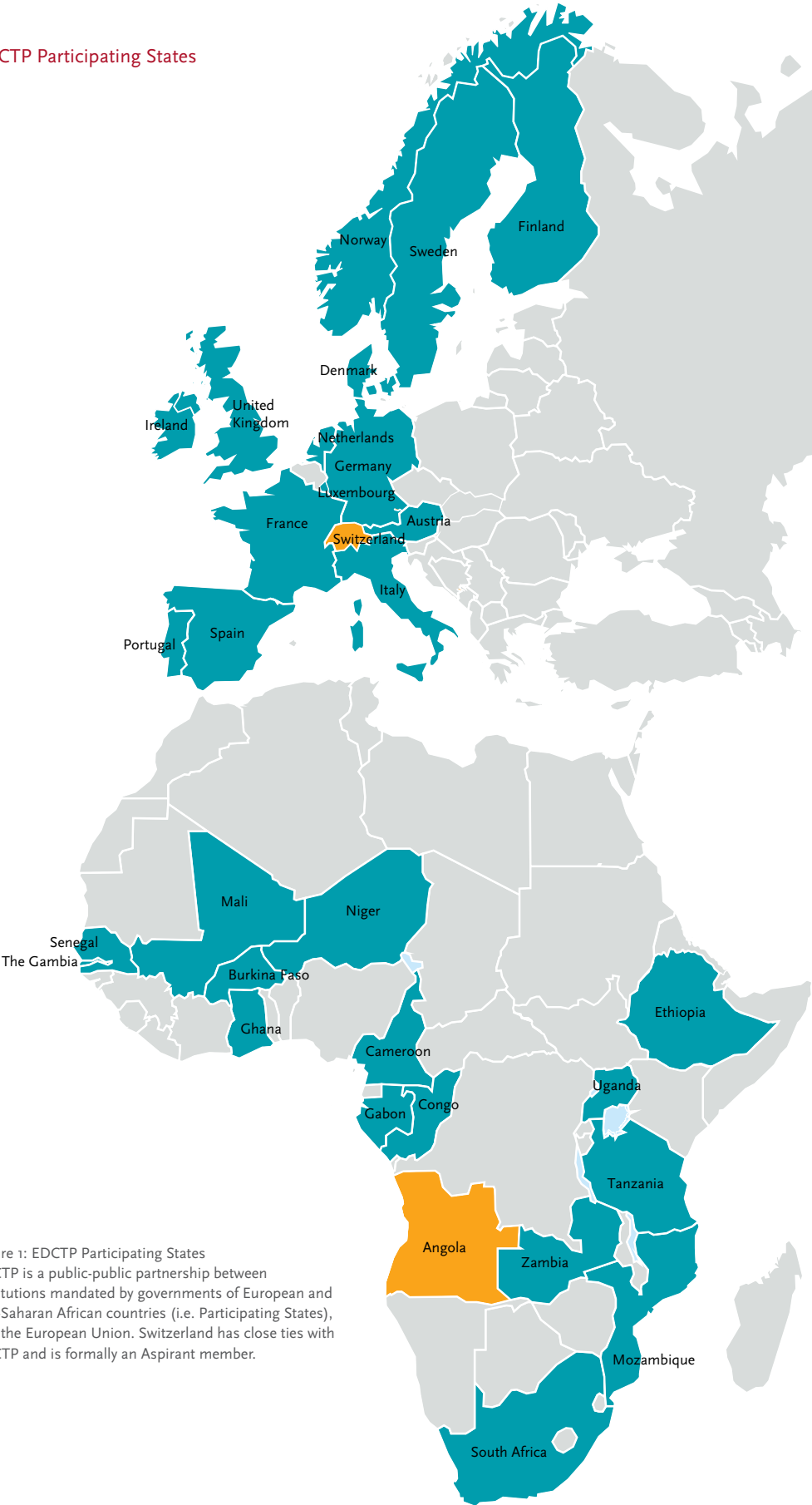


Figure 1: EDCTP Participating States
EDCTP is a public-public partnership between institutions mandated by governments of European and sub-Saharan African countries (i.e. Participating States), and the European Union. Switzerland has close ties with EDCTP and is formally an Aspirant member.

The global health challenge

EDCTP is focused on some of the greatest areas of unmet medical need in sub-Saharan Africa – infectious diseases that blight the lives of millions.

Globally in 2013, lower respiratory tract infections were responsible for some 2.7 million deaths, HIV 1.3 million, TB 1.3 million, diarrhoeal diseases 1.3 million and malaria 850 000. Most of these deaths occurred in low-income countries, particularly in sub-Saharan Africa where the burden of infectious disease is highest. In addition, many millions of people are affected by multiple other ‘neglected’ infectious diseases (Box 2), as well as emerging and re-emerging infectious diseases.

Diseases such as HIV and TB predominantly affect young and middle-aged adults in the prime of life, while other big killers such as malaria, pneumonia and diarrhoeal diseases exact a high death toll among children. As a result, infectious diseases are a leading contributor to poverty in Africa.

Weak health systems in sub-Saharan Africa, with limited research capacity, present a further challenge in many countries. Moreover, Africa has limited research capacity, although there is increasing research activity led by African scientists, in part due to EDCTP's work.

Meeting the challenge

The development and clinical evaluation of new medical interventions is expensive, and commercial organisations are often reluctant to invest in diseases that mainly affect low-income countries. The product development pipeline for poverty-related diseases is thus poorly stocked and progress is often slow. Nevertheless, innovative mechanisms have

been established to accelerate the discovery and assessment of new medical interventions for poverty-related diseases, including major international public–private partnerships. The first EDCTP programme made an important contribution to this landscape, boosting the capacity of sub-Saharan African countries to host clinical trials in HIV, TB and malaria (Box 3).

The drive to achieve Millennium Development Goals provided important impetus for the creation of EDCTP. Equally, the second EDCTP programme will make a significant contribution to Sustainable Development Goals (SDGs). SDG3: ‘Ensure healthy lives and promote well-being for all at all ages’, will require concerted action on poverty-related diseases in Africa. Furthermore, improved health and its attendant economic benefits will contribute to multiple social and economic goals.

Maintaining momentum

Encouragingly, several new medicines have been developed for common infections such as HIV, TB and malaria. However, many groups – such as children and pregnant women – have yet to benefit fully from these treatments and preventive interventions. There is also a growing need to identify the most effective and sustainable ways to deliver interventions to populations in need.

In addition, there is a continuing need for additional and more effective treatments, while the inevitable development of resistance demands a constant stream of new drugs. Treatment and control programmes would also greatly benefit from affordable and easy-to-use diagnostics for identifying specific infections and drug resistance.

Box 2: Neglected infectious diseases

- Buruli ulcer
- Chikungunya
- Dengue
- Dracunculiasis (guinea-worm disease)
- Echinococcosis
- Foodborne trematodiasis
- Human African trypanosomiasis (sleeping sickness)
- Leishmaniasis
- Leprosy (Hansen's disease)
- Lymphatic filariasis
- Mycetoma
- Onchocerciasis (river blindness)
- Rabies
- Schistosomiasis
- Soil-transmitted helminthiasis
- Taeniasis/Cysticercosis
- Trachoma
- Yaws (Endemic treponematoses)

* Based on the 2016 WHO list of neglected tropical diseases (excluding Chagas disease).

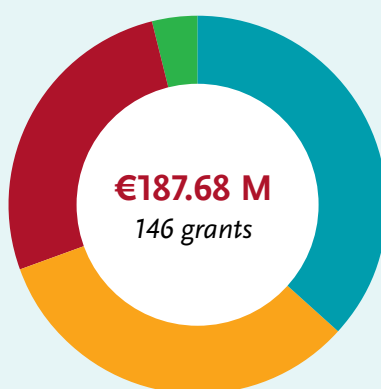
Box 3: The first EDCTP programme at a glance

1. Ran from 2003 to 2015
2. Focused on HIV, TB and malaria
3. Published 65 calls for proposals
4. Awarded 254 grants
5. Awarded €208M funding (€149.3M EU funding plus €58.7M co-funding from participating countries and third parties)
 - Supported 521 African researchers, including 51 senior fellows and 400 PhD and master's students
 - Supported consortia spanning 30 African countries and 16 European countries
 - Funded 102 clinical trials and 13 diagnostics studies in 24 countries
 - Generated more than 700 peer-reviewed publications
 - Supported studies influencing national policies and WHO treatment guidelines
 - Supported ethics-related activities in 23 countries (including an African research ethics manual)
 - Established four regional Networks of Excellence
 - Created a Pan-African Clinical Trials Registry
6. Leveraged €169.7M additional funding in cash and in kind to projects.

By disease

Note:

A further €20.31M for 108 grants was awarded to topics such as ethics & regulatory support, capacity building, support to meetings, and other non-disease specific grants, including the EDCTP Networks of Excellence.

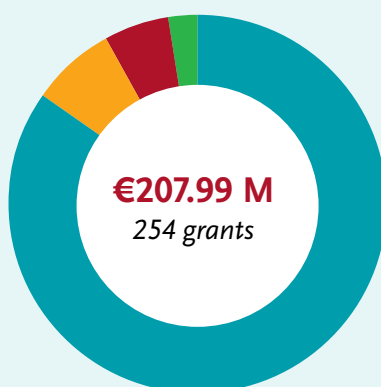


- Tuberculosis, 36 grants
€68.97M
- HIV, 56 grants
€61.41M
- Malaria, 42 grants
€50.17M
- HIV/TB, 12 grants
€7.13M

By topic

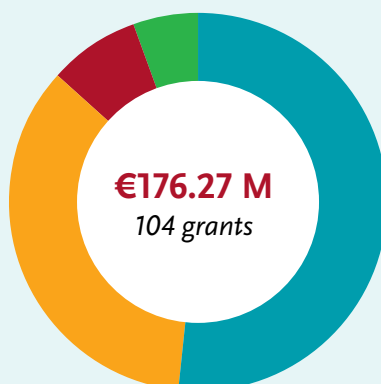
* including treatment and prevention, special populations, and laboratory investigations.
** defined as capacity development and networking activities.

*** cross-cutting activities not related to a particular intervention.



- Clinical trials by intervention*, 104 grants
€176.27M
- Other**, 30 grants
€15.32M
- Cross-cutting***, 42 grants
€11.41M
- Ethics and regulatory, 78 grants
€4.99M

By intervention



- Drugs, 60 grants
€91.08M
- Vaccines, 26 grants
€61.74M
- Diagnostics, 13 grants
€14.07M
- Microbicides, 5 grants
€9.38M

An overview of EDCTP and the EDCTP2 programme

EDCTP is a public–public partnership between institutions mandated by the governments of, currently, 14 European and 14 African countries (Figure 1), and supported by the European Union. The ten-year EDCTP2 programme, running from 2014 to 2024, is due to receive up to €683M funding from the EU through its Horizon 2020 initiative, to match equivalent funding committed by the European Participating States.

Vision

To reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa, by supporting collaborative research to develop accessible, suitable and affordable medical interventions.

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.

Objectives

The EDCTP programme has five specific objectives:

1. Medical interventions: To accelerate the development of new or improved medical interventions for poverty-related infectious diseases – HIV, TB, malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infectious diseases.
2. Collaboration and capacity development: To strengthen cooperation between European and sub-Saharan African countries, in particular to build the latter's capacity for conducting high-quality innovative clinical research consistent with fundamental ethical principles and international and national regulatory standards.
3. European coordination: To better coordinate, align and, where appropriate, integrate national programmes to increase the impact and cost-effectiveness of European investments in health research on poverty-related infectious diseases.
4. External partnerships: To work with a broad range of public and private partners to maximise the impact of research, to attract additional investment, and to fully exploit the opportunities for high-quality clinical research offered by EDCTP's integrated approach.
5. EU cooperation: To increase impact through collaborations with other EU initiatives, particularly those related to development assistance.

Key features of EDCTP

EDCTP generates valuable new evidence on medical interventions and how they can best be implemented in practice, and enhances the capacity of countries in sub-Saharan Africa to undertake collaborative clinical research. Several features of EDCTP ensure that it is well-placed to achieve its mission.



EDCTP has established itself as a key contributor to the **Africa–EU Strategic Partnership** and a recognised global player funding clinical research and product-focused implementation research, as well as associated capacity development. It is now a **focal point for European research activities**, promoting coordinated action to maximise impact on poverty-related infectious diseases.



We **enhance the capacity of sub-Saharan Africa countries** to conduct clinical studies, by investing in new research infrastructure and the development of the next generation of African researchers. EDCTP also strengthens the ethical review, regulatory and legal frameworks for clinical research in sub-Saharan Africa.



EDCTP operates as a true **'partnership of equals'** between North and South. African partners are involved at all levels, including priority setting, strategy development, implementation of plans, and leadership. This contributes to a sense of co-ownership and political commitment that increase the likelihood that research results influence policy and practice.



The EDCTP programme **encompasses populations often excluded** from clinical studies but with major unmet medical needs – including pregnant women, newborns, children, other vulnerable populations, and people with co-infections and co-morbidities.



EDCTP covers **product-focused implementation research** on delivery and uptake of medical research. This makes our work even more relevant to health services in sub-Saharan Africa countries. It also provides new opportunities for partnerships with development organisations working on health systems and optimisation of health services.



We have a strong practical focus on **clinical challenges and policy-relevant questions**, ensuring results of funded research feed directly into national and international policy-making and practice.



We are committed to **working with like-minded partners**, to promote wider use of the opportunities established for collaborative research. We have set up multiple highly effective partnerships with global public and private sector organisations.

OBJECTIVES

OUTCOMES

TARGETS



Medical interventions

New or improved medical interventions against poverty-related infectious diseases

- Deliver at least one new medical intervention
- Contribute to at least 30 guidelines for improved or extended use of medical interventions
- Progress the clinical development of at least 20 medical interventions.

- Launch at least one phase III trial each year
- Fund at least 150 clinical trials
- Maintain or increase proportion of clinical trials with African leadership
- Generate at least 1000 peer-reviewed articles
- Reduce time to completion of clinical trials.



Collaboration and capacity development

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

- Strengthen clinical research capacity in sub-Saharan Africa
- Increase clinical research expertise and scientific leadership
- Enhance ethics and regulatory capacities.

- Fund at least 74 capacity building activities
- Maintain involvement of 31 African countries and add at least two new countries
- Provide personal support for at least 400 African researchers
- Ensure 80% of countries hosting clinical trials have functional ethics committees
- Ensure 50% of countries hosting clinical trials have functional regulatory bodies.



European coordination

Improve coordination alignment and integration of European National Programmes

- More closely align national research programmes and activities on poverty-related diseases, at scientific, management and financial levels.

- Ensure that at least 50% of public investments in Participating States is integrated or aligned with EDCTP2
- Attract additional countries as EDCTP2 Participating States or partners.



External partnerships

Increase international cooperation with public and private partners

- Increase cooperation and organise joint actions with other public and private funders.

- Increase contribution from sub-Saharan African countries to at least €30M (€14M in EDCTP1)
- Increase contribution from public or private partners to €500M (€71M in EDCTP1).



EU cooperation

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

- Cooperation and joint actions with development partners, including WHO initiatives
- Increase awareness, endorsement and acknowledgement of EDCTP2.

- Organise one joint cooperation per year
- Secure increased funding by development partners
- Increase consultation with development partners.

Box 4: European Union context of EDCTP

EDCTP was established by the EU in 2003. It was the first initiative based on Article 185 of the Treaty on the Functioning of the EU (ex-Art. 169), which allows the EU's participation in research programmes undertaken by EU and Associated Member States.

The EU is a major contributor to international health aid and research. Several policy statements and collaborative agreements have laid out the EU's position in this area. In 2010 the Commission Communication and Council Conclusions on the role of Europe in global health established a conceptual framework, with emphasis on strengthening national health systems, maternal health, and the fight against HIV, TB and malaria.

The 2007 EU Programme for Action and its 2009 Progress Report highlighted the key role of EDCTP in its own right and as a model for other programmes aiming at coordinated international collaboration. This aspect of EDCTP has also been emphasised in multiple policy declarations, programmes and reports. The Africa–EU Strategic Partnership, emanating from the 2007 Lisbon Declaration and re-emphasised in the Europe 2020 Strategy, identifies EDCTP as an important body in its first Action Plan for implementation of this Strategic Partnership.

The EDCTP programme contributes to the European Commission flagship initiative 'Innovation Union' as the programme will enhance the effectiveness, visibility and coherence of global health research in Europe. It offers a shared approach to clinical research of poverty-related infectious diseases and has the potential to contribute to a European Research Area, as envisaged for EU's international science and technology cooperation programmes. Further, at their Berlin meeting in 2015, the G7 Ministers of Science expressed their resolve to support the fight against "poverty-related infectious diseases and neglected tropical diseases", with EDCTP recognised as one of the mechanisms to be built upon.

Photo:
Laboratory staff at the Ahero Sub-district
Hospital in Nyanza, Kenya
part of the PfSPZ Challenge study (led by
Dr Bernhards Ogutu)



Integrated approach of the EDCTP programme

The EDCTP programme is supporting clinical research, research capacity development and international networking to address the key infectious diseases affecting Africa.

Target diseases: EDCTP supports research on HIV, TB, malaria, neglected infectious diseases (Box 2), diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections relevant to sub-Saharan Africa, including Ebola and yellow fever.

Medical interventions: EDCTP supports clinical studies on medicinal products designed to detect, prevent or treat target diseases. These include novel drug treatments and formulations, new therapeutic regimens, microbicides, vaccines and diagnostics.

Type of research: Interventional clinical studies make up the bulk of the EDCTP2 portfolio. We support phase I–III safety and efficacy studies, with a particular emphasis on phase II and III trials. We also support phase IV pharmacovigilance and post-licensing effectiveness studies (pragmatic trials), and product-focused implementation research (Figure 2).

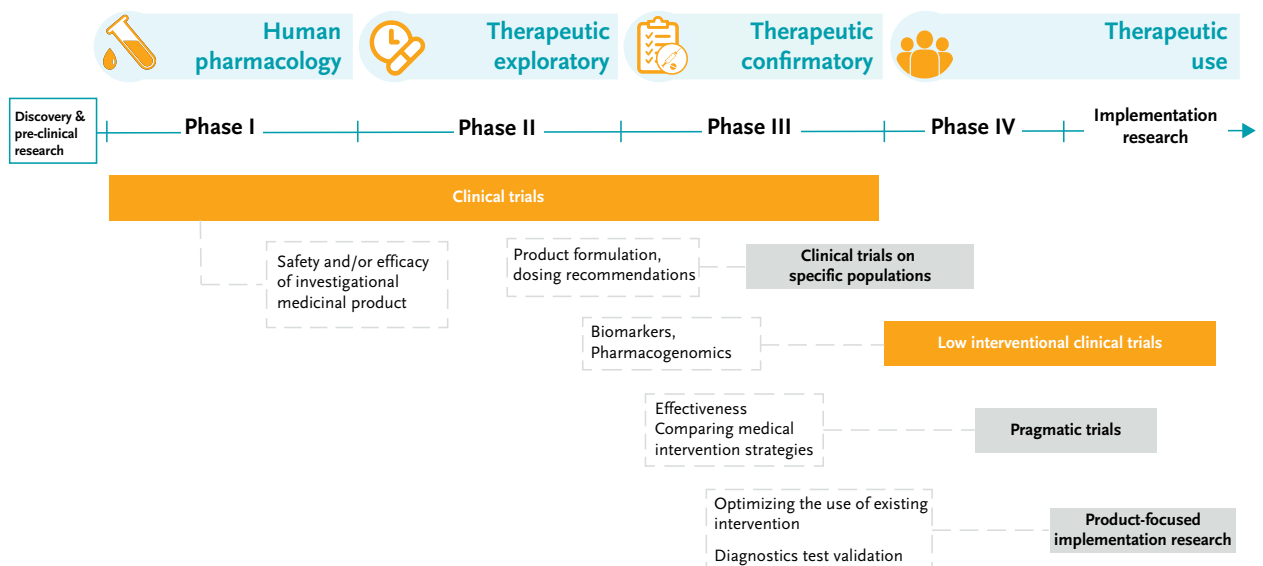


Figure 2: Clinical studies supported by EDCTP.

An overall target of at least 150 clinical trials has been set for EDCTP2. EDCTP expects to fund a higher number of phase II (efficacy) and IV (post-licensing) studies and fewer phase I (clinical pharmacology) and III (therapeutic confirmatory) studies. Capacity to conduct phase I trials is still limited in sub-Saharan Africa. The number of phase III clinical trials will be relatively small due to the expected large size and associated high costs of these studies. Consequently, though relatively few in number, phase III clinical trials will account for a substantial part of the EDCTP2 expenditure. The programme portfolio will be closely monitored and evaluated by the Executive Secretariat, with advice of the Scientific Advisory Committee.

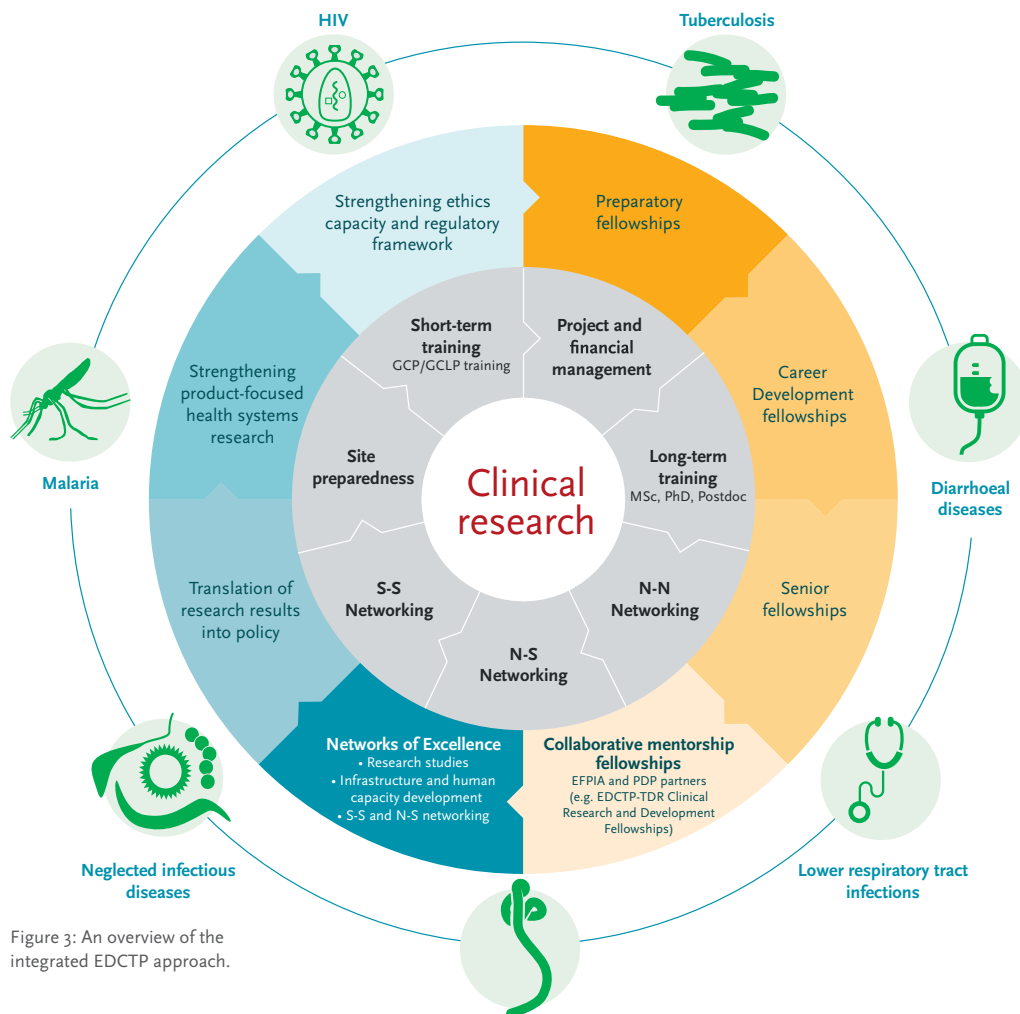


Figure 3: An overview of the integrated EDCTP approach.

Capacity development: EDCTP makes an important contribution to the development of clinical research capacity in sub-Saharan Africa, within its scope.

- **Infrastructure development:** EDCTP funds upgrades to clinical and laboratory facilities to support high-quality clinical research (but not new building work).
- **Expertise and scientific leadership:** EDCTP has a strong focus on human capacity building, through research training (master's and PhD) and fellowship schemes, and through needs-driven short-term training, mentoring and exchange.
- **Regulatory environment:** EDCTP supports the development of the ethical review, legal and regulatory capacities in sub-Saharan Africa to ensure clinical research is managed to the highest possible international standards.

Networking and partnerships: Collaboration, cooperation and coordination are integral to EDCTP.

- **North–South networking:** North–South research collaborations play a key role in

developing research capacity in sub-Saharan Africa and in applying the expertise and resources of Northern institutions to the health challenges of the South.

- **North–North networking:** North–North coordination ensures cross-fertilisation of ideas between institutions working on target diseases, focuses national activities on shared goals, and minimises duplication, to maximise the impact of European investments in research within the scope of EDCTP2.
- **South–South networking:** South–South collaboration supports sharing of research and training resources, knowledge, and expertise across sub-Saharan Africa countries, and enables multinational platforms for clinical research.
- **External partners:** We are committed to developing partnerships with like-minded organisations in order to achieve our mission. We work with private companies as well as non-profit organisations engaged in product development. In addition, we seek to work with other funders and international organisations towards common goals.

EDCTP priorities

Criteria for setting priorities

To maximise its impact, EDCTP has identified strategically important areas of unmet medical need. Its annual calls for proposals reflect specific current needs for each target disease area and research capacity development.

The scope of EDCTP's overall programme of work is set out in its Strategic Business Plan for 2014–24. This was put together with extensive input from Participating States, EDCTP's Scientific Advisory Committee and Secretariat through consultation with global scientific bodies, like-minded partner organisations and other stakeholders.

The broad priorities outlined in the Strategic Business Plan form the basis of more specific

three-year plans and annual work plans (Figure 4). Three-year plans, put together by EDCTP's Scientific Advisory Committee with input from thematic stakeholder meetings, outline medium-term priorities, while annual plans include details of the specific calls for proposals for the year ahead.

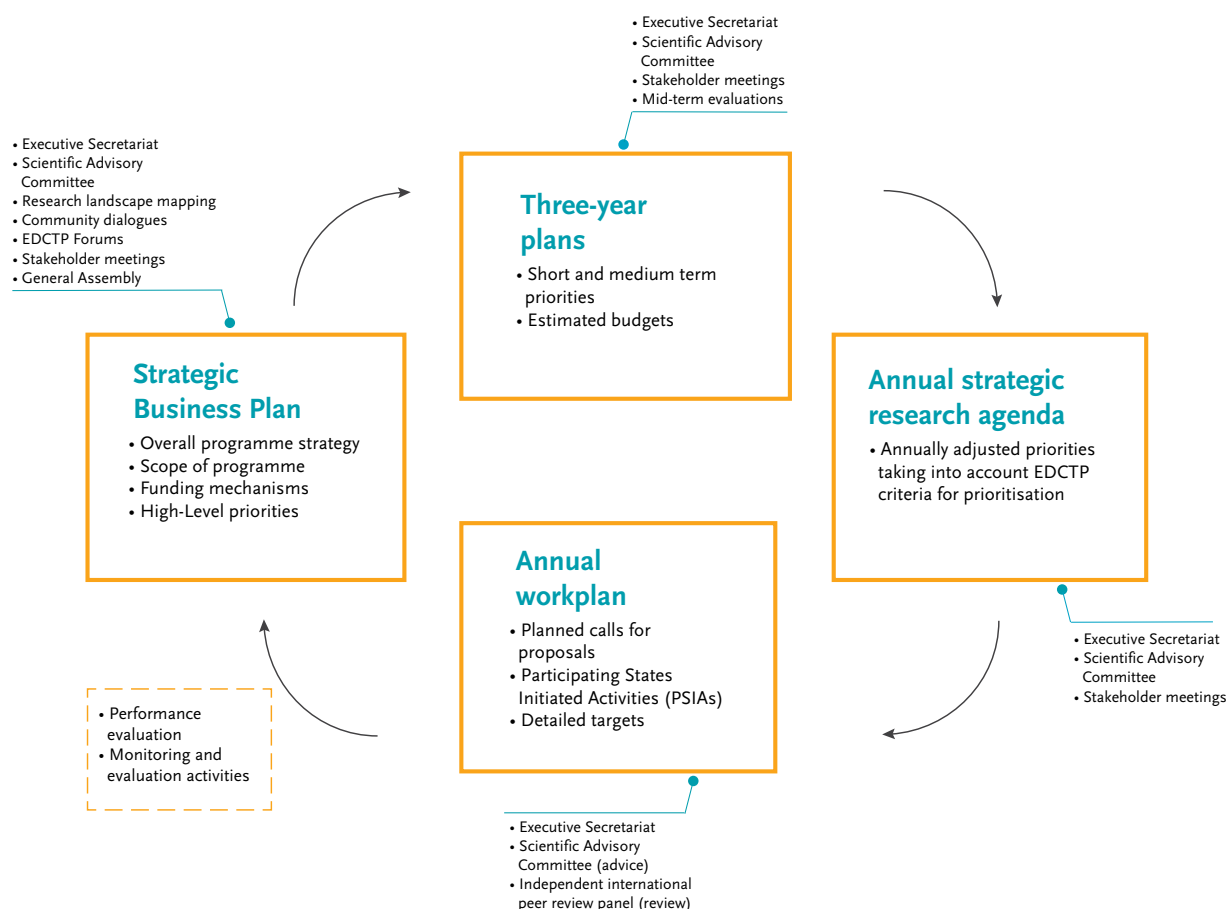


Figure 4: An overview of EDCTP priority-setting mechanisms.

To avoid duplication and to maximise the impact of our work, prioritisation takes account of the following criteria:

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.

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

Disease burden and treatment/prevention priorities: These analyses identify key knowledge gaps and need for new evidence.

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

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.

Priority setting aims to balance the need for a coherent framework to guide the programme's work with the flexibility to respond to emerging opportunities and health challenges.

The following priorities for targeted disease areas give an indication of the kinds of research likely to be funded through the EDCTP2 programme. They are not intended to be definitive or comprehensive, and are likely to evolve throughout the programme as circumstances change.



Priorities for HIV

Although effective antiretroviral therapy (ART) is now available, optimised treatment regimens and formulations are required for key groups, such as children, pregnant women, and older people with co-infections and co-morbidities.

Multiple challenges in HIV management need to be addressed, from timely diagnosis and initiation of ART to retention in care. Given the availability of therapeutic options, product-focused implementation research to enhance access to evidence-based interventions is a high priority.

The number of new HIV cases remains stubbornly high, emphasising the urgent need to assess innovative methods of prevention, including microbicidal products, ARV-based interventions and, ultimately, HIV vaccines.



Treatment

- Better formulations and optimisation of ART for target populations (e.g. infants/children, pregnant and breastfeeding women, men who have sex with men, and older HIV-positive individuals).
- Novel therapeutics and novel use of existing therapeutics (e.g. to counter resistance).
- HIV-associated co-infections and co-morbidities.



Diagnosis

- Diagnosis of HIV in young infants born to HIV-infected mothers.
- Point-of-care diagnosis of HIV drug resistance.



Prevention

- Women-initiated HIV prevention, such as injectable long-acting ARVs and multipurpose technologies such as vaginal rings containing ARVs and contraception.
- Testing of novel HIV vaccines, in partnership with vaccine developers.
- Product-focused implementation research on combination prevention methods (encompassing behavioural, structural and clinical interventions) in high-risk populations, and on treatment as prevention and universal test and treat.



Implementation research (product-focused)

- Delivery models for sustainable, equitable and full-scale access to diagnostics, prevention and treatment interventions, particularly community-oriented and integrated approaches.
- Improved approaches to HIV counselling and testing and linkage to care.
- Integration of HIV, sexual and reproductive health, TB and other services, to improve linkage to and retention in care.

Priorities for tuberculosis

Important goals for TB research include new approaches for early diagnosis of active TB, shortening the duration of therapy, improving treatments for both drug-sensitive and drug-resistant TB, preventing relapse, reducing drug resistance, preventing long-term lung damage, and preventing latent TB infection progressing to active TB. Ultimately, TB control will require affordable, short, effective and well-tolerated treatments for all forms of TB (latent TB infection, drug-susceptible and drug-resistant TB disease), point-of-care diagnostic tests able to characterise drug resistance, and an effective vaccine.

EDCTP2 will support the evaluation of new TB treatment regimens for both drug-sensitive and drug-resistant TB, as well as adjunct ‘host-directed therapies’ based on repurposed drugs, cellular therapies and other immunomodulators.

Product-focused implementation research will be required to support the introduction of evidence-based interventions into policy and practice. Strategies for integrated delivery of TB and HIV care will be an important focus.



Treatment

- Novel interventions using new TB drugs or formulations with new combination regimens.
- Treatment regimens including adjunct host-directed therapies.



Diagnosis

- New diagnostics, particularly those suitable for use at all points of healthcare to identify both drug-sensitive and drug-resistant TB.
- Diagnostic and prognostic pathogen and host biomarkers.



Prevention

- New vaccines and chemoprophylactic TB drug regimens.



Implementation research (product-focused)

- Delivery methods for validated diagnostics and drugs.
- Scale-up and integration of HIV/TB prevention, treatments and services.
- Innovative use of existing and new strategies to prevent, diagnose and manage TB, MDR-TB and HIV/TB co-infections.



Epidemiology

- Tracking of drug-resistant TB in both HIV-infected and HIV-uninfected adults and children, particularly to support evaluation of novel products or regimens.

Priorities for malaria

EDCTP2 will evaluate new drugs and drug combinations, with a particular focus on children and pregnant women and on uncomplicated malaria. As many HIV-infected individuals live in malaria-endemic areas, it is increasingly important to understand interactions between antimalarial drugs and ARVs.

Field testing of diagnostics to identify infection and resistance mutations will be a key focus. In coming years, there is likely to be a need to evaluate new malaria vaccines, in partnership with vaccine developers.

EDCTP2 will support the evaluation of strategies for enhancing access to drugs, vaccines and diagnostics, as well as malaria elimination strategies, potentially incorporating improved methods of monitoring and surveillance.

As management of *Plasmodium falciparum* improves, detection, treatment and control of *Plasmodium vivax* is likely to become increasingly important.



Treatment

- Safety and efficacy of new drugs and optimisation of existing combinations.
- Drug-drug interactions in HIV, TB and neglected infectious disease co-infections.
- Optimising new antimalarials for treatment and prevention among HIV-infected individuals, including children and pregnant women.



Diagnosis

- Novel tools, particularly point-of-care tests, including those for *P. vivax*.
- Innovative use of existing technologies to support malaria control and elimination efforts.



Prevention

- Novel drugs and vaccines targeting populations such as infants and pregnant women, in partnership with other funders.
- Elimination feasibility studies.



Implementation research (product-focused)

- Scale-up of access to drugs, vaccines and diagnostics.
- Novel delivery channels and mechanisms for existing and new interventions.
- Defining indicators for surveillance, changing from measuring morbidity and mortality to detecting infections and measuring transmission.
- Feasibility, efficiency and cost-effectiveness of new information systems.

Priorities for neglected infectious diseases

Where effective treatments already exist, the main priorities will be clinical trials of combination therapies and implementation research to identify the most effective ways to deliver treatments in particular settings. For diseases where treatments are inadequate or lacking entirely, phase I clinical trials will be required.



Treatment

- Novel drugs, drug combinations and formulations, in partnership with stakeholders.



Diagnosis

- New diagnostics for key neglected infections, including products characterising host responses.



Prevention

- Candidate vaccines as they become available, in collaboration with partners.



Implementation research (product-focused)

- New drug combinations, and optimisation and integration of management of co-endemic infections.
- Evaluation of disease burden (e.g. regional versus local).
- Effect of mass drug administration, especially for diseases targeted for elimination.

Priorities for diarrhoeal diseases

Epidemiological studies have provided a clearer picture of the microbiological causes of diarrhoeal disease in sub-Saharan Africa, revealing a drop in mortality without a corresponding fall in morbidity, which reflects a shift from severe life-threatening diarrhoeal episodes towards recurrent disease. Persistent infections contribute to abnormalities in gut function (enteropathy), affecting nutrient uptake and response to oral vaccines, and creating a vicious circle of diarrhoea and malnutrition leading to stunting and delayed development.

Vaccines are likely to offer cost-effective ways to manage diarrhoeal diseases. Rotavirus vaccines are beginning to have a major impact globally, but their effectiveness is significantly affected by enteropathy. Vaccines against other viral and bacterial pathogens are beginning to be tested in clinical trials.

EDCTP has prioritised the following diarrhoeal disease-causing pathogens: rotavirus, *Shigella*, enterotoxigenic *E. coli*, *Cryptosporidium* and norovirus.



Treatment

- Novel therapies, including repurposed drugs, for cryptosporidiosis.



Diagnosis

- Point-of-care multiplexed diagnostic tools.



Prevention

- Impact of paediatric environmental enteropathy on the effectiveness of oral vaccines.
- Vaccines against *Shigella* and enterotoxigenic *E. coli* as they become available.
- Vaccine-testing infrastructure encompassing the development of companion tools for immune monitoring of clinical trials, and for optimisation of the routes and mode of administration.



Implementation research (product-focused)

- Implementation of novel vaccines within existing immunisation programmes.

Priorities for lower respiratory tract infections

There is a dearth of information about the disease burden attributable to lower respiratory tract infections (LRTIs) and specific causes of disease in many settings. Evidence on effective antibiotic regimens is incomplete, and antibiotic resistance is a major and growing problem.

Important priorities include the need for simple methods to identify patients requiring antibiotics on the basis of clinical signs. There is a need to identify and evaluate the most appropriate antibiotic regimens. Low-cost methods for oxygen delivery to treat children with hypoxaemia (low blood oxygen levels) are also required.

As well as immunocompromised HIV-infected individuals, target populations will include children and the elderly and those hospitalised with LRTIs. Priority pathogens have been identified that affect particular population groups: group B streptococci, respiratory syncytial virus (RSV) and pneumococcus in neonates; RSV, pneumococcus and cytomegalovirus in children; and pneumococcus in adults.



Treatment

- New antibiotic regimens for community-based LRTI treatment.
- Simplified tools for management of hypoxaemia in children.
- Host-directed therapies to improve outcomes and prevent pulmonary disability.



Diagnosis

- Clinical diagnostic algorithms for LRTIs according to age group, co-morbidities and severity.
- Rapid diagnostic platforms for bacterial causes of LRTIs.
- Innovative specimen collection methods suitable for lower-level health facilities.



Prevention

- Impact of existing vaccines on the rates and aetiologies of LRTIs.
- Adjunct therapies, such as nutritional products and probiotics, for LRTI prevention in children.
- Optimising delivery and scaling-up of new vaccines (e.g. for RSV).
- Immunisation of pregnant women to prevent RSV-associated LRTI in infants.



Implementation research (product-focused)

- Diagnosis and management of LRTIs and HIV and TB co-infections.
- Surveillance to identify the impact of preventive and curative strategies for paediatric LRTIs.



Epidemiology

- Diagnosis and management of LRTIs and HIV and TB co-infections.
- Surveillance to identify the impact of preventive and curative strategies for paediatric LRTIs.

Priorities for emerging and re-emerging infectious diseases

Emerging and re-emerging infectious diseases with epidemic potential are a persistent threat to global health security, as well as to public health in many African countries. Ebola and yellow fever are native to sub-Saharan Africa, but infectious disease threats with epidemic potential can also be imported from other continents. Key priorities include surveillance and response strategies for newly detected outbreaks. For diseases where treatments are inadequate or lacking entirely, phase I clinical trials will be required.



Treatment

- Novel drugs, drug combinations and formulations, in partnership with stakeholders.



Diagnosis

- Diagnostic tests and facilities for characterising emerging and re-emerging infections.



Prevention

- Candidate vaccines as they become available, in collaboration with product development partners.



Implementation research (product-focused)

- For emerging infections, surveillance systems and international networks to detect and respond to emerging threats to health.
- 'One health' cross-sectoral systems for identifying and responding to emerging and re-emerging infections.

Priorities for capacity development

EDCTP aims to develop the capacity of sub-Saharan Africa countries to conduct high-quality clinical trials and implementation research consistent with fundamental ethical principles and recognised international regulatory standards and good practice.

To achieve this objective, EDCTP is investing in both physical infrastructure and people in sub-Saharan Africa, and promoting the exchange of ideas, information and people between institutions in Europe and those in Africa. It is also supporting activities strengthening the ethical, regulatory and legal framework for conducting trials within the EDCTP scope in sub-Saharan Africa.



Developing research infrastructure

- EDCTP is investing in the equipment and laboratory and clinical facilities required for high-quality research and the IT and other systems required for enrolment into clinical trials (but is not supporting new building work).
- To facilitate clinical research activities, EDCTP is strengthening health systems' resilience to emerging epidemics. Through its implementation studies, it is also enhancing the capacity of health systems to utilise new or improved interventions.



Training fellowships and mentorship programmes

- EDCTP is supporting researchers at various career stages, from master's and PhD training through to senior fellowships. The overall aim is to support the development of African research leadership.
- EDCTP is also promoting skills development via staff exchanges, mentoring of early-career researchers by senior scientists, and via research training networks operated through regional Networks of Excellence. An alumni platform will encourage collaboration between EDCTP trainees.



Ethics and regulatory support

- EDCTP is committed to supporting research of the highest possible ethical standards and consistent with recognised international regulatory standards. In order to strengthen local capacity, EDCTP is providing support in several areas:
 - Establishing and strengthening national ethics committees
 - Supporting ethics training through courses and seminars
 - Promoting regional cooperation for research ethics activities
 - Strengthening national regulatory frameworks by collaboration with the WHO and African Union.

Priorities for networking

EDCTP aims to build relationships and broker sustainable partnerships – promoting North–South, South–South and North–North networking and developing relationships with multiple private- and public-sector organisations.

We support networking activities with a range of objectives:

- Fostering productive relationships between European and African individuals and institutions.
- Concentrating efforts, promoting efficiency and avoiding duplication by aligning European and African funders, institutions and authorities.
- Attracting investment from partners in the private, public and charitable sectors.



North–South networking: strengthening project and institutional collaboration

Existing collaborations between European and African scientists and institutions have generally been developed on an ad hoc basis, with little strategic planning, leading to fragmentation and duplication of efforts. We aim to raise awareness of common interests and promote collaboration between institutions and research groups with shared goals.

Through its calls for proposals and funding principles, EDCTP helps to establish new North–South collaborations to conduct multicountry, multisite studies in sub-Saharan Africa. The biennial EDCTP Forum provides a platform for scientists from Europe and Africa to share findings and ideas, and to establish collaborative links.



North–North networking: coordination of national funding

We promote the coordination and pooling of resources at a national level, by encouraging European Participating States to develop calls for proposals together and with countries in sub-Saharan Africa and/or other partners through the EDCTP framework.

The resulting studies can be financed and managed by EDCTP or run by Participating States themselves as ‘Participating States-Initiated Activities’ (PSIAs).



West African NoE for TB, AIDS, and Malaria (WANETAM)



East African Consortium for Clinical Research (EACCR)



Central African Network for TB, AIDS, and Malaria (CANTAM)



Trials of Excellence in Southern Africa (TESA)

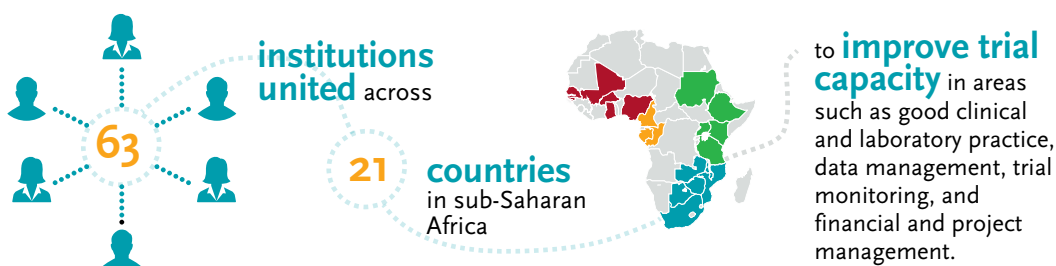


Figure 5: The existing Networks of Excellence in sub-Saharan Africa under EDCTP1.



South–South networking: sharing expertise and experience

South–South networking builds on existing regional Networks of Excellence (Figure 5). The Networks provide a mechanism for sharing of resources, knowledge and expertise, and enable less well-established institutions to participate in multicentre clinical trials. They also support mentoring and training of early-career researchers. Networks also conduct epidemiological and demographic studies to facilitate the planning of future trials.



External networking: strengthening collaboration with partners

We are committed to working to mutual advantage with partners with common interests in the public, private and charitable sectors. Other international funders of health research are natural allies, and we actively seek collaboration on best practices and organise joint activities, such as EDCTP–TDR Clinical R&D Fellowships, run in partnership with the WHO's Special Programme for Research and Training in Tropical Diseases (TDR).

EDCTP offers a comprehensive approach and funding for non-profit and for-profit organisations and product development partnerships to evaluate innovative new medicinal products in high-quality clinical trials. We have established links with individual companies and industry representative bodies to discuss co-funding of major product-related projects or jointly funded open calls.

For EDCTP2, development cooperation agencies are also an important focus, both at the EU and national level. In particular, with EDCTP also supporting product-focused implementation research, new opportunities exist for collaboration on health system strengthening through improving delivery of medical interventions.

Implementation of the EDCTP2 programme

EDCTP has established governance structures and operating procedures to ensure it can achieve its objectives successfully and function efficiently.

Funding arrangements

EDCTP receives funds from the European Union through the Horizon 2020 programme. Participating States also make contributions (cash or in-kind) to activities aligned with EDCTP's goals. Third parties, including industry, product development partnerships, development organisations and research institutions, also make cash or in-kind contributions to EDCTP calls (Figure 6).

Mechanisms of support

The EDCTP2 programme supports three types of Horizon 2020 actions: Research and Innovation Actions; Coordination and Support Actions; and Training and Mobility Actions.

Research and Innovation Actions (RIAs)

support clinical research activities and clinical trials. Actions may involve additional research studies embedded within a trial and can also support capacity development of researchers, institutions and sites in sub-Saharan Africa and networking activities.

Coordination and Support Actions (CSAs)

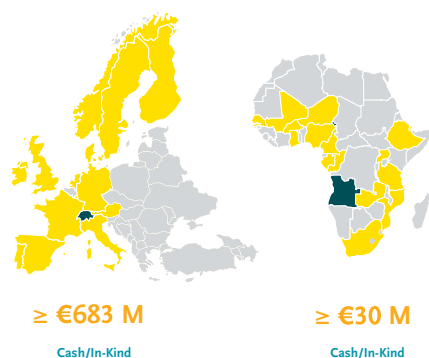
support activities to (1) strengthen clinical research capacities in sub-Saharan Africa, (2) promote networking and collaboration both between European and African researchers and among African researchers, institutions and sites, and (3) foster collaboration with public and private funders. In particular, CSAs enable sub-Saharan African countries to develop robust ethical and regulatory frameworks for conducting clinical trials. CSAs also support EDCTP regional Networks of Excellence in sub-Saharan Africa.

Training and Mobility Actions (TMAs)

support activities promoting the career development of junior and senior researchers from sub-Saharan Africa, training and mentorship, and the mobility of individual researchers and research staff.

Figure 6: An overview of EDCTP2's funding arrangements.

EDCTP Participating States



Participating States' Initiated Activities

- Selected and administered by Participating States
- Funded by Participating States
- Application of Participating States' funding rules

European Union



≤ €683 M

Cash

Third parties

- Private sector
- PDPs
- Development organisations
- Research institutions

≥ €500 M

Cash/In-Kind

EDCTP Calls for Proposals

- Selected and administered by EDCTP
- Funded by the European Union, Participating States and third parties
- Application of Horizon 2020 rules for participation

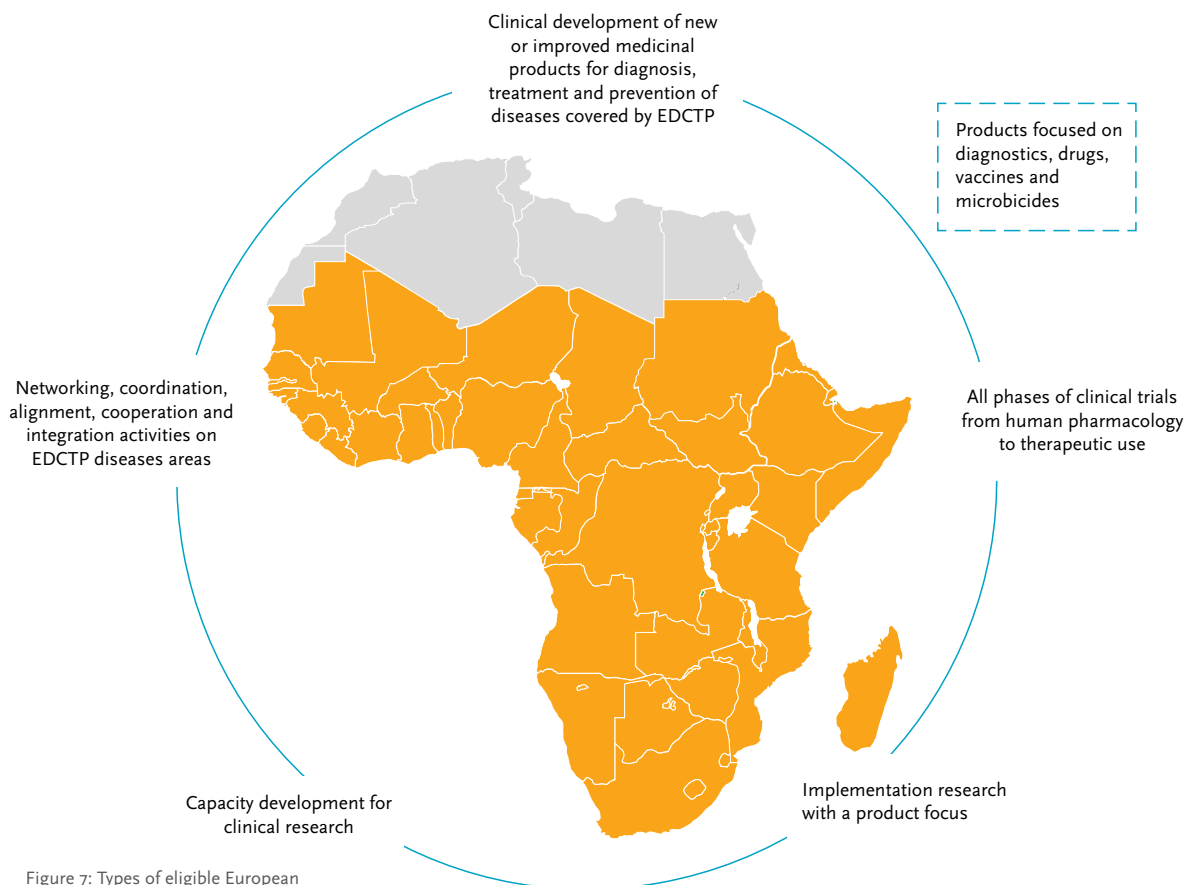


Figure 7: Types of eligible European Participating States-Initiated Activities.

Participating States-Initiated Activities

The EDCTP2 portfolio also includes activities that, although they are implemented or funded by one or more Participating States, fall within the scope of EDCTP2. These Participating States-Initiated Activities (PSIAs) are included in EDCTP2 annual work plans to promote coordination and, where appropriate, integration of national programmes and activities.

EDCTP Forums

As well as a grants programme, we also organise regular EDCTP Forums. Held every two years, these conferences enable EDCTP-funded teams to share their findings and experience with researchers, policy-makers and other stakeholders, and provide opportunities for networking, identification of new research and capacity development priorities, and building of new relationships.

EDCTP Prizes

We make four prestigious international prizes to honour achievements in health research and Africa–Europe collaboration and to recognise role models (Box 5). The Prizes are announced every two years at EDCTP Forums.

Box 5: EDCTP Prizes

Scientific Leadership: Awarded to world-class scientists in Africa up to 50 years of age.

Outstanding Female Scientist: Awarded to world-class female scientists working and residing in sub-Saharan Africa with no age restriction.

Outstanding Research Teams: Awarded to outstanding research teams in Africa and Europe.

Dr Pascoal Mocumbi Prize: Named in honour of EDCTP's first High Representative and former Prime Minister of Mozambique, and awarded to a senior scientist, policy-maker or advocate for health and research (aged 51 years and above) from anywhere in the world.

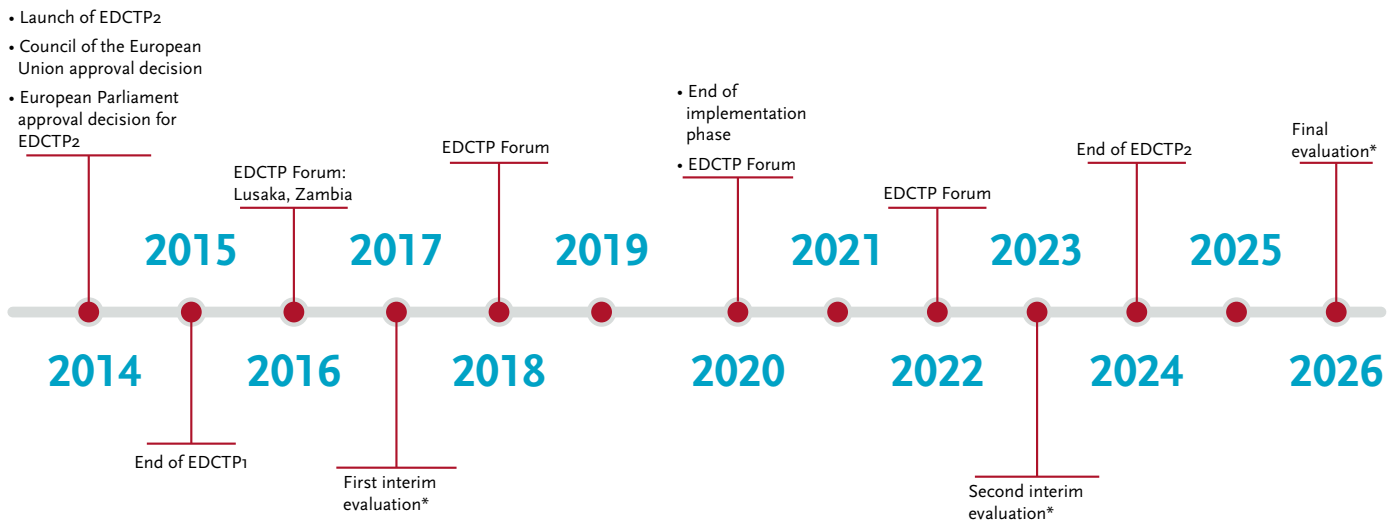


Figure 8: EDCTP2 strategic road map.

*Independent evaluations commissioned by the EC.

Strategic road map 2014–24

The EDCTP2 programme consists of an implementation phase (2014–20) followed by a phasing out and conclusion of grant management processes (2020–24) (Figure 8). We will have an independent interim evaluation towards the end of 2016 till early 2017 followed by a second one towards the end of 2022 till early 2023 commissioned by the European Commission. We will publish a final programme evaluation in 2026.

EDCTP management structure

The EDCTP Association, established in April 2014 and registered in The Netherlands under Dutch law, is the legal governing, executive

and representative body of the EDCTP programme.

This legal structure enables countries from Europe and sub-Saharan Africa to become members of the EDCTP governing body. The EDCTP Association reflects EDCTP's commitment to equal partnership built on joint ownership and leadership. Currently, 14 European countries and 14 African countries are full members of the Association (Participating States; Figure 1).

EDCTP's governance structure consists of a General Assembly, the Board and the Secretariat. The EDCTP **Scientific Advisory Committee** provides advice on scientific and strategy matters (Figure 9).

The ultimate decision-making body of the EDCTP Association is the **General**

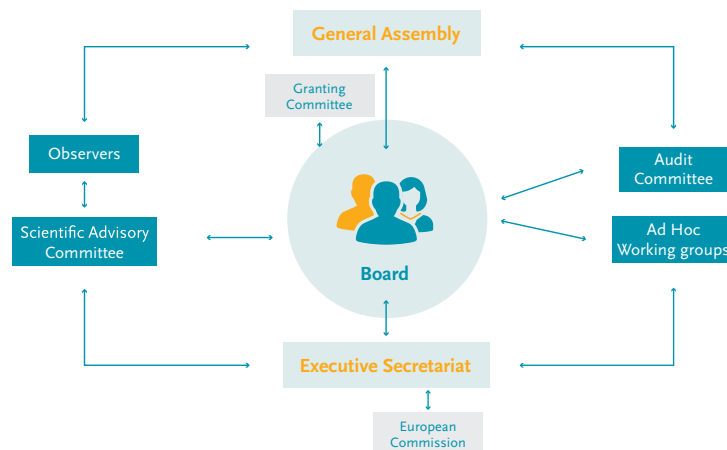


Figure 9: EDCTP's governance structure.

Assembly, on which all Participating States are represented. Its principal responsibility is to ensure that the statutory objectives of the programme are achieved, and that its resources are properly and efficiently managed.

The **Board of the EDCTP Association** is appointed by the General Assembly from among its members (representatives and their deputies). The Board is responsible for the management of the Association and supervises the Secretariat, the executive body that implements the EDCTP2 programme, manages EDCTP's day-to-day work and supports the other EDCTP bodies. The **Secretariat**, led by the Executive Director, has offices in Europe and in Africa. To support its advocacy role, it includes two High Representatives, one based in Europe and one in Africa, who represent the organisation at the highest levels.

Expected impact of EDCTP2

The activities of the EDCTP programme are expected to impact international and national health policy and practice for poverty-related diseases.

- EDCTP will generate high-quality research data relating to the safety and efficacy of new and improved medicinal products, and how they can be implemented most effectively in sub-Saharan Africa.
- By developing clinical research capacity in sub-Saharan Africa countries, as well as ethics review, regulatory and legal capacities, EDCTP will enhance the ability of such countries to conduct and host clinical trials.
- By encouraging greater coordination and alignment of national research efforts, EDCTP will also maximise the impact of European investments in global health research.
- Partnerships with public and private organisations (both for-profit and non-profit) will ensure that additional use is made of the clinical research capacity established in sub-Saharan Africa to accelerate the evaluation of new medical interventions.

- Through partnerships with development agencies and related organisations, EDCTP will contribute to sustainable delivery of validated medical interventions through strengthened healthcare systems.

Monitoring and evaluation

We will monitor and evaluate the EDCTP2 programme and the operational performance of EDCTP. The aim is to ensure that the programme achieves its objectives and delivers the expected results.

We will collaborate with other organisations to identify best practices for monitoring and evaluation of activities.

Programme impact evaluation

At the end of each three-year term, we will conduct an internal evaluation to assess the progress of the EDCTP programme and determine its impact, including its influence on health policies, healthcare, research capacity, strengthening of partnerships and synergy with other programmes. These internal evaluations will feed into the external interim evaluations (see road map).

The external interim evaluations of the EDCTP programme due in 2016-2017 and 2022-2023 as well as the final programme evaluation in 2026 will be commissioned by the European Commission.

Operational performance

We will monitor implementation of the EDCTP programme on a regular basis using key performance indicators (KPIs). These will cover critical areas such as:

- Outcomes of stakeholder meetings
- Degree of participation of third parties
- Degree of participation of Participating States
- Contributions of Participating States.

Monitoring will be a continuous process and will support the results-based management function at EDCTP.



Photo:
Dr Sodiomon Sirima and research team at the
Regional Hospital of Banfora, Burkina Faso
part of the WANEAM project (led by Prof.
Abdoulaye Djimdé)



Europe Office

Postal address
P.O. Box 93015
2509 AA The Hague
The Netherlands

Africa Office

Postal address
P.O. Box 19070
Tygerberg 7505, Cape Town
South Africa

Visiting address

Anna van Saksenlaan 51
2593 HW The Hague
The Netherlands

Visiting address

Francie van Zijl Drive,
Parowvallei 7505, Cape Town
South Africa

Phone: +31 70 344 0880/0897

Phone: +27 21 938 0690

Fax: +27 21 938 0569

Email: info@edctp.org

Web: www.edctp.org

Twitter: @EDCTP

YouTube: [edctpmedia](https://www.youtube.com/user/edctpmedia)

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The power of sharing science