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Assessment of the performance and impact of the first programme of the European & Developing Countries Clinical Trials Partnership (EDCTP)

Report



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List of abbreviations

AIDS	Acquired Immunodeficiency Syndrome
AO	Africa Office
AU	African Union
CANTAM	Central African Network for Tuberculosis, HIV/AIDS and Malaria
DCCC	Developing Countries Coordinating Committee
EAC	East African Community
EACCR	East African Consortium for Clinical Research
ECCAS	Economic Community of Central African States
EDCTP	European and Developing Countries Clinical Trials Partnership
EDCTP1	First EDCTP programme (2003 – May 2015)
EDCTP2	Second EDCTP programme (May 2014 – 2024)
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ERC	Ethics Review Committee
EU	European Union
GA	General Assembly
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HR	High Representative
IRB	Institutional Review Board
JP	Joint Programme
KPI	Key Performance Indicator
NID	Neglected Infectious Disease
NoE	Network of Excellence
PACTR	Pan African Clinical Trials Registry
PB	Partnership Board
PDP	Product Development Partnership
PRD	Poverty-related disease
R&D	Research and Development
RCT	Randomised Clinical Trial
SAC	Strategic Advisory Committee
SME	Small and Medium-sized Enterprise
TB	Tuberculosis
TESA	Trials of Excellence in Southern Africa
WANETAM	West African Network of Excellence for TB, AIDS and Malaria
WHO	World Health Organization

Executive Summary

The European & Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 by 15 European countries under the European Commission's Sixth Framework Programme (FP6) for Research and Technological Development in response to the global health crisis caused by the three main poverty-related diseases HIV/AIDS, tuberculosis and malaria. The aim of the first EDCTP programme, which will end in 2015, is to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against these three diseases based on a partnership approach. This progressively developed into a partnership that unites 48 sub-Saharan African countries and 14 European Union member states plus Norway and Switzerland (the EDCTP Participating States). During the first ten-year period, the programme not only supported clinical trials (with a focus on phase II and III clinical trials in sub-Saharan Africa) but also strengthened the capacity to conduct clinical research, promoted the establishment and integration of national programmes within the scope of EDCTP and developed a genuine partnership with African countries.

In January 2014, an independent external evaluation was mandated to provide EDCTP (the General Assembly (GA) and the Executive Secretariat), the Strategic Advisory Committee (SAC) and its stakeholders with the necessary information on the performance and impact of its first programme. The evaluation was conducted, while in parallel the second phase of the programme (EDCTP2) was approved by the European Parliament on 15 April 2014 and the European Council on 6 May 2014¹. The overall strategy of EDCTP2 has not been revised, which means that EDCTP2 will continue to support clinical development of new or improved diagnostics, drugs, vaccines and microbicides against HIV/AIDS, tuberculosis and malaria. However in addition, EDCTP2 will also support studies on neglected infectious diseases (NIDs) and supports all clinical trial phases (from phase I to IV). The geographical focus of EDCTP2 will remain on sub-Saharan Africa, although collaborative research with other developing countries outside sub-Saharan Africa could be envisioned when possible and desirable.

The evaluation has both a summative and formative character and has four specific objectives:

1. To determine whether the different funding schemes have met their objectives;
2. To assess the output and outcome of the programme by highlighting specific case studies documenting any outstanding success or notable failures;
3. To assess the effectiveness, efficiency, relevance and potential sustainability of projects funded; and
4. To review the funding mechanisms², grant awarding and management processes.

These objectives have been evaluated both from a funder's and participant's perspective and have resulted in the formulation of recommendations for the future of the programme.

In the evaluation a variety of information sources and data collection and analytical methods were used to reach the conclusions and recommendations. The methods are combined to best fit the evaluation questions and increase the reliability of the results. The main methods applied in the evaluation are desk research, a considerable number of interviews (of which the majority through telephone conversation) with internal and

¹ European Union (2014). Decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States. PE-CONS 54/14.

² EDCTP uses three approaches: (1) open calls for proposals; (2) the brokered approach; and (3) the single source approach.

external EDCTP stakeholders, three site visits to South Africa, Tanzania and Republic of the Congo plus interviews in Mali to draft four country case studies, and a survey amongst researchers participating in EDCTP funded projects. Additional information was gathered during visits to the Executive Secretariat of EDCTP both in The Hague and Cape Town, the WHO regional office for Africa (WHO-AFRO) in Brazzaville, as well as the 7th EDCTP Forum held from 30 June to 2 July 2014 in Berlin.

Conclusions

In general, there is wide acknowledgement that EDCTP, after a difficult start during the first years of the programme, turned itself into a well-tuned and effective funder of clinical trials on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa.

During its first programme EDCTP distributed a total of 246 projects amounting to €212.12 million from EDCTP (situation by December 2013), balanced across the three disease areas and 16 different grant schemes that complement each other. There is a relative balance in the geographical coverage between European and African countries and institutions participating in the programme. However, four African countries (South Africa, Tanzania, Uganda and Kenya) and three European countries (UK, Germany and the Netherlands) are responsible for the largest number of project participations.

EDCTP has become a more equal and transparent partnership in which African countries have a much stronger voice than in the early days. The programme has increased African engagement over the whole spectrum of clinical research and has helped structure clinical research capacity in Africa. The planned integration with national activities under EDCTP2 is a step towards simplification and clarification, and shall generate higher engagement of Participating States.

The combination of support for clinical trials with capacity building and networking (the 'holistic approach') is considered unique and a best practice in funding clinical research activities in Africa. Through EDCTP, African researchers are given the opportunity to become principal investigators of projects and develop their own research questions based on local needs and challenges.

However, it is as yet hard to judge the 'value for money' as it will take years before the benefits can be reaped of the 100 clinical trials that were funded during the first programme, in terms of new products and long-term improvements in health outcomes. Even though EDCTP's financial contribution remains small compared to that of institutions such as the Wellcome Trust and the Bill & Melinda Gates Foundation, EDCTP is one of the only clinical trial funders who also engage in capacity building and networking activities. As such, it has found a niche where its intervention is absolutely relevant.

EDCTP is now at a point where the necessary infrastructure has been developed and strengthened in order to conduct clinical trials, and where people from different backgrounds and levels have been trained. Further impact of funded projects on product development can therefore be expected in the years to come.

Recommendations

EDCTP constantly tries to improve itself by way of self-assessments and external assessments. Many efforts have been made since its conception in 2003. Most of the recommendations made during the previous independent external evaluation, conducted in 2009, have been addressed. Nevertheless, for the future of EDCTP, some further recommendations have been drafted.

General

It is strongly recommended that EDCTP continues its 'holistic approach' of supporting clinical trials, combined with capacity building and networking activities. In addition to broadening its scope to include neglected infectious diseases and all phases of clinical development, it is recommended to build on the projects that have been funded so far in order to bring them one step further.

EDCTP should keep the long term funding commitment, vision and engagement with African partners and aim for an increase of resources.

Governance and management

The challenge for the future of the programme is to sustain African countries' contribution and engagement and the actual financial means provided by these countries.

The definition of a strategic vision and direction based on portfolio management of the results from EDCTP1 is something that could be strengthened under EDCTP2. The SAC is considered responsible for the development of such a strategy, including an implementation plan.

A specific point of attention for the future of the programme is the continuity of the composition of the SAC. The rate of renewal of SAC members can be adjusted by prolonging the duration of members' mandate and/or phasing new appointments in thirds or halves.

It will be essential for the EDCTP to maintain good leadership through its Executive Director, particularly as the Executive Secretariat is likely to grow.

Based on the progress of the clinical trials funded and the strategic and scientific opportunities for each disease area, a brokered approach could be implemented, similar to the establishment of the PanACEA consortium. The SAC could play a role in defining the specific areas, based on the portfolio of projects funded and scientific challenges.

As the experiences with WHO on strengthening regulatory activities via a single-source approach proved very positive, there is no drawback to following this same route for supporting capacity building activities in the future.

As the project proposals have been perceived as too detailed and the financial report templates as too complicated by the project participants, it is recommended to add more flexibility to timelines of the projects, budgets and activities and to reconsider the structure and complexity of the information to be provided in the financial templates.

It is also suggested to reconsider the mechanisms in place for final payments, since for institutions that are largely publicly funded it can be very challenging to fund the final stages of a project in case the payment from EDCTP is withheld.

It is further recommended that EDCTP considers the scientific review procedures of other funding organisations to ensure that the best research is funded, and to view how they deal with potential conflicts of interest.

Communication and advocacy

With regard to the communication and advocacy approach of EDCTP, it is recommended that electronic newsletters be distributed to all project participants and, where possible – due to privacy regulations –, to other contacts, to adopt a more proactive way of disseminating the results of EDCTP funded projects and of the programme in general. In addition to the current electronic newsletter, specific information could be provided through electronic communication to dedicated target groups (e.g. Senior Fellows, Master and PhD students, but also African and European researchers) about aspects that are of particular interest to these groups.

As more clinical trials funded under EDCTP¹ have finished or are about to finish, it is important to highlight the programme's impact and key successes. Therefore the following suggestions are made to improve the communication and advocacy approach of EDCTP:

- The website should contain more information on project outcomes;
- A list of five to ten top successes from projects should be listed that can be taken up by, for instance, health ministries and politicians;
- It is a good approach to have the homepage in three languages (English, French and Portuguese). However not all parts of the website are comparable in size and level of detail. This is something that should be improved;
- There should be more direct contact with the press and other media to showcase key successes;

In order to maintain the visibility of EDCTP as a scientific and a political initiative, it is important to find a new candidate for the position of High Representative.

Monitoring and evaluation

There is room for EDCTP to better demonstrate its achievements through a more systematic and integrated monitoring and evaluation system that is based on the following elements:

- Creation of a dedicated unit for Monitoring and Evaluation;
- Monitoring and evaluation focused on longer-term results and impacts, as well as follow-up of projects 3 years after they have ended;
- Satisfaction surveys among the grantees;
- Site visits by members of the Executive Secretariat to institutions that have received funding;
- Organisation of events to share results.

Clinical trials

To strive for better alignment and integration of research efforts, it is recommended not to fund too many small projects in too many different areas. This implies a focus on projects with a larger budget, based on the portfolio of projects funded, potentially through a brokered approach like the PanACEA consortium.

It is strongly recommended to continue the support of Strategic Primer Grants as the innovative angle of the programme. Additionally, to allow researchers to further investigate new insights gained during current projects, opportunities could be provided to investigators to request 'add-on' grants. For this reason EDCTP could reserve funds for adding interesting studies to current projects or for responding to new research questions or opportunities that arise after the start of the core study. This can also be combined with a mechanism to retain human capacity.

In its second programme, EDCTP could focus on enhancing product development through better involvement and earlier engagement of regulatory groups, Product Development Partnerships (PDPs) and industry partners.

A financial guarantee system for participating institutions should be explored to minimise the risk taken when partnering in clinical trials with weaker institutions (in financial terms). One potential system to be investigated is the European Commission's Guarantee Fund for External Actions implemented by the European Investment Bank.

As it is likely that health impacts of the funded activities will only become apparent under EDCTP2, it will be essential to closely monitor the progress made in the respective areas.

Capacity building

As a considerable number of sub-Saharan countries have not been involved in the initiated clinical trials, in seventeen of these countries no formal training has taken place. It is worth investigating to what extent students and researchers from these countries could benefit from training opportunities, even if their institutions do not take part in integrated projects or clinical trials.

As trained individuals are essential in raising the overall quality of clinical research in sub-Saharan countries, EDCTP should continue its approach towards investing in all scientific career levels (Bachelor's, Master's and PhD students, postdoctoral researchers and senior fellows). Especially reintroducing career development fellowships for postdoctoral researchers will complete funding opportunities for all career levels.

Furthermore, it is recommended to train other staff (in the lower cadres) as well as those who are involved in clinical research (e.g. medical doctors, nurses, epidemiologists, laboratory technicians and biostatisticians), management and financial aspects of clinical research. However, as it is not directly the remit of EDCTP, this could be achieved through advocating for inclusion of modules on conducting clinical trials and research ethics in medical education.

Capacity building in Africa requires considerable investments and long-term engagement. EDCTP should therefore build on the capacity that has been developed during its first phase. A situation in which incentives are put in place to retain people for at least a couple of years after the EDCTP projects have finished would be preferable to secure transfer of knowledge they have gained. A post-project grant to conduct another related project could be a good incentive. To avoid distortion of competition, this should not be systematic but based on performance, output and achievements of the other previous projects.

An EDCTP alumni association, which is currently under development, will support the creation of a community of researchers and will be beneficial in monitoring career development of those who have received training. These researchers can act as real ambassadors of the programme.

For the second phase of the programme, it is recommended that African scientists continue taking up leadership roles.

As only a limited number of people are familiar with the existence and aim of the Pan African Clinical Trials Registry (PACTR), communication about the intention and benefits of the registry is something that needs to be strengthened. The Pan African Clinical Trials Alliance (PACTA) is another initiative that aims to integrate clinical trial registration, such as PACTR, with clinical trials regulation and ethical approval through national ethics committees and institutional review boards. Efforts can be put towards aligning these two initiatives to explore synergies and increasing their visibility.

Networking

It will be important for a second programme to try to engage countries in sub-Saharan Africa that did not participate in the first programme, and to fund capacity building activities to develop a basis for clinical research.

As the south-south networking approach is a big achievement, it is strongly recommended to maintain this in the second programme. To further increase its results, the capacity and resources for networking and motivation of researchers to network should be increased.

Although EDCTP projects have received considerable contributions from the private sector (primarily from PDPs, philanthropic organisations, big pharmaceutical companies, and Small and Medium Enterprises), it is considered necessary to expand and structure future engagement with the private sector on a more strategic level. The question ‘*how to bring pharmaceutical and biotechnology partners on board?*’ remains open and will have to be addressed.

As not all countries involved in the Networks of Excellence (NoEs) have adequate financial resources to contribute significantly and guarantee their sustainability, it is strongly recommended that EDCTP renew its NoE scheme. It will be important to open up the NoEs to include other countries in the region, as well as other institutions in the already participating countries. More initiatives should also be encouraged to engage all partners of the four NoEs. Lastly, the NoEs should be institutionalised at a higher level, rather than at the level of researchers or institutions. Regardless of their composition, people and strong leadership will play an important role in the popularity, success and dynamism of the NoE.

In the future, measuring in-kind and cash contributions from African countries more systematically could give more credit to the African share and ownership of the partnership. To remain successful, EDCTP needs continuity of investments and this money should not only come from European, but also from African countries. Concerted political action is needed to make sure that these contributions are increased. The current move for African countries to become full member of the EDCTP partnership is a step in the right direction.

Introduction

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a not-for-profit organisation, which was created in 2003 under the European Commission's Sixth Framework Programme (FP6) for Research and Technological Development in response to the global health crisis caused by the three main poverty-related diseases of HIV/AIDS, tuberculosis and malaria. Currently EDCTP is a partnership between 14 European Union member states plus Norway and Switzerland (the EDCTP Participating States) with 48 sub-Saharan African countries. The aim of the programme is to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against these three diseases. This is done through supporting clinical trials, strengthening capacity to conduct clinical research and promoting the integration of national programmes of EDCTP Participating States and the development of a genuine partnership with African counterparts.

This report presents the results of the assessment of the performance and impact of the first programme of EDCTP (hereafter referred to as 'the evaluation'). The Technopolis Group conducted this evaluation of EDCTP's first programme between January 2014 and August 2014 on behalf of EDCTP³.

Rationale for the evaluation

As stated in the Terms of Reference (included in Appendix B), the rationale for conducting this evaluation is to provide EDCTP (the General Assembly (GA) and the Executive Secretariat), the Strategic Advisory Committee (SAC) and its stakeholders with the necessary information on the performance and impact of its first programme from 2003 to date. The evaluation will lead to comprehensive insights into EDCTP funded activities, provide case reports of lessons learned and give recommendations that contribute to the planning and further implementation of the second phase of the programme (EDCTP2), which has been approved by the European Parliament on 15 April 2014 and the European Council on 6 May 2014⁴.

The aim, scope and objectives of the evaluation

This report aims to provide information on the performance and impact of the entire first programme from 2003 to date. The main focus of the evaluation is the contribution of the programme to conduct clinical research, to strengthen clinical research capacity and to support networking among researchers and institutions, within Europe (north-north), within sub-Saharan Africa (south-south) and between the European and African continent (north-south). The evaluation has both a summative and formative character and has four specific objectives:

1. To determine whether the different funding schemes have met their objectives;
2. To assess the output and outcome of the programme by highlighting specific case studies documenting any outstanding success or notable failures;

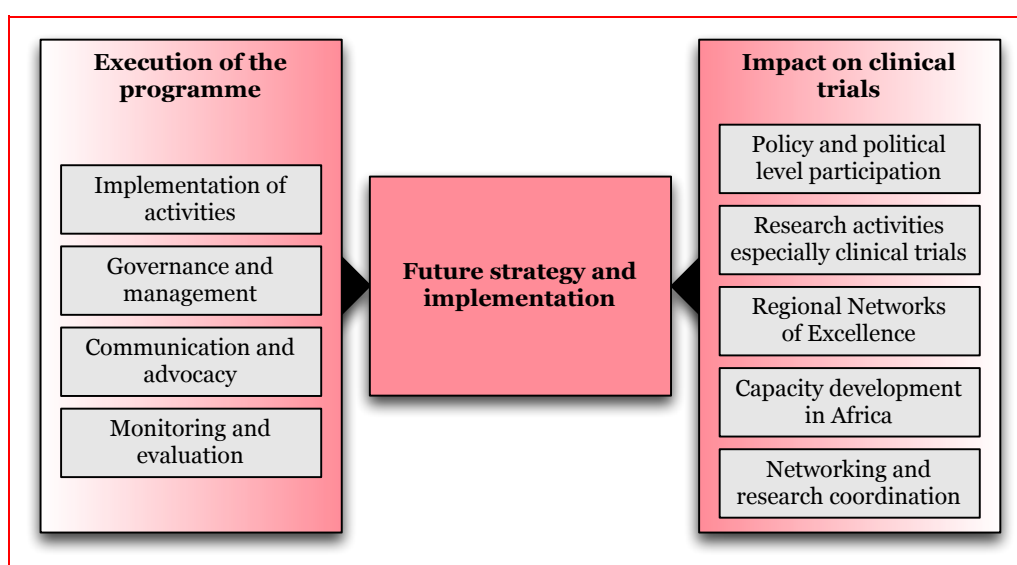
³ The actual evaluation was commissioned by public procedure and the evaluation brief laid down in the 'Terms of Reference for a Consultancy to assess the performance and impact of the first Programme of EDCTP' dated 30 October 2013. The Terms of Reference is included in Appendix B to this report.

⁴ European Union (2014). Decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States. PE-CONS 54/14.

3. To assess the effectiveness, efficiency, relevance and potential sustainability of projects for each funding scheme (viewed both from a funder's and participant's perspective);
4. To review the funding mechanisms⁵, grant awarding and management processes delineating any specific constraints and make recommendations where necessary (also viewed both from a funder's and participant's perspective).

The evaluation concentrates on two main pillars: (1) the execution of the programme and (2) the impact on clinical trials. These pillars include a set of specific evaluation topics, which are presented in the next figure (Figure 1). The findings from both pillars feed into recommendations for future strategy and implementation of EDCTP. A full list of evaluation topics and questions as well as the methods applied is included as Appendix C to this report.

Figure 1 The two pillars of the evaluation including specific evaluation topics



Source: Technopolis Group (2014), based on Terms of Reference.

The methodology

In the evaluation a variety of information sources and data collection and analytical methods are used to reach conclusions and recommendations. These methods target all of the evaluation questions that are listed in Appendix C. The methods are applied in different combinations to best fit the evaluation questions. We made use of multiple techniques in parallel in order to increase the reliability of the results (in evaluation terminology this is called triangulation)⁶. The more the evaluation questions relate to effects and impacts (the second pillar from the figure above), the more we will rely on data collection through the electronic survey and case studies.

The methods applied in this evaluation are summarised as follows:

- Desk research on already existing information to gain a good understanding of the activities undertaken by EDCTP from 2003. This concerns amongst others

⁵ EDCTP uses three approaches: (1) open calls for proposals; (2) the brokered approach; and (3) the single source approach.

⁶ Erik Arnold and Ken Guy (1997), 'Technology diffusion programmes and the challenge for evaluation' in OECD, Policy Evaluation in Innovation and Technology: Towards Best Practices, Paris: OECD.

information on the delivery of projects (call texts), the outputs and results of activities; the financial organisation and governance; the distribution of countries and (third party) participation; communication and advocacy activities. The sources of information used in this evaluation are listed in Appendix A.

- To investigate the opinions and experiences of both internal and external stakeholders of EDCTP and to assess the performance and impacts achieved, more than 40 interviews (of which the majority through telephone conversation) have been conducted. The interviewees are identified in consultation with EDCTP taking into account different backgrounds and positions (e.g. representation of both European and African stakeholders and those that are involved in EDCTP for a relatively long time versus those that are quite new to the programme). As a result a distinction is made between the following stakeholder groups:
 - The Executive Secretariat of EDCTP, both the Management Team and other staff members (both in the premises in The Hague and Cape Town);
 - Members from the General Assembly (GA) of EDCTP, both representatives from European member countries and African countries;
 - Members of EDCTP's Strategic Advisory Committee (SAC) and previous advisory boards;
 - A selection of co-funding partner organisations; and
 - Representatives from the organisations that host the two offices of EDCTP's Executive Secretariat (in The Hague and Cape Town).

The annexes to this report provide a comprehensive list of all interviewees (Appendix E) and the interview questions (Appendix F).

- An electronic survey has been distributed amongst both coordinators and participants of all projects that EDCTP has granted since 2003. This survey has been accessible between April and June 2014. The survey methodology, including response rates and some characteristics of the respondents are included in Appendix G. The overall questionnaire that has been distributed is included in Appendix H.
- Four case studies of a selection of sub-Saharan African countries based on country visits, covering the four regions:
 - i) Southern Africa: South Africa visited between 28 April and 2 May 2014;
 - ii) Eastern Africa: Tanzania visited between 19 and 23 May 2014;
 - iii) Central Africa: Republic of the Congo (also referred to as Congo Brazzaville) visited between 26 and 28 May 2014;
 - iv) Western Africa: Mali, because of the current political instability no visit has taken place during the course of this evaluation.

The four country case studies, including the programme of the visit, the details of all interviewees, background on the health situation and the complete qualitative descriptions are available in Appendix I to Appendix L. These descriptions consist of an overview of the organisations visited, the disease burden in the respective countries, the achieved impacts on clinical trials, capacity building and networking as well as an investigation of the perceptions on the execution of the programme and EDCTP's strengths, weaknesses, opportunities and threats (SWOT).

A survey amongst successful applicants might be considered as a potential limitation to the methodology. As the survey mainly focuses on questions related to the progress, results and impacts of the projects funded it was agreed that the unsuccessful applicants are not taken into account. However there is always a risk for a positive bias in the responses collected from this group of respondents.

The report tries to maintain a balance between the two pillars of the evaluation: the execution of the programme and the impact on clinical trials. However the final composition is influenced by the results and responses collected during field consultations. One example is that it was easier for the field to respond extensively to the capacity building and networking activities of EDCTP funded projects rather than the current impact on clinical trials, as a majority of the projects are still in the phase of execution or analysis of the results.

Structure of the report

The report is structured as follows: Chapter 1 introduces the EDCTP programme in terms of its history and sets out its mission, objectives and activities as well as its current governance structure. It also presents the recommendations made during the previous assessments of the programme. These will be reflected upon at the end of this report to assess to what extent they have been taken into account. Chapter 2 shows some factual information on the activities that have been put in place by EDCTP. This comprises the number and type of funded grants, the distribution per disease area or topic and the geographical coverage of European and African countries and institutions participating in the programme. In Chapter 3 the execution of the programme is assessed in terms of its overall performance, governance and management, the communication and advocacy approach and its monitoring and evaluation procedures. The subsequent chapters provide more detailed information on the impact of the programme on conducting clinical trials (Chapter 4), capacity strengthening in sub-Saharan Africa (Chapter 5) and networking and research coordination (Chapter 6). Chapter 7 presents the analysis of the strengths and weaknesses of EDCTP and the opportunities and threats for EDCTP's future. The last chapter (Chapter 8) of the report includes the main findings, conclusions of the evaluation and formulates recommendations for further improvement and implementation of EDCTP during a second phase.

Acknowledgements

This evaluation of the first programme of EDCTP would not have been possible without the support from the Executive Secretariat by providing all the necessary information, arranging interviews, freeing up their valuable time for being interviewed and assisting in the organisation of the country visits.

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Finally, during the three country visits helpful practical support has been received from the different institutions that assisted us in arranging visas, facilitated in-country transfers and showing around facilities supported by EDCTP.

1. The EDCTP programme

1.1 A brief history

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases HIV/AIDS, tuberculosis and malaria⁷. These are three of the world's most devastating communicable diseases that are affecting many of the world's poorest people (especially in sub-Saharan Africa). The diseases are characterised as poverty-related diseases not only because they are endemic in impoverished populations but also because they impede economic development and cause unnecessary death and suffering. EDCTP provides resources and training for researchers in sub-Saharan countries to take up a leadership role in clinical trials and to create a sustainable environment for conducting high-quality medical research.

Key facts on HIV/AIDS

The Human Immunodeficiency Virus (HIV) targets the immune system and weakens people's surveillance and defence systems against infections and some types of cancer. As the virus destroys and impairs the function of immune cells, infected individuals gradually become immunodeficient. Immune function is typically measured by CD4 (a type of lymphocyte, or white blood cells) cell count. Immunodeficiency results in increased susceptibility to a wide range of infections and diseases that people with healthy immune systems can fight off.

The most advanced stage of HIV infection is Acquired Immunodeficiency Syndrome (AIDS), which can take from 2 to 15 years to develop depending on the individual and whether or not the individual is on antiretroviral therapy. AIDS is defined by the development of certain cancers, infections, or other severe clinical manifestations.

- HIV continues to be a major public health issue, having claimed more than 36 million lives worldwide so far.
- There were approximately 35.3 million people living with HIV in 2012.
- Sub-Saharan Africa is the most affected region, with nearly 1 in every 20 adults living with HIV. Sixty nine per cent of all people living with HIV are living in this region.
- HIV infection is usually diagnosed through blood tests detecting the presence of HIV antibodies.
- There is no cure for HIV infection. However, effective treatment with antiretroviral drugs can control the virus so that people with HIV can enjoy healthy and productive lives.
- In 2012, more than 9.7 million people living with HIV were receiving antiretroviral therapy (ART) in low- and middle-income countries.

Source: WHO Factsheet on HIV/AIDS (updated October 2013).

From the start, the European Commission, the European Union Member States plus Norway and Switzerland supported EDCTP. Around 2000, both the European Commission as well as the Member States recognised the need to coordinate research and development (R&D) and capacity building efforts to combat HIV/AIDS, tuberculosis and malaria epidemics in developing countries, in particular in sub-Saharan Africa.

In 2000 and 2001 the European Council and European Parliament endorsed a programme for accelerated action on these diseases in the context of poverty reduction, focusing on promoting prevention, encouraging treatment, making essential medicinal products more affordable, and stepping up R&D⁸. The latter priority was aimed, among other things, at developing new clinical interventions to combat the three diseases through a long-term partnership between Europe and developing countries. In 2002 the

⁷ Website of EDCTP, to be found at: <http://www.edctp.org/>.

⁸ In Council Resolutions of 10 November 2000 and 14 May 2001, and the European Parliament Resolution of 4 October 2001.

European Parliament and Council decided⁹ that the European Community would contribute €60 million to the Global Fund to Fight AIDS, Tuberculosis and Malaria¹⁰. However, as the fund did not finance R&D, additional funding sources for such activities were still required.

In 2001 the Council¹¹ had already called on European Union Member States to select specific areas for pilot programmes on research and development to be undertaken by the Member States themselves, if necessary in close collaboration with the Commission. In 2002, as part of the European Commission's Sixth Framework Programme (FP6) for Research and Technological Development¹², the provision for participation in research and development programmes undertaken jointly by several Member States was announced, including the structures created for the execution of those programmes. At this time, Member States were already undertaking individual research and development programmes or activities in long term partnerships with developing countries aimed at developing new clinical interventions to combat the global problem of HIV/AIDS, tuberculosis and malaria. However these were *"not sufficiently coordinated and did not allow a coherent approach at European level for an effective research and technological development programme to combat the diseases in developing countries, or to find optimal treatments suited to the conditions in these areas"*¹³.

Key facts on Tuberculosis

Tuberculosis is caused by bacteria (*Mycobacterium tuberculosis complex*) that most often affect the lungs. It is curable and preventable. Tuberculosis is spread from person to person through the air. When people with lung tuberculosis cough, sneeze or spit, they propel the germs into the air. A person needs to inhale only a few of these germs to become infected. About one-third of the world's population has latent tuberculosis, which means people have been infected by the tuberculosis bacteria but are not (yet) ill with disease and cannot transmit the disease.

People infected with the tuberculosis bacteria have a lifetime risk of falling ill with tuberculosis of 10%. However persons with compromised immune systems, such as people living with HIV, malnutrition or diabetes, or people who use tobacco, have a much higher risk of falling ill. When a person develops active tuberculosis (disease), the symptoms (fever, night sweats, weight loss etc.) may be mild for many months. This can lead to delays in seeking care, and results in transmission of the bacteria to others. People ill with tuberculosis can infect up to 10-15 other people through close contact over the course of a year. Without proper treatment up to two thirds of people ill with tuberculosis will die.

- Tuberculosis is 2nd only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent.
- In 2012, 8.6 million people fell ill with tuberculosis and 1.3 million died from tuberculosis.
- Over 95% of tuberculosis deaths occur in low- and middle-income countries, and it is among the top three causes of death for women aged 15 to 44 years.
- In 2012, an estimated 530,000 children worldwide became ill with tuberculosis and 74,000 children died.
- Tuberculosis is a leading killer of people living with HIV causing one fifth of all deaths worldwide.
- Multi-drug resistant tuberculosis (MDR-TB) is present in virtually all countries surveyed.
- The estimated number of people falling ill with tuberculosis each year is declining, although very slowly, which means that the world is on track to achieve the Millennium Development Goal to reverse the spread of tuberculosis by 2015.
- The tuberculosis mortality rate dropped 45% between 1990 and 2012.
- An estimated 22 million lives saved through use of Direct Observance Treatment, Short-Course (DOTS) and the Stop TB Strategy (WHO).

Source: WHO Factsheet on Tuberculosis (updated March 2014).

⁹ Decision No 36/2002/EC.

¹⁰ <http://www.theglobalfund.org/>.

¹¹ Council Conclusions of 30 October 2001.

¹² Decision No 1513/2002/EC.

¹³ Decision No 1209/2003/EC.

Wishing to have a coherent approach at European level and to act effectively against diseases in developing countries, a number of European countries took the initiative, with developing countries, to set up a research and development programme that would gather a critical mass in terms of human and financial resources to support clinical development of new medical interventions. It would also provide expertise and resources available in the different countries. In order to increase the impact of this programme, the European Parliament and Council decided to participate in this programme by making a financial contribution to allow the European Union to participate in the programme¹⁴.

Key facts on Malaria

Malaria is caused by Plasmodium parasites. The parasites are spread to people through the bites of infected Anopheles mosquitoes, called “malaria vectors”, which bite mainly between dusk and dawn. According to the latest estimates there were worldwide about 207 million cases of malaria in 2012 and an estimated 627,000 deaths. Malaria mortality rates have fallen by 42% globally since 2000, and by 49% in the WHO African Region. Most deaths occur among children living in Africa where a child dies every minute from malaria. Malaria mortality rates among children in Africa have been reduced by an estimated 54% since 2000.

- Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected mosquitoes.
- In 2012, malaria caused an estimated 627 000 deaths (with an uncertainty range of 473 000 to 789 000), mostly among African children.
- Malaria is preventable and curable.
- Increased malaria prevention and control measures are dramatically reducing the malaria burden in many places.
- Non-immune travellers from malaria-free areas are vulnerable to the disease when they get infected.

Source: WHO Factsheet on Malaria (updated March 2014).

During the preparatory period to FP6, the European Commission, some of the European Union Member States, Norway and partners from developing countries, examined how to join and coordinate their efforts to accelerate the development of new interventions through clinical trials against HIV/AIDS, tuberculosis and malaria. An ‘accompanying measure’ ran from 2002-2003 (co-funded through the Fifth Framework Programme) uniting authorities and scientists from interested countries. This concluded that national programmes could develop into a ‘joint programme’ that could be co-funded by the European Commission (by applying Article 169 of the Treaty). This led to the establishment of the EDCTP programme as the result of subsequent decisions to pool resources, funding and activities in order to achieve a greater impact against the three poverty-related diseases. It was established under FP6 and was the first ever Article 185 (ex Article 169 TEC) initiative (relating to the participation of the European Union in the joint implementation of research and development national programmes).

¹⁴ Decision No 1209/2003/EC.

1.2 Mission, objectives and activities

EDCTP aims to develop new clinical interventions to fight HIV/AIDS, tuberculosis and malaria, through European research integration and in partnership with African countries. Through this approach, which will improve the health of populations in developing countries, EDCTP contributes to the societal challenge of poverty reduction in these countries¹⁵. Through the following mission EDCTP tries to address this goal:

“to accelerate the development of new clinical interventions to fight HIV/AIDS, tuberculosis and malaria in developing countries, particularly sub-Saharan Africa, and to improve the quality of research in relation to these diseases through European research integration and in partnership with African countries”.

According to the Joint Programme of the Action (the document, published in 2003 and updated in 2011, that sets out EDCTP’s strategy), the main objectives of EDCTP are¹⁶:

- To support clinical trials of new or improved drugs and vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa with a focus on phase II/III trials;
- To strengthen clinical research capacities in sub-Saharan Africa, especially for conducting clinical trials against poverty-related diseases;
- To coordinate and integrate European national programmes on EDCTP-related activities into a Joint Programme.

1.2.1 Activity areas, funding schemes and activities

In its strategic documents (mainly the Joint Programme of the Action), EDCTP distinguishes between seven activity areas, which are the basis for the development of specific activities. These activity areas are:

1. Networking and coordination of European national programmes (North-North network and coordination);
2. Networking and coordination of African national programmes (South-South networking and coordination);
3. Supporting relevant clinical trials;
4. Strengthening the African capacity in this field;
5. Advocacy and fundraising;
6. Management;
7. Information management.

The first four activity areas directly relate to the objectives defined above, the latter three have a more internal character and support the other areas in terms of providing the right conditions.

In order to create a sustainable environment for high-quality medical research in sub-Saharan countries, EDCTP financially supports clinical trials, as well as capacity strengthening and networking activities. The different schemes, spanning the entire period of EDCTP1, are listed in the table below (Figure 2).

¹⁵ EDCTP (2007). Joint Programme of the Action Part A.

¹⁶ Joint programme of Action A (2003 and 2007).

Figure 2 Overview of the different EDCTP funding schemes by grant scheme category

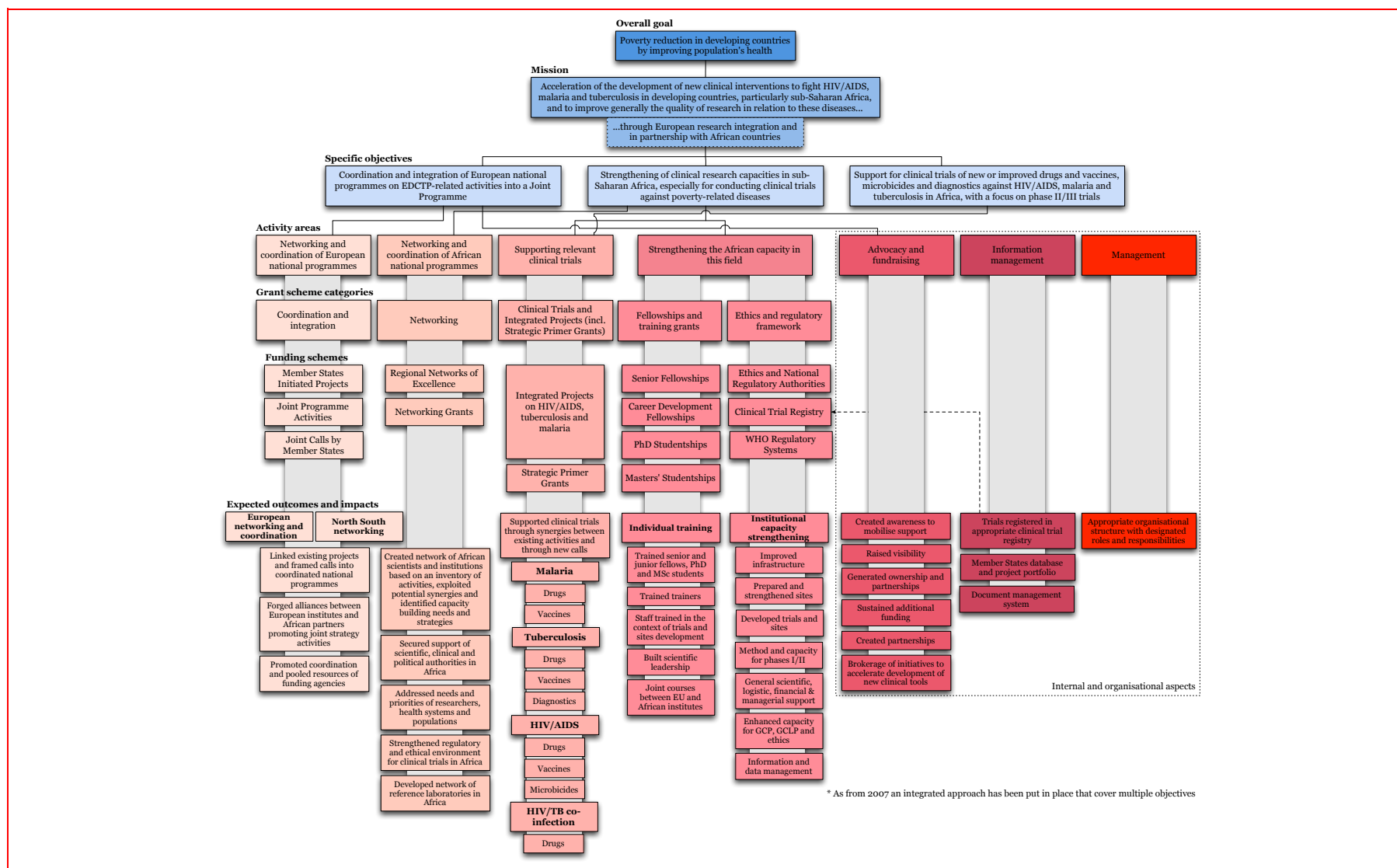
	Funding scheme	Brief description of the funding scheme
Clinical Trials and Integrated Projects	Clinical Trials and Integrated Projects on HIV/AIDS	<p>Integrated Projects are the largest of all EDCTP grant schemes in terms of budget and complexity. A multicentre and multinational clinical trial on one of the three disease areas (HIV/AIDS, tuberculosis and malaria) is the core activity. Linked to the trial a series of work packages are distinguished to ensure successful outcomes and sustainability:</p> <ul style="list-style-type: none"> • Clinical trials; • Networking and coordination of European national research and development programmes; • Networking and coordination of African national programmes; • Capacity strengthening (i.e. through conducting baseline epidemiological studies, site infrastructure upgrades, short-term training, Masters and PhD studentships, and Postdoctoral fellowships).
	Clinical Trials and Integrated Projects on tuberculosis	
	Clinical Trials and Integrated Projects on malaria	
Fellowships and training grants	Senior Fellowships	<p>The Senior Fellowships aims to identify senior researchers capable of building and leading research groups and support them at different career stages. The expectation is that the groups will become internationally competitive and capable of attracting funding from international funding bodies. The objectives of this scheme are to:</p> <ul style="list-style-type: none"> • develop capacity for research in sub-Saharan African institutions; • promote the career development of researchers by encouraging them to upgrade their profile and/or return to or continue to work in Africa; • strengthen the capacity to undertake clinical trials of interventions on any of the three major poverty related diseases in Africa.
	Career Development Fellowships	<p>The Career Development Fellowships enable experienced researchers to acquire competence in the conduct of clinical trials either at sites with on-going EDCTP supported studies or other sites of trials involving HIV/AIDS, tuberculosis and malaria in Africa. The objectives of this fellowship programme are to:</p> <ul style="list-style-type: none"> • develop capacity for research in sub-Saharan African institutions; • promote the career development of sub-Saharan African researchers by encouraging them to upgrade their profile; • strengthen the capacity to undertake clinical trials of interventions on any of the three major poverty related diseases (PRDs) in Africa conducted at internationally acceptable standards.
	PhD Studentships	<p>PhD Studentships enable researchers to register in a PhD programme either at a sub-Saharan African institution or a sandwich model programme involving a sub-Saharan African university/institution and a university in any of the EDCTP Participating States. The objectives of this PhD programme are to:</p> <ul style="list-style-type: none"> • provide sub-Saharan African researchers with the knowledge and skills to conduct independent and collaborative research on HIV/AIDS, tuberculosis and malaria; • prepare African scientists and/or research clinicians for leadership roles nationally and internationally.
	Master's Studentships	<p>Master's studentships intend to support students from sub-Saharan Africa who are pursuing a Master's degree in a clinical trial related discipline. The objectives of these studentships are to:</p> <ul style="list-style-type: none"> • help ensure a reliable supply of suitably qualified and skilled personnel with training tailored to the needs of sub-Saharan African sites that receive funding from EDCTP; • provide talented aspiring African scientists that work on sub-Saharan African sites that receive funding from EDCTP with the knowledge, skills and competencies necessary to embark on and critique their own research.
Ethics and regulatory framework	Ethics and National Regulatory Authorities	<p>In order to strengthen local capacity in both ethical review and the national regulatory framework in Africa, EDCTP, through ethics and regulatory projects, provides support in the following areas:</p> <ul style="list-style-type: none"> • Establishment and strengthening of institutional and national ethics committees; • Ethics training in Africa through courses and seminars; • An African coordinating office that oversees activities in clinical trials and related research ethics; • Strengthening of the national regulatory framework in Africa through collaboration with the World Health Organization (WHO).
	Clinical Trial Registry	
	WHO Regulatory Systems	

	Funding scheme	Brief description of the funding scheme
Coordination and integration	Member States Initiated Projects	European Member States through their national programmes fund projects that fall within the remit of EDCTP. The purpose of this grant is to provide funding and added value to these initiatives by supporting the integration of various projects and programmes that have been independently initiated and/or funded by European Member States. This scheme provides a platform for strengthening of north-north and north-south partnerships, coordinating and networking of African researchers and establishing sustainable capacity building in Africa.
	Joint Programme Activities	
	Joint Calls by Member States	
Networking	Regional Networks of Excellence	EDCTP supports Networks of Excellence (NoEs) that are involved in clinical trials. These networks facilitate regional collaboration in sub-Saharan Africa, by uniting various institutions based on their individual strengths. The objectives of these Networks of Excellence are to: <ul style="list-style-type: none"> • create and strengthen African institutions to become specialised research and training centres in clinical research; • strengthen their capacity in skills required to conduct clinical and other research; • strengthen their capacity to hold training across disciplines and techniques; • enhance research collaboration and networks between African institutions, coordinated by the centres themselves; • ensure sustainability and avoid duplication, the networks strive to collaborate with similar initiatives at the country and regional level.
	Networking Grants	Networking Grants aim to support cooperation and coordination of European and sub-Saharan African national research and capacity building programmes on HIV/AIDS, tuberculosis and malaria. European integration and avoidance of fragmentation are goals as well. The objectives of the networking grants are to: <ul style="list-style-type: none"> • forge alliances between European funding agencies, institutes and university departments and their sub-Saharan African partners to promote joint strategies and activities in building infrastructure, training, research and capacity strengthening in Africa; • improve the environment for relevant research activities in sub-Saharan Africa.
Other	Strategic Primer Grants	The Strategic Primer Grants aim to provide pump-priming for researchers to explore novel and innovative lines of research that may lead to the development and testing of new or improved clinical interventions against HIV/AIDS, tuberculosis or malaria. The objectives of the strategic primer grants are to: <ul style="list-style-type: none"> • generate results to inform future clinical trials; • sustain and strengthen the capacity built up under EDCTP; • increase networking of African and European research programmes.

Source: Information provided by EDCTP (2014).

Based on EDCTP's mission, objectives, activity areas and activities (the funding schemes presented in the previous table) the following graph (Figure 3) schematically shows the intervention logic of EDCTP. This is an analytical tool that provides a structured approach looking at the programme and is considered to be good starting point for the development of proper indicators of performance. These indicators could be beneficial in monitoring and evaluating the programme against its mission, objectives and activities.

Figure 3 Intervention logic of EDCTP

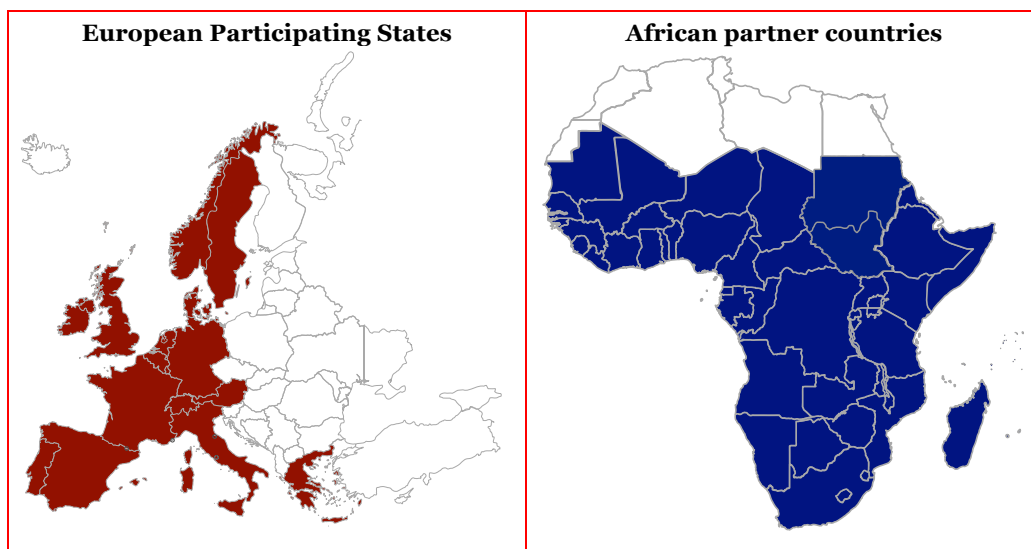


Source: Technopolis Group (2014), based on strategic documents of EDCTP.

1.3 The countries involved in EDCTP

EDCTP is jointly undertaken by participating countries in Europe and those of sub-Saharan Africa. By applying Article 185, each Participating State mobilises its publicly funded organisational and institutional activities to synchronise and pool resources into a joint programme. The partnership under the first phase of EDCTP consists of 14 European Union Member States, plus Norway and Switzerland (the EDCTP Participating States) and 48 sub-Saharan African countries (see Figure 4). Appendix D provides a full list of all countries involved in the partnership.

Figure 4 EDCTP partner countries



Source: Website and other information of EDCTP (2014).

1.4 The second phase of EDCTP (2014-2024)

On 15 April 2014 and 6 May 2014, the European Parliament and the European Council respectively approved the second phase of the EDCTP Programme (EDCTP2). This as a result of a lengthy process, which included amongst others a consultative process to gather inputs and recommendations from an independent external expert review, an impact assessment conducted by the European Commission, an open public consultation and an all-EDCTP-constituency meeting. The European Commission allocated a total budget of €683 million for another period of ten years conditionally that the Participating States will match at least this contribution. The overall strategy has not been revised, which means that EDCTP2 will continue to support clinical development of new or improved diagnostics, drugs, vaccines and microbicides against HIV/AIDS, tuberculosis and malaria. However in addition, EDCTP2 will also support studies on neglected infectious diseases (NIDs) and supports all clinical trial phases, from phase I to IV, though the main focus will still be on phase II and III clinical trials. The geographical focus of EDCTP2 will remain on sub-Saharan Africa, although collaborative research with other developing countries outside sub-Saharan Africa could be envisioned when possible and desirable.

In its Strategic Business Plan for EDCTP2¹⁷ the following aspects will be continued:

- Multicentre projects that combine clinical trials, capacity building and networking;
- Capacity development for clinical trials and clinical research in sub-Saharan countries;
- Closer collaboration with industry, like-minded organisations, product development partnerships (PDPs), research funders and development cooperation agencies.

Prior to the actual approval of a second phase, EDCTP received specific funding (EDCTP-Plus) from the European Commission to bridge the period between the end of the first phase and the start of EDCTP2.

1.5 Previous assessments and their recommendations

During the first phase of EDCTP a number of both internal and external assessments have been performed. In 2007 and again in 2009 the European Commission requested an independent external review of EDCTP^{18,19}. In 2009 the Swiss Centre for International Health (SCIH), part of the Swiss Tropical Institute (STI) performed an internal assessment on the first years of EDCTP²⁰. Finally, in 2013, as part of the process towards a decision on the second phase of the EDCTP programme, the European Commission conducted an impact assessment²¹. The main findings and recommendations of each of these assessments are listed in the table on the following pages (Figure 5). A distinction is made between three different topics (activities, governance and operations) and a selection of issues. Where possible the evolution in terms of the uptake of the recommendations is included in the two grey columns indicated by the “Δ”-sign.

The last chapter of this evaluation report (Chapter 8) will assess what progress has been made taking into account the recommendation from the previous assessments.

¹⁷ Strategic Business Plan for the second phase of the European & Developing Countries Clinical Trials Partnership programme (EDCTP2, 2014-2023) undertaken by several Member States under Article 185 of the Treaty on the Functioning of the European Union (EU).

¹⁸ Independent External Review Report (2007).

¹⁹ Independent External Evaluation Report (2009).

²⁰ Swiss Centre for International Health (SCIH), Internal Assessment of the 2003-2009 EDCTP Programme (2009).

²¹ European Commission, Impact Assessment for a decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States.

Figure 5 Recommendations made by previous assessments per topic and issue

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009
Activities	Capacity Development	n.a.	+	<ul style="list-style-type: none"> • Recommends involvement of Northern and Southern partners in all aspects of capacity strengthening of African research institutions. 	+	<ul style="list-style-type: none"> • EDCTP is strengthening capacity development through various efforts e.g. senior fellowships, training of PhDs, MScs, et cetera; • Focus on training shall not let down other capacity building components such as logistical support to institutions, motivation of researchers, improving behaviours, action on national research systems. 	<ul style="list-style-type: none"> • Survey respondents highly appreciate the capacity building efforts of the EDCTP.
Activities	Networking	n.a.	n.a.	n.a.	+	<ul style="list-style-type: none"> • EDCTP has improved networking (South-South, North-South, North-North); • Brings a new model of international research cooperation, promoting African ownership and Africa/EU networking; • Underrepresentation of non-English speaking countries but CANTAM NoE recently set up. 	<ul style="list-style-type: none"> • Respondents believe that the promotion of partnerships and networks between EU and African institutions for project application and implementation has significantly increased collaboration opportunities between European and African institutions (North-South) and between African institutions (South-South); • North-North collaboration has not been particularly mentioned by the survey respondents, neither in positive nor in negative sense; • The Networks of Excellence are highly valued.
Activities	Clinical trial strengthening	n.a.	+	<ul style="list-style-type: none"> • Recommends involvement of Northern and Southern partners in all aspects of product development (product specification/design of clinical phase); • Encourages EDCTP to associate with likeminded and comparable actors to assure up-to-date know-how, capacity development and expertise. 	+	<ul style="list-style-type: none"> • It is the core activity of EDCTP and EDCTP is continuously investing in staying updated on new developments and seeks collaboration with important likeminded actors; • Equity in participation of African researchers; • 43 % are preparedness studies; • 38 countries are participating to clinical trials (CT) with UK participating to 70% of all CT; • Good representation of specific groups; • Few epidemiological studies were initially conducted to determine incidence or prevalence; • Slow progress in cohort recruitment; • No outcome evaluation measures as final indicators; • Many researchers participate to 3 projects or more at a time. 	<ul style="list-style-type: none"> • Survey respondents believe that EDCTP is filling an important gap in clinical trial conduct for the three poverty related diseases.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009
Activities	Regulatory environment and ethics	n.a.	n.a.	n.a.	+	<ul style="list-style-type: none"> EDCTP is strengthening the regulatory environment and ethical standards e.g. through the establishment of an African public clinical trial registry. 	<ul style="list-style-type: none"> The majority of comments are rather positive; Survey respondents highly appreciate EDCTP's efforts in this field.
Activities	African ownership	n.a.	+	<ul style="list-style-type: none"> Broaden DCCC membership to increase engagement of African governments and organisations. 	+	<ul style="list-style-type: none"> African ownership has been improved as is shown by the increased involvement of African countries and increasing numbers of African project coordinators. 	<ul style="list-style-type: none"> The level of African EDCTP project ownership is either rated as average (40%) or high (31%) by the majority of survey respondents, acknowledging the fact that it might well vary between projects. Compared to other similar mechanisms, if similarities do exist, 45% of stakeholders believe that African ownership is "higher than" average or at least "average" (33%).
Activities	Sustainability	n.a.	n.a.	n.a.	+/-	<ul style="list-style-type: none"> The major challenge is the long term sustainability of the positive impacts; Would be beneficial if EDCTP would implement an impact evaluation process to allow prospective analysis of EDCTP achievements and consider advances in research by other funders. 	<ul style="list-style-type: none"> Respondents repeatedly voice their concern regarding the sustainability of existing EDCTP projects in case EDCTP funding should come to an end.
Activities	Integrating national programmes	n.a.	n.a.	n.a.	n.a.	<ul style="list-style-type: none"> Progressing too slowly; Member States national programme integration and financial commitment does not follow a realistic strategy and common shared vision (only 40% integration indicator). 	n.a.
Governance	African presence in GA	n.a.	+	<ul style="list-style-type: none"> The African presence in the General Assembly should be reinforced. 	+/-	<ul style="list-style-type: none"> A decision has already been made to increase African representation on the General Assembly. It will be implemented. 	<ul style="list-style-type: none"> In general, survey respondents tended to rate African representation at decision-making level with an "average" (28%) to "high" rating (24%) with quite a few stakeholders (26%) not really knowing how to evaluate this question at all.
Governance	More Political representation of GA	n.a.	+/-	<ul style="list-style-type: none"> Make the General Assembly more political and create and Executive Steering Committee. 	o	<ul style="list-style-type: none"> A steering committee has been composed; A number of Member States have taken steps to improve political representation and engagement with EDCTP e.g. Netherlands, Belgium and UK. 	<ul style="list-style-type: none"> The majority of survey participants (55%) are not aware of an improved political representation of the EDCTP programme as recommended in the 2007 external review. They refer to a lack of visibility, which does not really allow them to make a valid assessment of this issue.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009
Governance	Scientific independence	n.a.	+	<ul style="list-style-type: none"> Install adequate firewall protection from political and other external pressures for scientific independence and at Partnership Board level. 	n.a.	n.a.	n.a.
Governance	EDCTP Mandate	n.a.	+	<ul style="list-style-type: none"> Agree on EDCTP component mandates and clarify dialogue between components. 	n.a.	n.a.	n.a.
Operations	PDP/ Private sector engagement	n.a.	+/-	<ul style="list-style-type: none"> Expand association with major PDPs/private partnerships to encourage participation and mobilisation. 	+/-	<ul style="list-style-type: none"> Engagement with PDPs has grown and EDCTP projects have received considerable funds from the private sector. A working group of experts has been initiated by EDCTP to prepare a strategy document and business plan on how to effectively engage with the private sector. 	<ul style="list-style-type: none"> The majority of survey respondents are not aware of improved engagement with the private sector focusing on product development.
Operations	Streamline co-funding	<ul style="list-style-type: none"> Develop an overview of Member State funding mechanisms. 	+/-	<ul style="list-style-type: none"> Simplify and streamline co-funding form virtual to an actual common pot by 2009 and renewal of vows to finance EDCTP. 	0	<ul style="list-style-type: none"> EDCTP is still engaging in discussions with Member States on this issue to identify ways to streamline co-funding. Some members are in the process of making changes and EDCTP is continuously working on improving the co-funding arrangements. It is a burden on the researchers. 	<ul style="list-style-type: none"> Funding and co-funding is one of the two topic areas receiving most criticism from survey respondents. 40% stakeholders did not know how to evaluate the interest of major funders to invest in EDCTP and 40% noted only "some" or "average interest from funders. Many are not aware of efforts to establish a common funding pot.
Operations	Information Management/ Visibility	<ul style="list-style-type: none"> Recommends developing a communication plan and guidelines on how to have a more direct contact with the research community. 	+	<ul style="list-style-type: none"> Recommends publishing a web page with KPI, minutes, annual reports and official key documents, ethical judgements on projects, EDCTP Intellectual Property policy; Implement a communication plan to make EDCTP an attractive and visible player. 	+	<ul style="list-style-type: none"> EDCTP has introduced various mechanisms to increase visibility e.g. website, quarterly newsletters in 3 languages, et cetera; Recommends publishing on the website how it verifies compliance with international ethical principles and IP rights. 	<ul style="list-style-type: none"> The majority of survey respondents highly appreciate and are aware of the various visibility measures initiated by the EDCTP e.g. webpage, quarterly newsletter, et cetera.
Operations	Call procedures	<ul style="list-style-type: none"> Improve process of call initiation has damaged EDCTP reputation (the 2nd call was cancelled). Inconsistencies in proposal evaluations exist. Standard Operating Procedures (SOPs) need to be developed. 	+	<ul style="list-style-type: none"> Implement quality assurance of call process; Renew calls for appropriate projects to be submitted rapidly to attract the best public/private partnership and to participate in major R&D initiatives. 	+/-	<ul style="list-style-type: none"> Review how proposal are handled and revise procedural guidelines; EDCTP increased the number of calls launched. In order to be more effective with regards to interested private and public parties, it has implemented stakeholder meetings before launching new clinical trials. 	<ul style="list-style-type: none"> Varying opinions exist: 47% believe the call system is effective, while 33% claim it to be only partially effective.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009
Operations	Scientific and ethical evaluation	n.a.	+/-	<ul style="list-style-type: none"> Accept one single integrated scientific and ethical evaluation utilising a pool of the best national experts. 	n.a.	n.a.	n.a.
Operations	Operational Structure	<ul style="list-style-type: none"> Employ an experienced Executive Director; Improve communication between EDCTP constituent bodies through joint meetings and information exchange as misconceptions of roles and responsibilities exist; Develop Standard Operating Procedures for roles and responsibilities. Familiarise with EC funding system. 	+	<ul style="list-style-type: none"> Draw lessons from past Executive Director instability and management weaknesses at Executive Secretariat level. 	+/-	n.a.	<ul style="list-style-type: none"> The slow start-up phase of the EDCTP, also marked by many managerial and strategy changes, was mentioned as the most detrimental factor limiting EDCTP's progress in the first few years of existence. However, many respondents now acknowledge that the initial hurdles have been overcome and that EDCTP has flourished in the past 3 years and is achieving and in some cases even exceeding its objectives, thanks to the current Executive Director. However, criticism of various aspects persists.
Operations	Strategy	n.a.	+/-	<ul style="list-style-type: none"> Regroup the various activities around clinical trials, capacity building and Networks of Excellence; Define a strategy, action plan with financial targets and deliverables, KPI and external benchmarks. 	+/-	<ul style="list-style-type: none"> KPI are so far a good start but should be narrowed; Need for a needs assessment approach; Absence of any a priori formulated measurable indicator for the expected outcome set at the start of the EDCTP programme; It is difficult to assess EDCTP's economic and societal impact. Monitoring and auditing of projects shall be done by an external contract organisation 	n.a.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009
Operations	Coherence	n.a.	+	<ul style="list-style-type: none"> • The need for EDCTP activities to be part of a broader international research agenda; • Ensure coherence with EC public health strategy; • Ensure coherence with priorities of African governments; • Ensure coherence with existing conditions required for the supply of accessible and affordable essential medicines; • Systematic review of all clinical trials developments and clinical capacity for poverty related diseases; • Comprehensive needs assessment of the requirements for capacity building for clinical research and health systems. 	+	<ul style="list-style-type: none"> • Compels EDCTP to find its strategic niche to similar research funding initiatives working in Africa; • Engage with European Commissions Directorate General on Development and Cooperation (DG DEVCO) and EU delegations. 	n.a.

Source: Various previous assessments of EDCTP, analysis Technopolis Group (2014).

2. Mapping the activities funded by EDCTP

This chapter presents some factual information on the activities funded by EDCTP. This includes the number and timing of calls for proposals per funding grant scheme category, the number of projects funded per disease area or topic, the geographical distribution of projects and the total contribution of both the European Commission, the EDCTP Participating States and third parties.

2.1 Overview of calls for proposals and supported projects

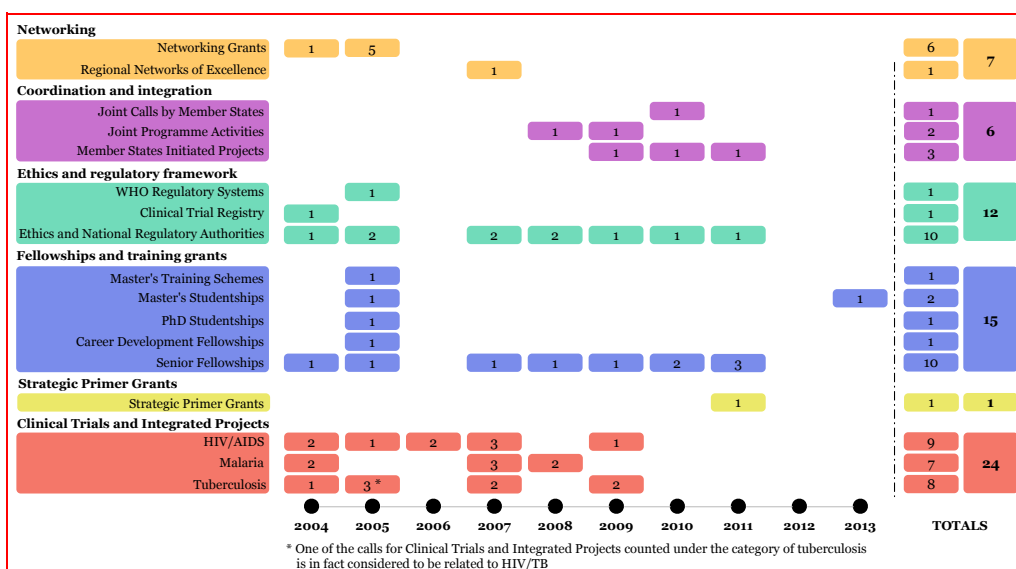
As mentioned in the previous chapter, EDCTP supports clinical research projects, with a focus on phase II and III clinical trials on HIV/AIDS, tuberculosis and malaria, as well as capacity building (through fellowships and studentships, ethics and regulatory strengthening activities) and networking and advocacy activities through its grants. The main grant scheme categories are:

- Clinical Trials and Integrated Projects: clinical trials as the core activity with associated capacity building and networking activities;
- Strategic Primer Grants: short term awards that provide seed funding for researchers to explore novel and innovative lines of research that may lead to the development and testing of new or improved clinical interventions;
- Fellowships and training grants: personal awards to African researchers, with a focus on Senior Fellowship awards to develop African research leaders;
- Ethics and regulatory framework activities: establishing and strengthening national ethics committees (NECs) and institutional review boards (IRBs) and the establishment of a clinical trial registry;
- Coordination and integration activities: projects enhancing the integration and coordination of European member states' research projects as well as thematic research projects funded through pooled funds from several EDCTP Participating States;
- Networking: the setup of regional Networks of Excellence (NoEs) for conducting clinical trials and support for regional consortia.

2.1.1 Calls for proposals

Figure 6 shows the timeline of the calls for proposals corresponding to the grant scheme categories listed above and the specific funding schemes. In total, EDCTP launched 65 calls for proposals between 2004 and 2013. The majority of the calls for proposals concerned Clinical Trials and Integrated Projects (24 in total, of which 9 focused at HIV/AIDS, 8 at tuberculosis and 7 at malaria), followed by Fellowships and training grants (14) and ethics and regulatory framework activities (13). The majority of the calls have been published in the years 2005 (17) and 2007 (12). Towards the end of the programme, EDCTP mainly focused on closing the active grants awaiting the decision on a second phase of the programme. This means that no new calls for proposals have been published in 2012 and only one (Master's studentship) in 2013. The majority of the actual clinical trials have been supported through the Clinical Trials and Integrated Projects grant scheme, however some of the Strategic Primer Grants, fellowships and training grants and coordination and integration activities grants also include clinical trials (a complete overview of all clinical trials supported by EDCTP is presented in Chapter 4, Impact on Clinical Trials).

Figure 6 EDCTP calls for proposals clustered according to grant scheme category



Source: Technopolis Group (2014), based on information (December 2013) provided by EDCTP (2014).

Figure 7 shows that the 65 calls for proposals resulted in 789 applications and 246 signed grants in the period 2003 to 2013 (situation by December 2013). This means an overall success rate of 31%. The success rate is highest for the Networking grant scheme category (68%), however this includes the fewest number of applications. For the Clinical Trials and Integrated grant scheme category almost half (49%) of the applications have been awarded. The success rate is lowest for the Strategic Primer Grants (16%). Of the awarded grants, 106 were still active at the end of 2013 (43%). Generally, grants are closed four months after the project end. The largest share of grants disbursed by EDCTP is devoted to Clinical Trials and Integrated Projects (€165.88 million or 78% of the total signed grant value), the average signed value per Clinical Trial and Integrated Project grant is around €3.19 million. This is significantly higher than the average grant values of the other grant scheme categories, but is logical according to the nature of the activities.

Figure 7 Overview of calls, applications and grants awarded

Grant scheme category	# of calls for proposal	# of applications	# of grant awards	# of active grants	# of closed grants	Total signed value (in m€)	Average signed value (in m€)
Clinical Trials and Integrated Projects	24	107	52	29	23	165.88	3.19
Strategic Primer Grants	1	89	14	14	0	10.17	0.73
Fellowships and training grants	15	344	70	24	46	11.91	0.17
Ethics and regulatory framework	12	179	78	24	54	5.10	0.07
Coordination and integration	6	48	17	11	6	6.26	0.37
Networking	7	22	15	4	11	12.80	0.85
TOTAL	65	789	246	106	140	212.12	0.86

Source: Information provided by EDCTP (2014).

2.1.2 Awarded grants per grant scheme category

Figure 8 shows the annual number of awarded grants per grant scheme category. The majority of the projects have resulted from calls in 2005 (55) and 2011 (49). The table also shows that the majority of the Clinical Trials and Integrated Projects have resulted from calls in 2007 (18) and 2006 (10). As mentioned before the actual number of clinical trials is presented in Chapter 4 as they are implemented under more than just the grant scheme category of Clinical Trials and Integrated Projects (i.e. also Strategic Primer Grants, fellowships and training grants and coordination and integration activities). Because of the focus on finishing the projects that have been funded, taking into account the no-cost extension period of EDCTP1 and process towards a second phase of the programme, no new calls within the Clinical Trials and Integrated Projects scheme have been published.

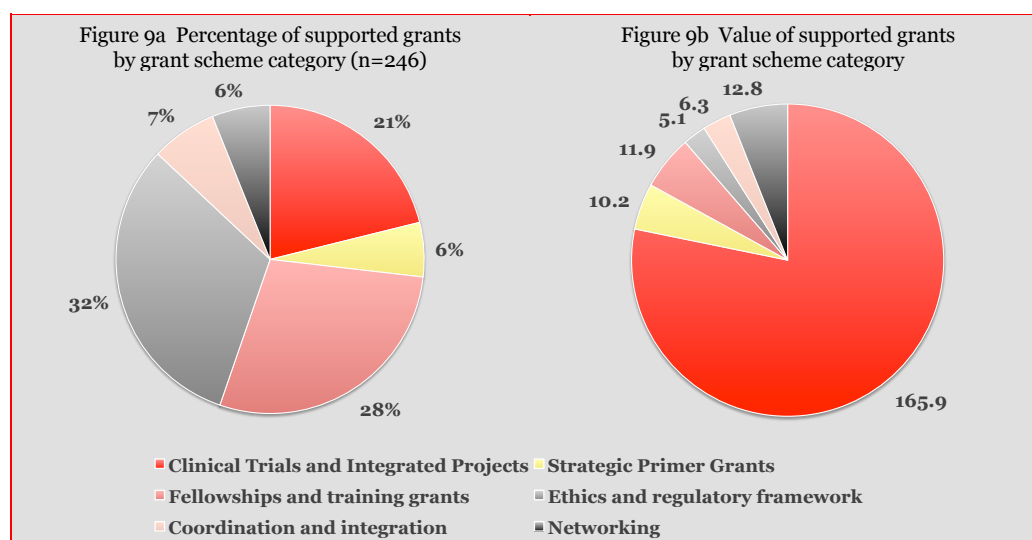
Figure 8 Number of awarded grants per grant scheme category and per year of call

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Clinical Trials and Integrated Projects	7	7	10	18	2	8					52
Strategic Primer Grants								14			14
Fellowships and training grants	6	23		6	6	8	8	13			70
Ethics and regulatory framework	1	16		9	11	5	15	20		1	78
Coordination and integration					2	6	7	2			17
Networking	2	9		4							15
TOTAL	16	55	10	37	21	27	30	49	0	1	246

Source: Information provided by EDCTP (2014).

Figure 9a shows that in terms of numbers the distribution of grants per grant scheme category is quite balanced; the majority of supported grants addressed strengthening ethics and regulatory framework activities in Africa (32%), followed by fellowships and training grants (28%). The Clinical Trials and Integrated Projects account for around one fifth of the total number of grants (21%). However, in terms of grant value (Figure 9b), the Clinical Trials and Integrated Projects represent the largest scheme of funded projects (78%). This aligns with the objective of EDCTP to support clinical trials.

Figure 9 Distribution of grants per grant scheme category (in numbers and grant value)



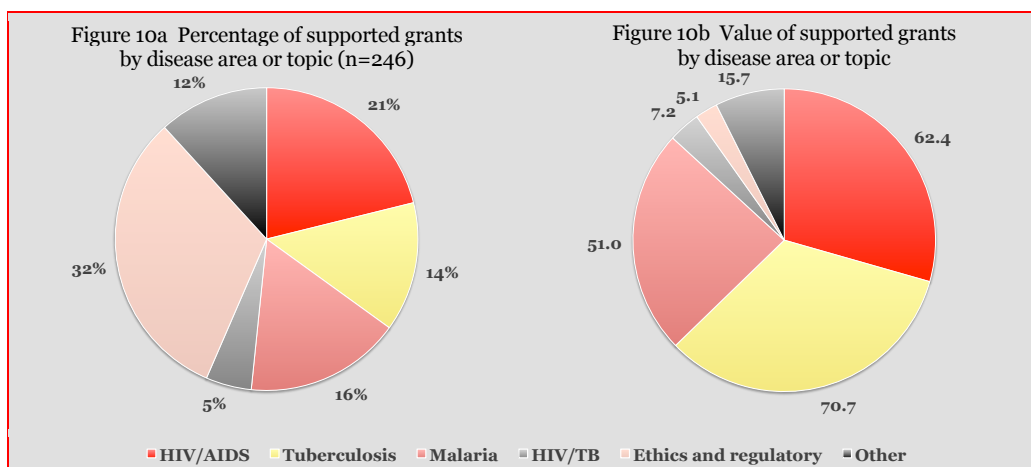
Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

2.1.3 Awarded grants per disease area

The grants can be categorised according to the disease areas or topics that are targeted by EDCTP: HIV/AIDS, tuberculosis, malaria and HIV/TB (four disease areas), ethics and regulatory grants and other (non-disease specific) grants. The number of awarded grants for the three main disease areas (HIV/AIDS, tuberculosis and malaria) are distributed evenly over the years. Apart from the Master's Fellowship in Epidemiology and Medical Statistics call that was launched in 2013 there were no other calls resulting in newly supported disease specific grants the last few years.

In terms of numbers of grants, 107 of the supported grants are non-disease specific (44%) (Figure 10a). The remaining 56% of the disease specific grants are distributed as follows: HIV/AIDS (52 grants), malaria (41), tuberculosis (34) and HIV/TB co-infection (12). In terms of grant value, the large majority of grants were awarded to disease-specific projects (90%), again distributed almost evenly over the three main disease-specific areas, of which the tuberculosis grants are responsible for the largest amount of funding (€70.7 million), followed by HIV/AIDS (€62.4 million), malaria (€51.0 million) and HIV/TB co-infection (€7.2 million) (Figure 10b).

Figure 10 Distribution of grants per disease area (in percentage and grant value)



Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

Of the 107 non-disease specific grants, 78 were focused at strengthening ethics and regulatory frameworks in Africa (see Figure 11).

Figure 11 Number of awarded grants per disease area and grant scheme category

Disease or topic	Clinical Trials and Integrated Projects	Strategic Primer Grants	Coordination and integration	Ethics and regulatory framework	Fellowships and training grants	Networking	Total
HIV/AIDS	22	5	3		22		52
Tuberculosis	16	5	3		10		34
Malaria	10	3	5		23		41
HIV/TB	4	1			7		12
Ethics and regulatory				78			78
Other			6		8	15	29
TOTAL	52	14	17	78	70	15	246

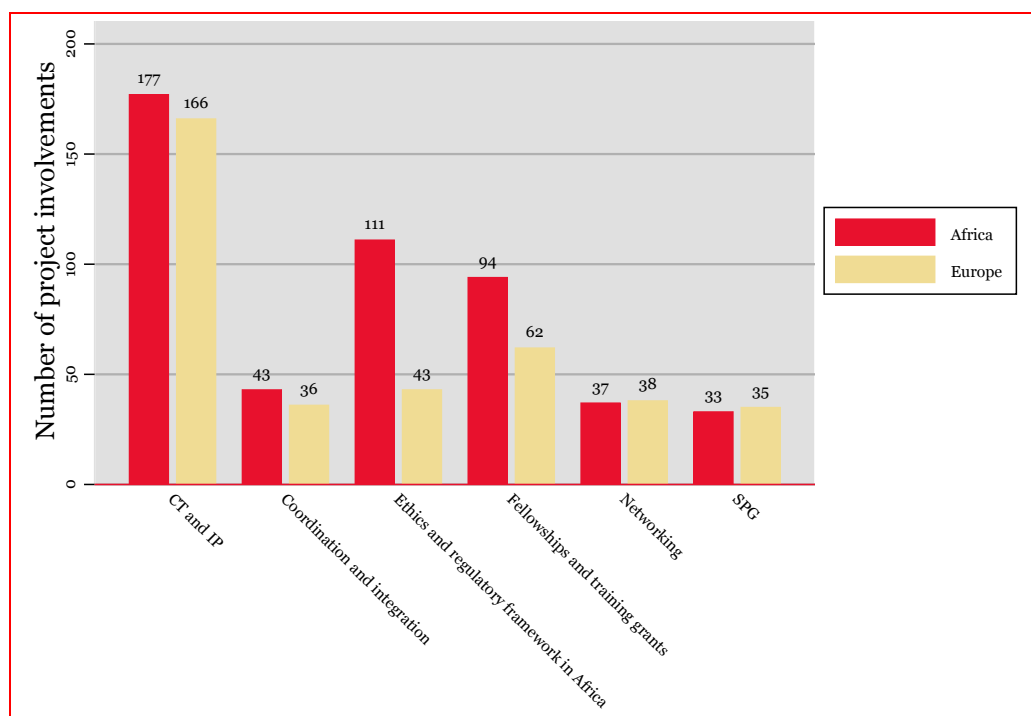
Source: Information provided by EDCTP (2014).

2.2 Geographical coverage of activities

It is worth noting that countries that are involved by means of research institutions taking part in EDCTP funded projects do not necessarily receive funds. Hence, we analysed the level of involvement of institutions (taking in part in projects but not necessarily receiving EDCTP funds) and the level of participation (receiving EDCTP funds).

Figure 12 shows that the level of involvement for African countries is high in all funding scheme categories. The upper figure depicts the level of involvement as the sum of all project involvements for all African countries versus European countries (each project may have one coordinator and multiple collaborators, hence the higher numbers of involvements related to the number of projects).

Figure 12 European and African project involvement

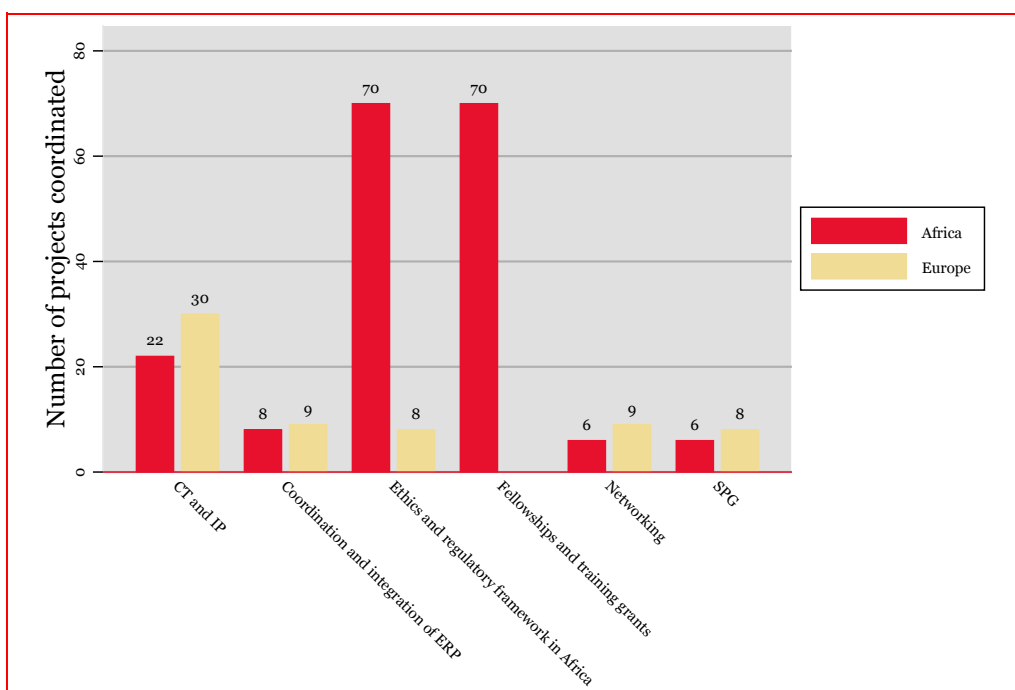


Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

Of the coordinators of all 246 awarded grants, around 74% is working in an African country and 72% is male.

The next figure (Figure 13) depicts the sum of projects coordinated by African versus European countries. This graph shows that although overall participation in the projects funded under the Clinical Trials and Integrated Projects grant scheme category is slightly higher for African countries, the majority of these projects is coordinated by European countries. All 70 fellowships and training grants are awarded to African researchers.

Figure 13 European and African project coordinators

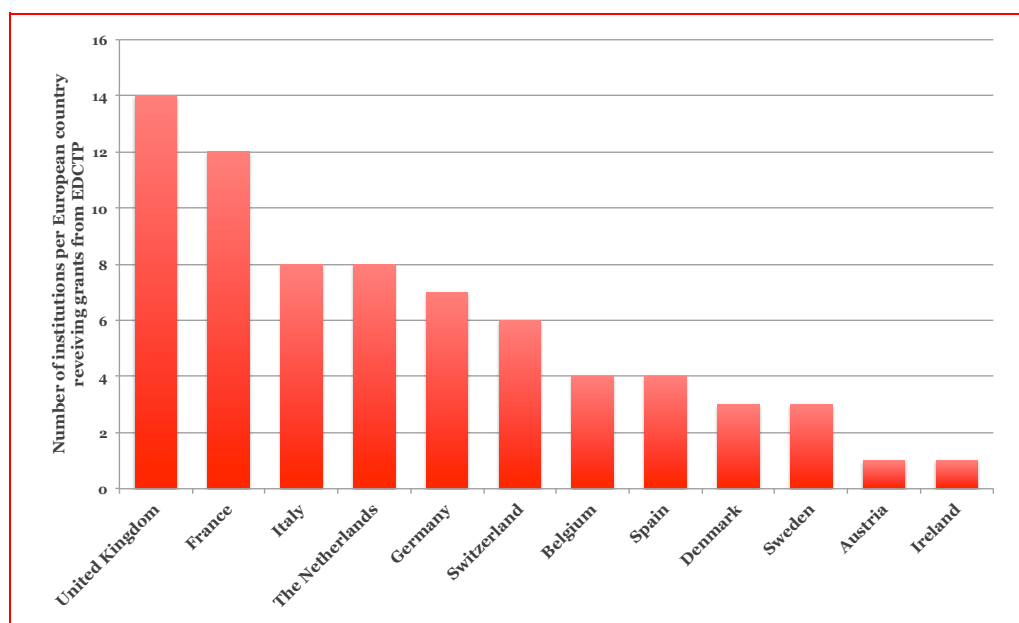


Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

The high participation rate of African countries is also confirmed in terms of geographical distribution of grants: African countries and African institutions have received the majority of the overall EDCTP grant value. African institutions have received €157.60 million (almost three quarters of the total grant values). European institutions received €54.23 million.

In total 259 different institutions across Africa and Europe have participated in EDCTP grants and have received funding: 188 from sub-Saharan and 71 from European countries. The European institutions that are involved in the projects are located in twelve of the sixteen Participating States of EDCTP1 (Figure 14). This implies that institutions from four of the countries do not receive EDCTP funds: Norway, Greece, Luxembourg and Portugal. The United Kingdom and France are the largest European participants in terms of number of institutions receiving funds; respectively 14 and 12.

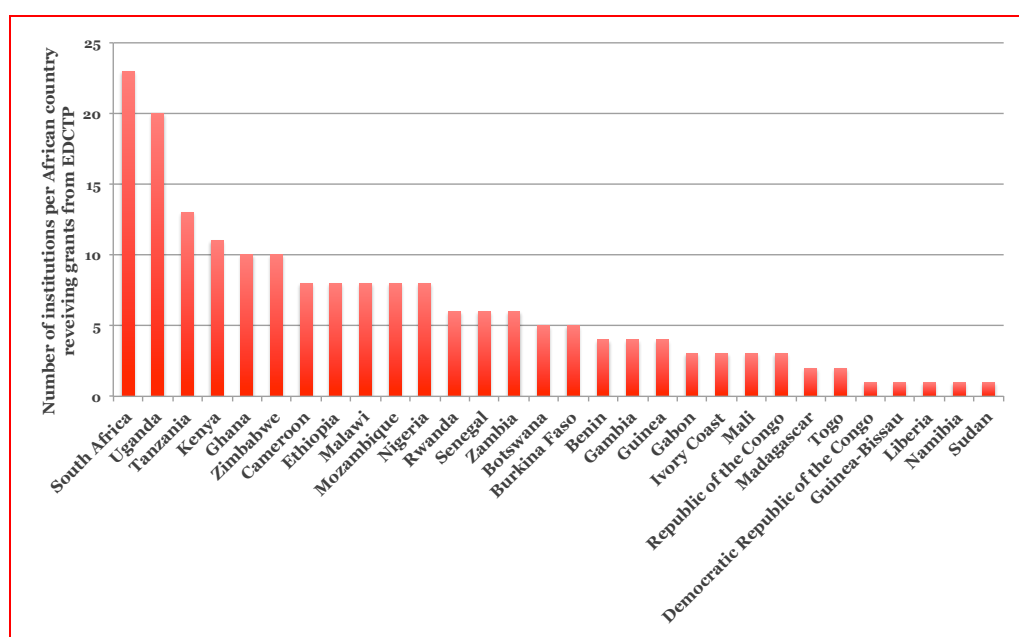
Figure 14 Number of institutions per European country receiving grants from EDCTP



Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

Institutions from 30 sub-Saharan countries are involved in the projects, which means that institutions from 18 countries are not receiving funding from EDCTP (Figure 15). These countries are Angola, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Eritrea, Equatorial Guinea, Lesotho, Mauritania, Mauritius, Niger, Sao Tome and Principe, Seychelles, Sierra Leone, Somalia, South Sudan and Swaziland. South Africa (23) and Uganda (20) are the most involved in terms of the number of institutions that participate in projects.

Figure 15 Number of institutions per African country receiving grants from EDCTP



Source: Information EDCTP (2014), analysis Technopolis Group (2014).

The table below lists the ten institutions that received the largest amount of EDCTP funding. These ten institutions together (€54.4 million) are responsible for just over 25% of the total value of the EDCTP grants (€212.1 million).

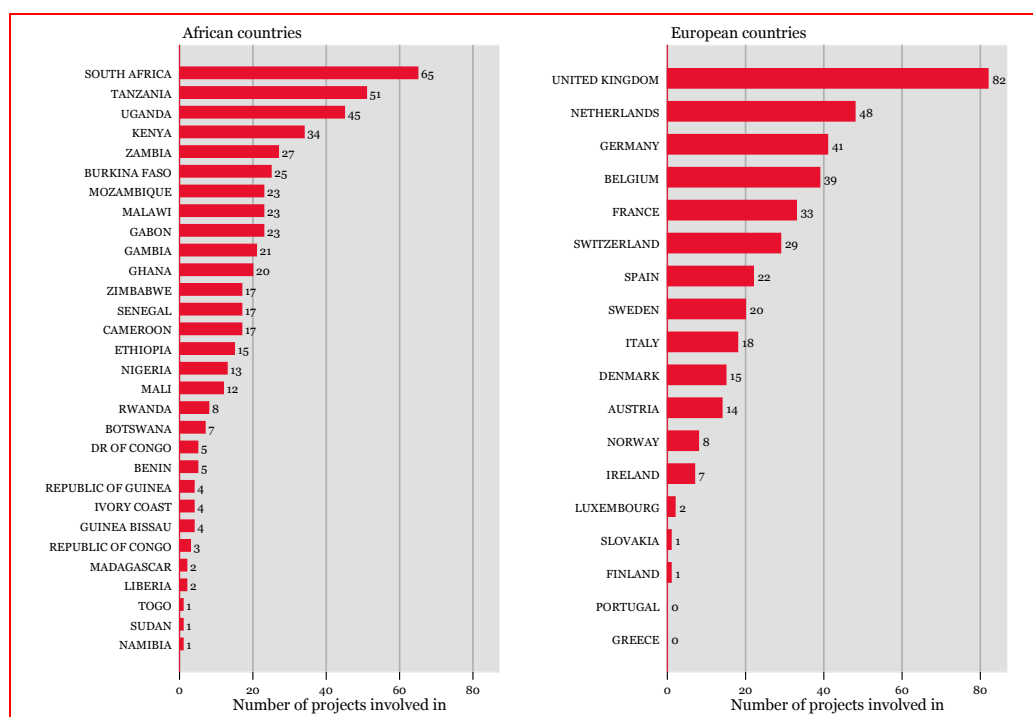
Figure 16 Top-10 recipients of EDCTP grants

Africa/ Europe	Country	Institution	EDCTP grant value (in €)
Africa	South Africa	University of Cape Town (UCT)	9,321,365
Africa	Tanzania	NIMR-Mbeya Medical Research Programme	5,447,268
Europe	United Kingdom	University of Oxford	5,432,688
Africa	The Gambia	Medical Research Council Unit	5,361,336
Africa	South Africa	Institute of Infectious Disease and Molecular Medicine (IIDMM)	5,245,618
Africa	Uganda	Infectious Diseases Institute (IDI)	5,017,509
Africa	Gabon	Fondation Internationale de l'Hôpital du Docteur Albert Schweitzer	4,748,056
Africa	Zambia	University Teaching Hospital Lusaka (UTH)	4,671,027
Europe	United Kingdom	Medical Research Council Clinical Trials Unit (MRC CTU)	4,613,727
Africa	Tanzania	Kilimanjaro Christian Medical College (KCMC/KCRC)	4,555,550
TOTAL			54,414,144
Total value of EDCTP grants			212,118,662

Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

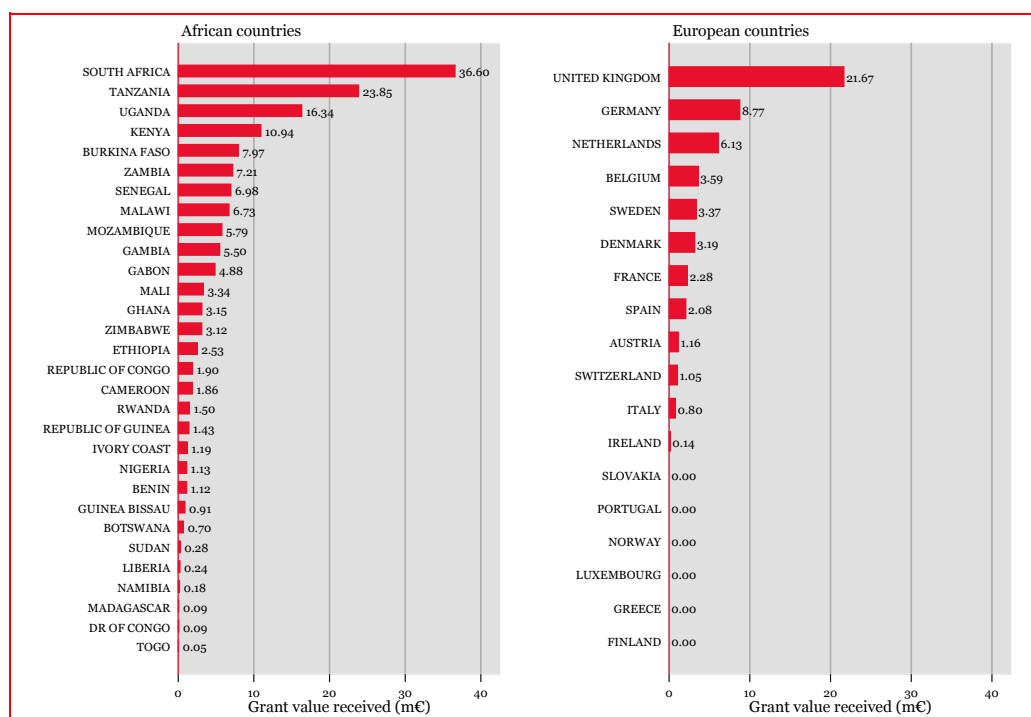
African participation is highest for South Africa followed by Tanzania and Uganda, both in terms of project numbers and received grant value (Figure 17 and Figure 18). European participation is highest for the United Kingdom, followed by the Netherlands and Germany.

Figure 17 African and European countries by grant involvement



Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

Figure 18 African and European countries by grant value received



Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

2.3 Funding sources

As mentioned before, EDCTP has awarded 246 grants by the end of 2013. The overall funding associated with these projects amounts to €382.7 million, with €212.12 million disbursed through EDCTP and €170.58 million direct cash and in-kind funding to projects. Overall funding included €154.9 million from the European Commission (including a grant of €2.08 million from the Seventh Framework Programme (FP7) associated with one of the EDCTP grants), €141.62 million from EDCTP Participating States, €14.42 million from African countries and €71.76 million from third-party organisations (see Figure 19). It is worth mentioning that there was no legal requirement/obligation for EDCTP to gather information on the contribution from African countries and third-party organisation. This will likely result in an underestimation of the actual contribution.

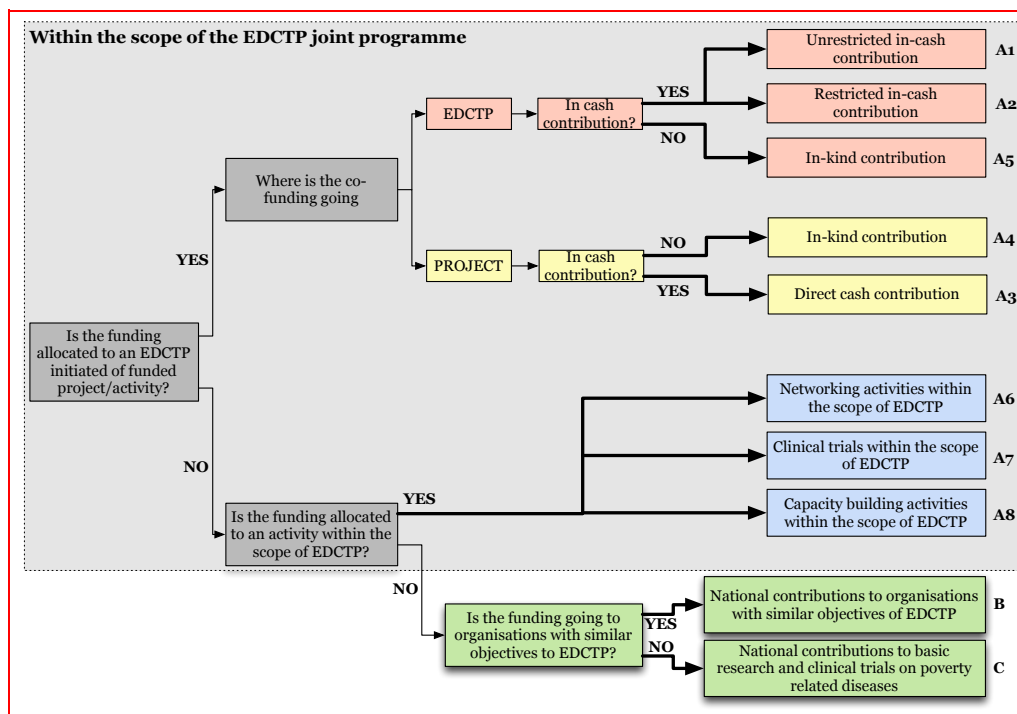
Figure 19 Total value of EDCTP grants 2003-2013 per funding source (in million €)

Type of funding	European Union	EDCTP Participating States	African countries	Third-party organisations	Total
EU funds	152.82	-	-	-	152.82
Cash via EDCTP	-	50.88	0.18	8.24	59.30
Direct cash to projects	2.08	43.36	0.86	24.35	70.65
In-kind	-	47.38	13.38	39.17	99.93
TOTAL	154.90	141.62	14.42 *	71.76 *	382.70

Source: EDCTP Interim Technical Report (2013). * Underestimation as there was no legal requirement to collect this information.

The following figure shows the funding flow chart on Participating States contribution to EDCTP, either cash or in-kind.

Figure 20 Flow chart on member states contribution



Source: Information provided by EDCTP (2014).

In this scheme, the categories A1 to A5 are the actual contributions to EDCTP (the ‘real’ co-funding), the figures presented before are based on these categories. Categories A6 to A8 are contributions to activities within the scope of EDCTP, but not awarded or administered through EDCTP. The contributions of the different European Participating States based on these categories are presented in more detail in section 6.1.2 (Shared vision and alignment of research strategies in Europe).

Figure 21 shows that South Africa (€6.0 million) has been the main contributor among the African countries, followed by Tanzania (€2.0 million) and Uganda (€1.9 million). Please note that the contribution from African countries is mainly in-kind as presented previously in Figure 19. This top-10 of African countries does not contain any country from the Central African region of the continent. These top-10 countries account for over 92% of the overall African co-funding to the EDCTP programme.

Figure 21 Top-10 African country co-funding contribution

Country	African region	Contribution (in €)	% of total African co-funding
South Africa	South	6,011,922	42%
Tanzania	East	2,037,982	14%
Uganda	East	1,866,099	13%
Zimbabwe	South	763,098	5%
Gambia	West	608,000	4%
Zambia	South	593,376	4%
Kenya	East	507,141	4%
Ethiopia	East	411,641	3%
Rwanda	East	282,871	2%
Burkina Faso	West	207,345	1%
TOTAL	-	13,289,475	92%
Overall African co-funding	-	14,423,554	100%

Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

Of the third-party contributors, the Global Alliance for TB Drug Development (€16.9 million) has been the main contributor followed by the Bill & Melinda Gates Foundation (€16.0 million) and the Aeras Global TB Vaccine Foundation (€10.6 million) (see Figure 22). The top-10 third-party contributors account for almost 90% of the overall third-party co-funding.

Figure 22 Top-10 third-party contribution

Organisation	Type	Contribution (in €)	% of total third-party co-funding
Global Alliance for TB Drug Development (TB Alliance)	PDP	16,948,136	24%
Bill & Melinda Gates Foundation	Foundation	16,029,722	22%
Aeras Global TB Vaccine Foundation	PDP	10,632,702	15%
Medicines for Malaria Venture (MMV)	PDP	4,513,209	6%
Sequella	Industry	4,375,765	6%
European Vaccine Initiative (EVI)	Other	3,490,869	5%
Wellcome Trust	Foundation	2,478,935	3%
Foundation for Innovative New Diagnostics (FIND)	PDP	2,375,000	3%
International Partnership for Microbicides (IPM)	PDP	1,477,443	2%
World Health Organization	Other	1,330,636	2%
TOTAL	-	63,652,417	89%
Overall third party co-funding	-	71,755,754	100%

Source: Information provided by EDCTP (2014), analysis Technopolis Group (2014).

3. The assessment of the execution of the programme

This chapter focuses on the assessment of the execution of the programme. Specifically EDCTP's governance and management structure, its communication and advocacy approach and its monitoring and evaluation processes are taken into account. The final section of this chapter assesses the overall performance and effectiveness of the programme.

3.1 EDCTP's governance and management

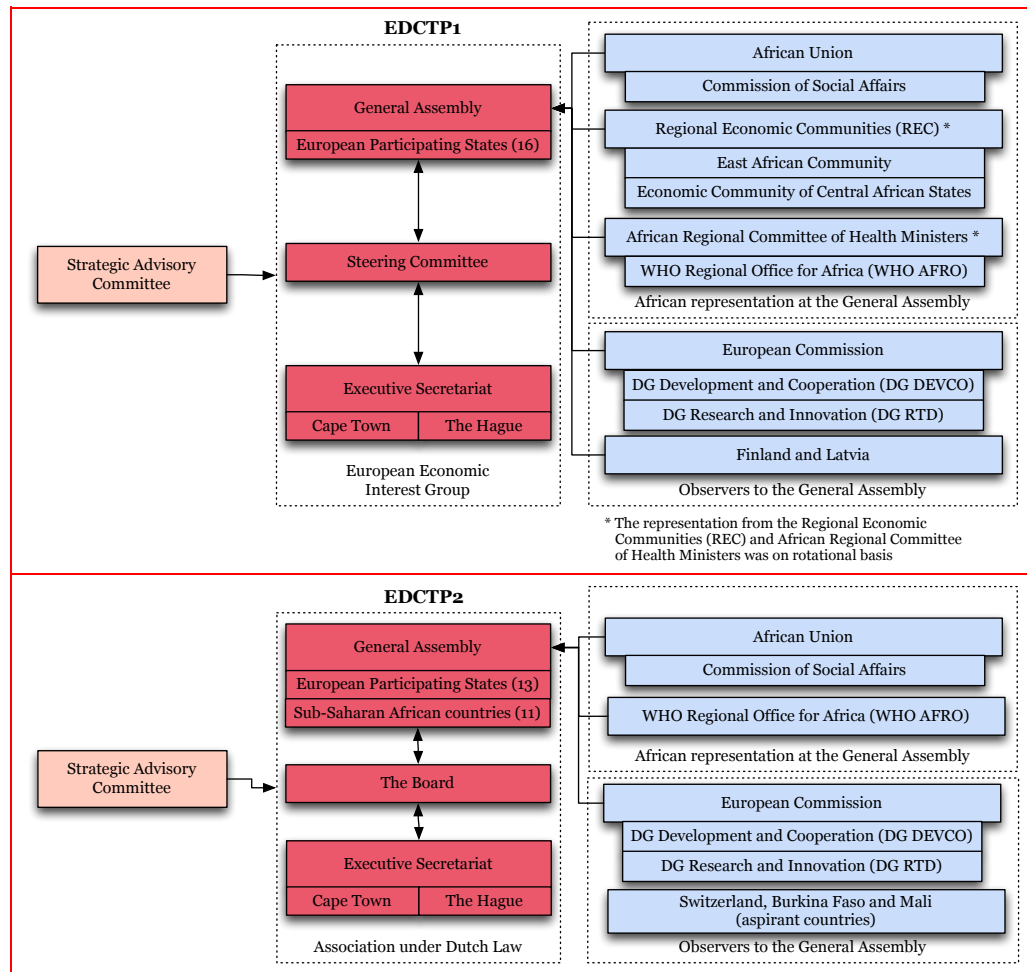
During the transition towards the second phase of the programme, the governance and management structure of EDCTP has changed considerably. The last few years of EDCTP1 the following elements have been the core of its governance structure:

- A European Economic Interest Group (EDCTP-EEIG), which is the legal entity for implementing the programme and managing the funding of grants, consisting of:
 - The General Assembly (GA) is the ultimate and exclusive decision-making body. Its principle responsibility is to ensure that all necessary activities are undertaken to achieve the objectives of EDCTP and that its resources are properly and efficiently managed. It has final and exclusive decision-making power over general programme strategies, annual work plans and calls for proposals, annual budgets and accounts, appointments and dismissals of the Executive Director, other directors and the High Representative of EDCTP, commitments with third parties, public release of information and appointment of members of the advisory bodies.
 - An Executive Secretariat, which currently consists of around 30 employees and assures the day-to-day management through a European (based in The Hague, The Netherlands) and an Africa Office (in Cape Town, South Africa).
- The Strategic Advisory Committee (SAC), established in 2013 by merging two previously active advisory committees, which were the Partnership Board (PB) and the Developing Countries Coordinating Committee (DCCC). The SAC consists of independent scientific experts from Europe and Africa and is responsible for the development of the strategic planning of the programme. In addition, the committee provides strategic and scientific advice to the General Assembly and the Executive Secretariat and oversees the scientific integrity of the programme²².

In EDCTP2 the legal structure of the European Economic Interest Group (EEIG) has changed to an Association under Dutch law. The main reason for this change is the opportunity for individual African countries as well as alliances of countries or institutions, when they have been mandated by their national governments, to become full members of the partnership. This point has been raised in the previous assessments of the programme by recommending that an African presence in the General Assembly (thus the decision-making process of the programme) should be reinforced. Another reason is to move to an organisational structure without joint and several liabilities between members. The following figure (Figure 23) shows the evolution in the governance and management structure from EDCTP1 to EDCTP2.

²² EDCTP (2013). Internal Regulations.

Figure 23 Evolution in governance structure of EDCTP



Source: Based on documentation about EDCTP.

Both the European and African members of the General Assembly interviewed greatly welcome the recent changes in the governance structure of EDCTP as it favours a real partnership of the African countries. Under EDCTP1 they mainly participated in terms of providing scientists, infrastructure and patient populations, but were not in fact involved in the decision-making process of the EDCTP programme. As mentioned before African countries will play a more prominent role in EDCTP2 by having the opportunity to become full members and part of the General Assembly. To date, a total of eleven sub-Saharan countries have completed their membership process and are now full members of the EDCTP partnership, namely South Africa, Tanzania, Republic of the Congo, Zambia, Uganda, Cameroon, Senegal, Ghana, Mozambique, the Gambia and Niger. One of the main requirements to become a member of EDCTP is to commit to an annual cash or in-kind contribution of €200,000 to activities in the scope of the EDCTP2 programme. The challenge for the future of the programme is to sustain the African countries' contribution and engagement and to see the actual input provided by these countries.

The General Assembly shows a large variety of different government departments and organisations that are involved. They range from universities and research organisations to national funding agencies and from departments of international development to departments of science, technology and innovation. Each of these different organisations have their own objectives and mandate. This leads to challenging decision-making and strategic processes. The previous evaluation of EDCTP recommended increasing the

political character of the General Assembly. Based on this evaluation it is questionable to judge to what extent this has been realised to date.

During the first phase of EDCTP the roles of the different governance and advisory boards have not been optimal in terms of decision-making power and the advisory role. The governance arrangements have not been always clear (i.e. the roles and mandate of the General Assembly and the different advisory boards since there were overlaps and to some extent duplications e.g. between the PB and the DCCC). This has resulted in a lack of real strategic vision based on the current portfolio of funded projects. The question “*where to put more emphasis in the future taking into account the current (scientific) state of affairs and projects funded?*” has not been raised and addressed sufficiently. Although there has been some improvement in this direction over the past few years by simplifying the overall structure, in particular by merging the PB and DCCC into one Strategic Advisory Committee (SAC) with a clear African voice, there is still some room for further improvement. The definition of a strategic vision and direction based on portfolio management of the results obtained during EDCTP1 is something that could be strengthened in EDCTP2. The Strategic Advisory Committee is considered to be responsible for the development of such a strategy, including an implementation plan. This can be formalised by means of clear (updated) terms of reference for the SAC.

A specific point of attention that was raised by the members of the GA and the SAC regarding the future of the programme is the continuity of the composition of the SAC. Of the fifteen persons that are currently appointed as members of the SAC, only two persons have been part of the Interim SAC (the advisory group to EDCTP during its transition towards the second programme). Previously these two persons have been members of the DCCC or the PB. Two other persons from the PB are currently member of the SAC.

3.1.1 The Executive Secretariat

In this evaluation the current capacity and professionalisms of the Executive Secretariat is assessed very positively. It shows an immense improvement compared to the start of EDCTP and has contributed significantly to EDCTP’s overall success. At the beginning the organisation lacked the experience and knowledge on how to run calls and fund projects on such a large scale and complexity. To strengthen this, the Netherlands Organisation for Scientific Research (NWO) as well as some participating countries (amongst others the United Kingdom and Norway) provided some assistance in this first phase.

The current staff at the Executive Secretariat, both in The Hague and in Cape Town (Africa office), are considered very approachable, dedicated, competent and supportive. The officers have a good understanding of the projects and the local context in which they are embedded. The support provided covers the entire timeline of the project, from the moment of the grant application until the final stages of the project (i.e. the final reporting, payments due, et cetera). According to almost all stakeholders EDCTP is a “*friendly environment and has good institutional culture*”. In addition, the current Executive Director (Prof. Charles S. Mgone) is considered an important contributing and decisive factor in the actual performance of EDCTP. Initially there have been some difficulties in finding the right person for the job of Executive Director. The appointment of an Executive Director from Africa has been key to the success of EDCTP. It will be essential for the future to sustain an Executive Director with great leadership and diplomatic skills in case the current Executive Director leaves the organisation.

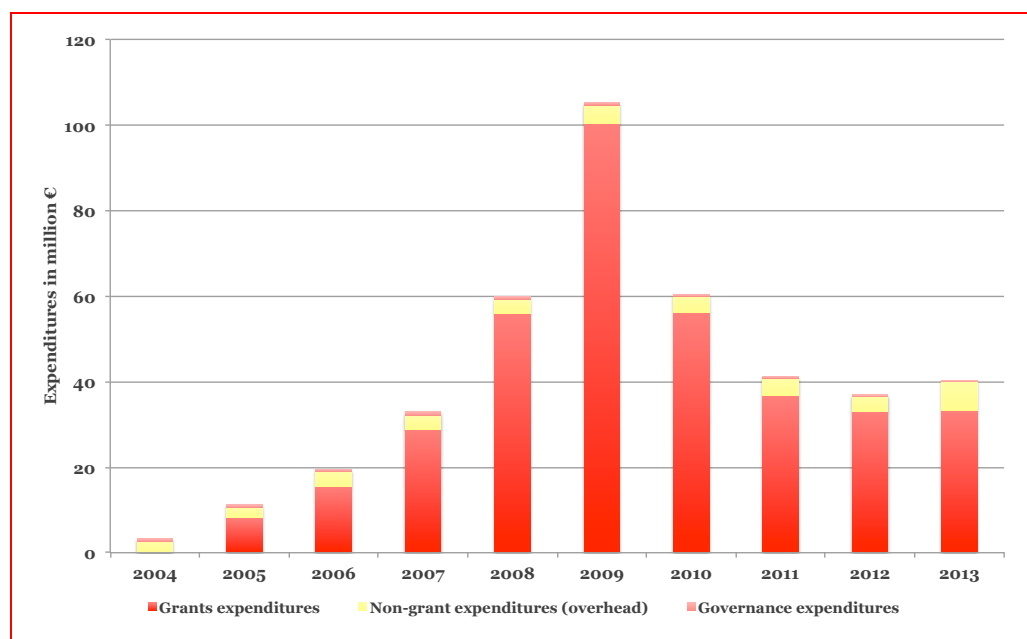
Although the current performance of the Executive Secretariat is highly embraced, a major point of concern is the fact that the Executive Secretariat has a high turnover and staff appear to be significantly overloaded. The relatively small size of the secretariat related to the huge amount of tasks and responsibilities calls for processes and assessment of the balance between the workload and staffing. This might have led to the fact that some of the tasks that should have been implemented before did not work out completely: this applies to the development of the logical framework of the programme including an associated monitoring and evaluation strategy as well as the engagement

with third-party organisations. These both two aspects, which have shown positive progress during the last few years, are described in more detail later in this report.

3.1.2 EDCTP's overall expenditures

As can be seen in Figure 24 showing the overall expenditures of EDCTP in the period 2004-2013, the majority of the grants expenditures are made in 2009 (based on the value of the grants signed), indicating the slow start of the EDCTP programme. It also shows the acceleration of grants signed from 2007 on. In addition to the grants expenditures, the annual reports of EDCTP distinguish between expenditures on supporting EDCTP activities (i.e. the overhead costs associated with the Executive Secretariat and other administrative costs) and governance expenditures (i.e. the costs associated with the costs of the different advisory boards).

Figure 24 Overall expenditures of EDCTP 2004-2013



Source: Annual reports EDCTP (2005-2013).

From the overview of EDCTP's overall expenditures the average overhead percentage over the period 2004-2013 has been calculated at 9.2% (calculated as the non-grant expenditures as a share of the total expenditures). For a funding programme of the scale and complexity of EDCTP this is reasonable overhead percentage and falls within the common range of 5% (minimum) to 15% (maximum). However, EDCTP2 must operate with an overhead of just 6%, which is very modest and could potentially limit its activities.

3.1.3 The funding approach and co-funding arrangements

During its first programme, EDCTP funded its activities through three different approaches. In addition to the more common and most frequently used open calls for proposals, EDCTP has applied two alternative (innovative) funding approaches, which consist of a brokered approach and a single-source approach.

The brokered approach has been used in establishing a consortium targeted at treatments for tuberculosis: the PanACEA consortium (see the box below).

The PanaCEA consortium has been valued very positively by the majority of the interviewees and is considered to be a best practice of clinical trial funding that could be

expanded in more directions and disease areas in the future. Based on the progress of current clinical trials and strategic and scientific opportunities for each disease area a similar brokered approach could be implemented.

As mentioned before, the Strategic Advisory Committee could play a role in defining these specific areas (e.g. treatments for HIV/TB co-infection, vaccines for HIV/AIDS, tuberculosis and malaria, et cetera) based on the portfolio of projects funded and scientific challenges.

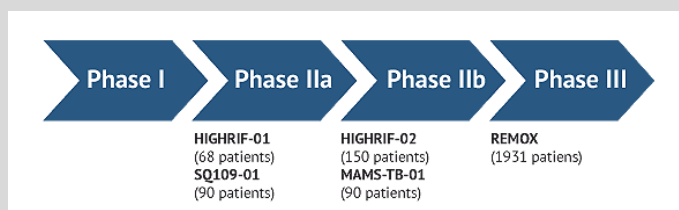
The PanACEA consortium: a new approach to tuberculosis research

The Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA)²³ has been established by EDCTP as a different approach towards funding clinical trials than through normal calls for proposals. It was concluded that the amount of funds for clinical trials and number of funding options were limited. For this reason a so-called brokered approach has been chosen as most efficient in setting up a pan-African consortium for developing innovative tuberculosis treatments with the aim to closely align with the overall objectives of EDCTP. The objectives have been defined specifically oriented towards tuberculosis:

- To shorten and simplify treatment of uncomplicated pulmonary tuberculosis;
- To increase the tuberculosis clinical trial capacity in Africa; and
- To develop sustainable tuberculosis clinical trials network in Africa.

The consortium brings together a group of scientists from more than 14 countries of which six sub-Saharan African Countries (Gabon, Kenya, South Africa, Tanzania, Uganda and Zambia) with skills in clinical trials design and implementation, pulmonology, mycobacteriology, pharmacokinetics, statistics and delivery of clinical service. In total twelve sub-Saharan clinical trial sites take part in the consortium.

Through meetings with external advisors (from the Bill & Melinda Gates Foundation and the Global Alliance) the most important trials goals for PanACEA have been designed, which are (1) to take the moxifloxacin development programme to completion (REMOX), (2) to study the optimal dosage of rifampicin (HIGHRI-01 and HIGHRI-02) and (3) to take a new compound SQ 109 through its early clinical trial phase (SQ109-01). The figure below shows the development phases of the different trials. The current portfolio ranges from small two-centre early phase II studies through to large-scale phase III studies in a multitude of sites and countries²⁴. The multi-arm multi-stage (MAMS) study design has set a new standard in TB combination therapy research, investigating all three drugs in different regimes in one trial. In 2012, the PanACEA approach towards the development of tuberculosis treatment was published as a peer-reviewed article in The Lancet Infectious Diseases journal.



The PanACEA consortium has been co-funded by EDCTP's Participating States (amongst others Germany, the United Kingdom and the Netherlands), the Bill & Melinda Gates Foundation, the Global Alliance and three pharmaceutical companies. The total funding of this consortium is €48.2 million with a contribution of €17.3 million from EDCTP.

The single-source approach has been applied in two phases during the first years of EDCTP. This is done by awarding a grant to the World Health Organisation (WHO) to facilitate the assessment of the national regulatory environment of various African countries and to support the development of a common regulatory framework where possible at a regional level. The total of the first grant awarded was €360,000

²³ <http://panacea-tb.net/>.

²⁴ <http://panacea-tb.net/clinical-studies/panacea-studies/>.

comprising €200,000 from EDCTP and €160,000 from the Netherlands–African Partnership for Capacity Development and Clinical Interventions against Poverty-Related Diseases (NACCAP). The second grant of a total value of €530,532 was awarded to WHO in 2008. The purpose of the grant was to further strengthen regulatory systems in African countries with focus on clinical trial application and inspection of clinical trials. The two grants led amongst others to the following achievements²⁵:

- The funding contributed the formation of the African Vaccine Regulators Forum (AVAREF);
- Regulators and members of national ethics committees from various African countries have been trained;
- Training has been provided on Good Clinical Practices (GCP) and site inspection for regulators;
- The Pan African Clinical Trials Registry (PACTR) as a WHO approved clinical trials registry has been developed (see more on this registry in section 5.3 of this report);

As the experiences with WHO on strengthening regulatory activities via a single-source approach proved very positive, there is no drawback to following this same route for supporting capacity building activities in the future.

Especially when it comes to the funding of the projects the word ‘bureaucracy’ is mentioned frequently by both members of the General Assembly and the interviewees during the country visits. This is mainly caused by the co-funding arrangements and requirements of and procedures set by the European Commission. This frequently made it very challenging and a time consuming process for researchers to get their projects funded, especially in case of larger multi-country project consortia. In EDCTP2 the co-funding arrangements are simplified as a result of upfront commitments by the Participating States.

The Executive Secretariat has invested considerable time and efforts to train participating African institutions (research organisations and universities) on (financial) management of their research projects. Some of the participating research organisations and universities lacked internal procedures for research management. Training has been delivered to these institutions and guidelines are provided and continuously updated. The EDCTP staff have made site visits to improve the financial control of the participating institutions and to help them implement the financial guidelines. Thus, EDCTP has also contributed to capacity building in this respect.

The lack of proper financial and research management procedures was one of the reasons why contract negotiations were delayed in the early years of EDCTP. Due diligence needed to be completed before advance payments could be released to all partners. This has now improved considerably due to training and guidelines. It is important that EDCTP continues this during the second phase of the programme.

In EDCTP’s Interim Technical report of 2012 the time-to-contract is presented from 2004 to 2012. In this period it has been significantly reduced from 19 months in 2004 to 3.6 in 2012.

The level of detail requested for the proposals is perceived as too high by the grantees (e.g. the proposal should provide information on who is going to travel when throughout the duration of the grant). This makes the projects budgets too strict. By definition research is unpredictable which means that you do not know the answer in advance, which implies that a certain level of flexibility is needed. Also the flexibility in timelines of the projects, budgets and activities could be improved so that researchers can respond to unforeseen circumstances and delays that are invariably out of their control. Finally the financial report templates that are in use are considered too complicated by many of

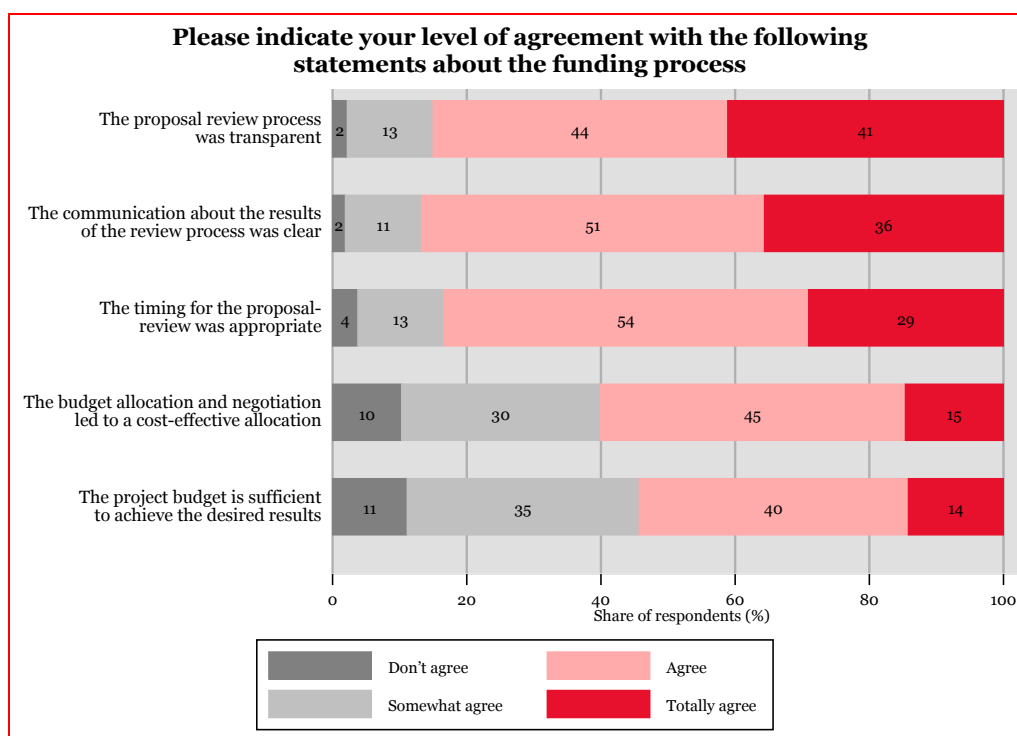
²⁵ EDCTP (2010). EDCTP support to regulatory affairs in sub-Saharan Africa, 2006 – 2010 (status report).

the grantees. Further simplification of the templates is advised in EDCTP2, and specific examples are included in the recommendation section of this report.

In addition, the current proposal review process is challenging when it comes to potential conflicts of interest. In the field of HIV/AIDS, tuberculosis and malaria almost all people know each other, which increases the chance of conflicts of interest, but also reducing the number of people that qualify to review proposals. Finding the right people without a potential conflict of interest is very challenging as in some cases they are not the ones that are renowned in the field or working at renowned institutions. This might lead to a situation in which not the best proposals are being funded.

Figure 25 provides insights into the perceptions about the funding process amongst EDCTP grantees. The overall picture is quite positive. More than 80% of the respondents (totally) agree with the review process to be transparent, the communication about the review process' results to be clear and the timing to be appropriate. There is a bit more variation in the perception about the financial aspects (i.e. budget allocation and budget size) of the funding process.

Figure 25 Perceptions about the funding process (N=326)



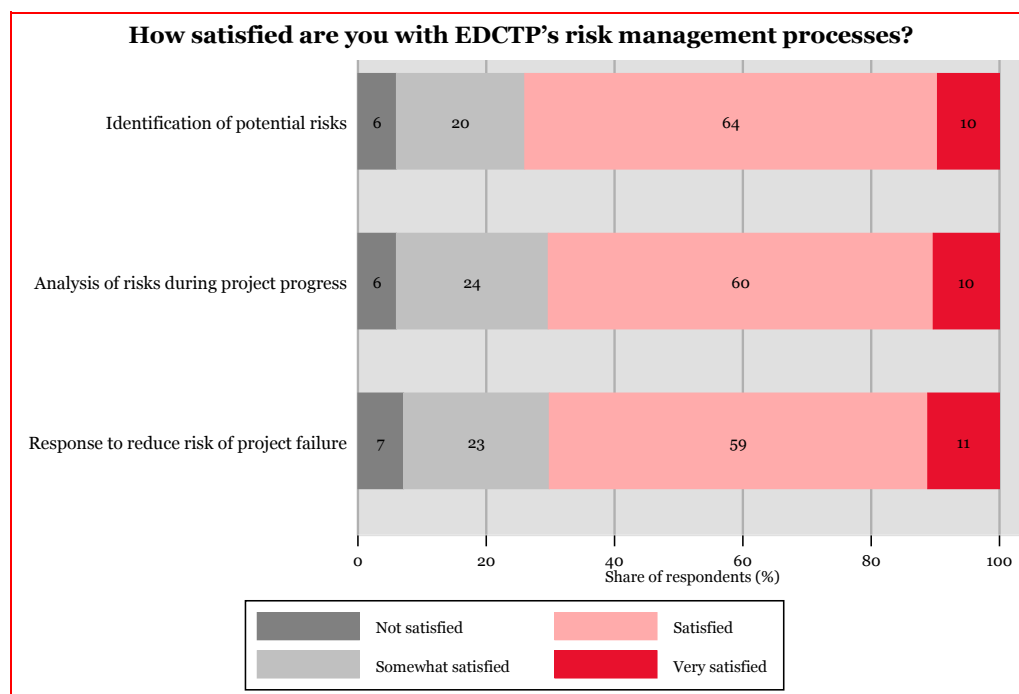
Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

The co-funding arrangements in place during the first phase of the programme are very complex for the Participating States. It was also confusing and tedious for grantees to find project-based matching through negotiations with the respective national agencies. This is mainly caused by legal restrictions in the countries to provide funding for a common pot model and the lack of real mechanisms to enforce countries to commit funding upfront. This made it very difficult to get the overall funding picture complete. This has been changed for EDCTP2, where it is no longer necessary to raise co-funding on a project-by-project level.

Below (Figure 26) the satisfaction of the grantees is presented about the perceived risk management processes of EDCTP in terms of follow-up on project progress and success. The grantees are quite consistent and positive in their satisfaction of the approach in

place to identify and analyse any potential risks that might occur during the project and to respond to reduce the risk of project failures.

Figure 26 Satisfaction about EDCTP's risk management process (N=303)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

3.2 Communication and advocacy

In 2010 EDCTP revised its communication strategy for the period 2010-2015²⁶, with the overall aim to:

- Create and maintain awareness and visibility for EDCTP and its mission and goals;
- Generate a sense of ownership and partnership amongst stakeholders;
- Keep all stakeholders regularly informed of the progress and outcomes of EDCTP supported activities;
- Increase substantially sustaining funding for EDCTP to achieve its mission.

Through a detailed action plan with actions targeting specific objectives, EDCTP tries to achieve this aim. These actions include showcasing achievements and impact of the programme, media coverage of EDCTP activities, improvement of the quality of communications through the public website and intranet and increasing brand recognition.

To showcase its performance in this area, from 2011 onwards EDCTP reports on its media appearances, mainly in terms of online news articles, blogs, publications and press releases. In three years time the total number of media mentions count to 172, however the impression is that this is an underestimation of the total media attention of the programme.

²⁶ EDCTP (2010). Revised Communication Strategy 2010-2015.

The website of EDCTP is the main platform to share information about the programme. The main language of the website is English, however some of the general parts are available as well in both French and Portuguese. The number of unique visitors shows an increase from 28,142 in 2012 to 39,289 in 2013.

Additionally, EDCTP distributes an electronic newsletter in three languages (English, French and Portuguese) currently to approximately 1,047 contacts (status end 2013). These contacts have to subscribe online via EDCTP's website. Hardcopy versions of each edition are mainly sent to African contacts.

In addition to these more traditional communication channels, EDCTP has become active on social media. Two examples are the Twitter account that EDCTP created (@EDCTP) to share information about the programme, disseminate project results and provide updates in the field of the diseases areas and funding and training opportunities in Europe. Currently (status August 2014) the Twitter account has 1,133 followers. To share video information, EDCTP also set up a YouTube channel (<http://www.youtube.com/edctpmedia>). Currently (status August 2014) the channel covers 16 videos, mainly from the Second High-Level Meeting on the preparation of EDCTP2, but also some of the videos focused at the three targeted diseases, capacity activities within EDCTP and included one example of a concrete project.

Regarding communication and advocacy the stakeholders mention that EDCTP is well known as a funding organisation with a focus on the African context. It is important now, as more clinical trials funded under EDCTP₁ have been finished or are about to finish, to show the impact and key successes (even if they move to the next clinical trial phase). EDCTP can do much more in this respect by disseminating the results, although realising EDCTP's modest resources on communication compared to other funding organisations (such as the Wellcome Trust) and the PDPs.

One other aspect that could get more attention is the communication to the private sector. EDCTP is known within the scientific and development communities, but there was not so much interest from the private sector during the first phase of the programme (see section 6.1.4 for more on the engagement with third-party organisations). EDCTP can make more use of its communication and public relations approach in making EDCTP known to the world and strengthen its approach directly towards governments or CEOs of private companies to further stress the importance of the partnership and demonstrate direct benefits from the projects funded.

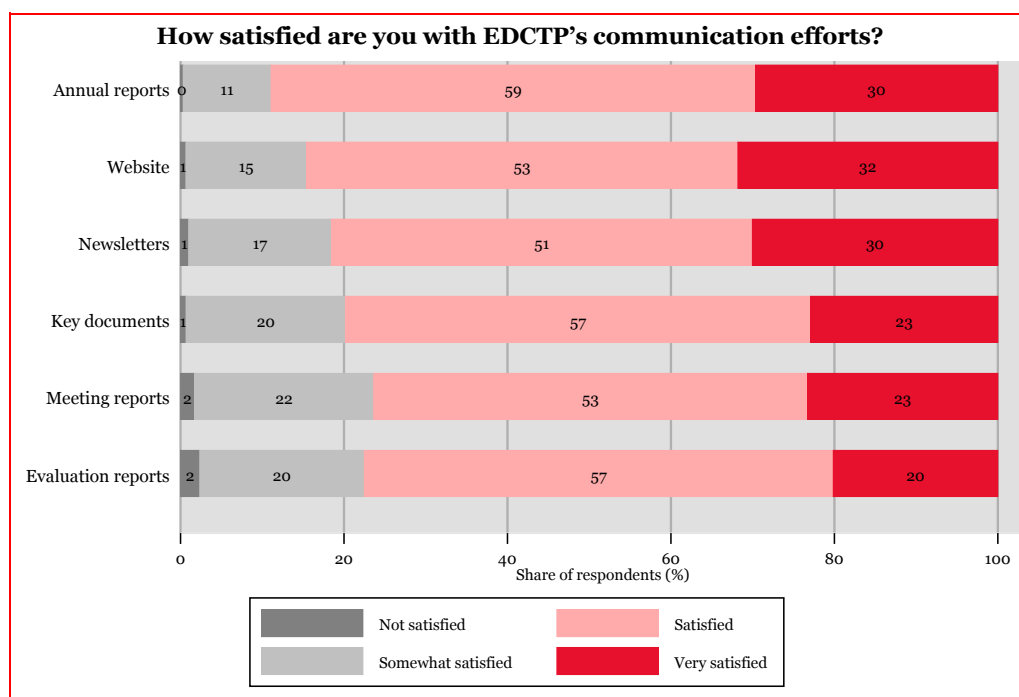
Dr. Pascoal Mocumbi, the former High Representative for EDCTP (as he took his leave in December 2013), has raised the visibility of EDCTP and has advocated for EDCTP in Africa. In order to maintain the visibility of EDCTP as a scientific and a political initiative, it is important to find a suitable replacement.

EDCTP High Representative: Dr. Pascoal Mocumbi

Dr. Pascoal Mocumbi, former prime minister of Mozambique, served as the High Representative for EDCTP from 2004 till 2014. In this period Dr. Mocumbi has played an important role in raising the profile of EDCTP, particularly in building political support in Africa. He represented EDCTP during high-level meetings with representatives from Africa and Europe (amongst others a meeting with the President of the European Commission, José Manuel Barroso).

Figure 27 presents the overall high satisfaction of the grantees about the communication of EDCTP. There are some minor concerns about the communication on meetings and results and impacts (by means of evaluation reports).

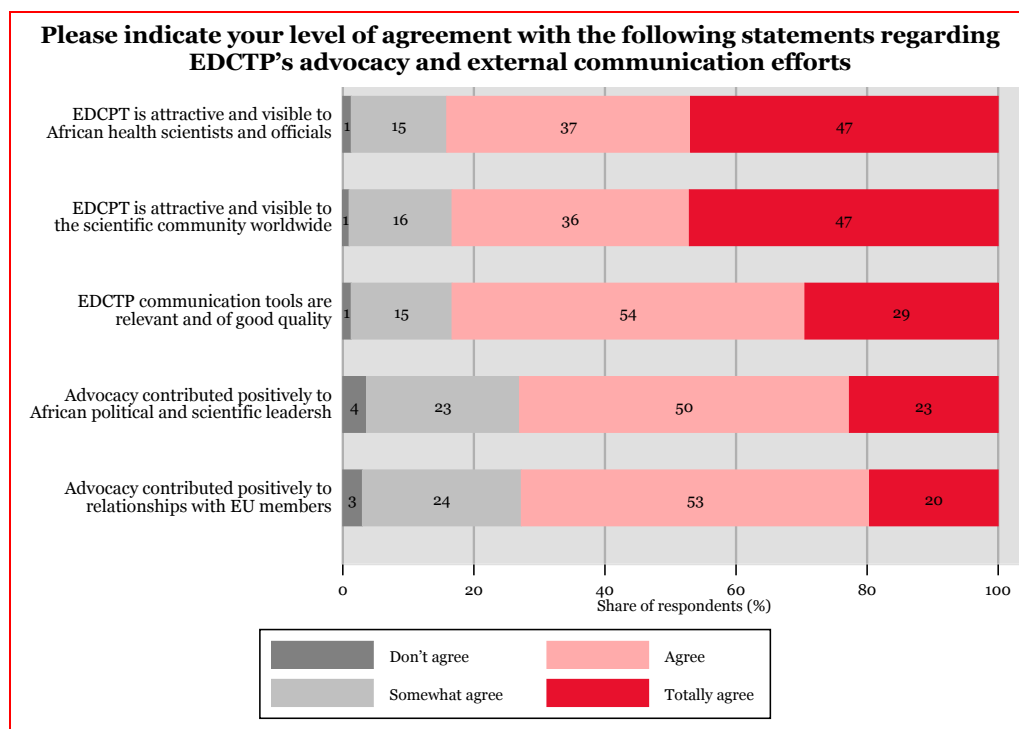
Figure 27 Satisfaction about EDCTP's communication efforts (N=310)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

The grantees are positive about the advocacy and external communication approach of EDCTP, especially African health scientists and officials and the scientific community are sensible to the attractiveness and visibility of the communication means used (see Figure 28).

Figure 28 Agreement with EDCTP's advocacy and external communication (N=316)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

3.3 Monitoring and evaluation

EDCTP makes use of Key Performance Indicators (KPIs) as quantifiable performance measurements in order to measure its progress against factors that are key to EDCTP's success. These KPIs are clustered into four categories. Figure 29 shows the actual KPIs including an explanation on how they are defined.

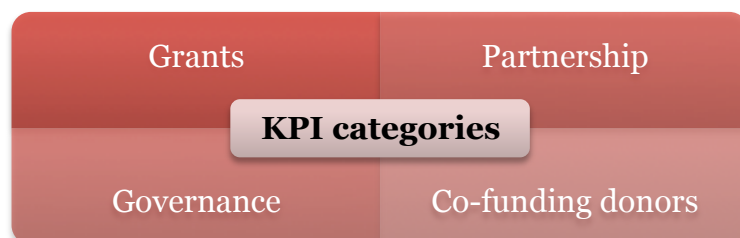


Figure 29 Overview of Key Performance Indicators currently in use

Category	Key Performance Indicators	Definition
Grants	Value of grants (projects) signed	The value of contracts signed (in € cash via EDCTP from European Commission, Participating States and third parties).
	Number of clinical trial/integrated project grants signed	The number of clinical trial and integrated project grants signed.
	Capacity building activities	PhD and Masters students supported or planned as part of EDCTP grants.
	Contract negotiation period for new grants (projects)	The average period (in months) between the approval of a proposal by the General Assembly and the signing of the contract by the coordinator.
Partnership	African countries involved in EDCTP on-going projects	The number of African countries participating in the (signed) projects (division between the four African regions: East, Central, West and Southern Africa).
	African institutions involved in EDCTP on-going projects	The number of Africa institutions involved in the (signed) projects (division between the four African regions: East, Central, West and Southern Africa).
	African project coordinators	The number and percentage of African and female coordinators involved in (signed) projects with clinical trials components.
Governance	EDCTP cash expenditure per year split by grants and other costs	EDCTP cash expenditure (in €) per year split by grant and other costs (governance, support costs and programme activities).
	EDCTP cumulative expenditure split by cost category	Breakdown of the total EDCTP budget (in €) by grants, programme costs, governance costs and support costs.
	EDCTP expenditure divided between African and European countries	The value (in €) of the signed grants and non-grants costs divided between African and European countries
Co-funding donors	Annual Participating States co-funding of EDCTP activities	Composition and level of Participating States co-funding of EDCTP activities (in €). Participating States co-funding can be given via EDCTP, directly to the project and in-kind.

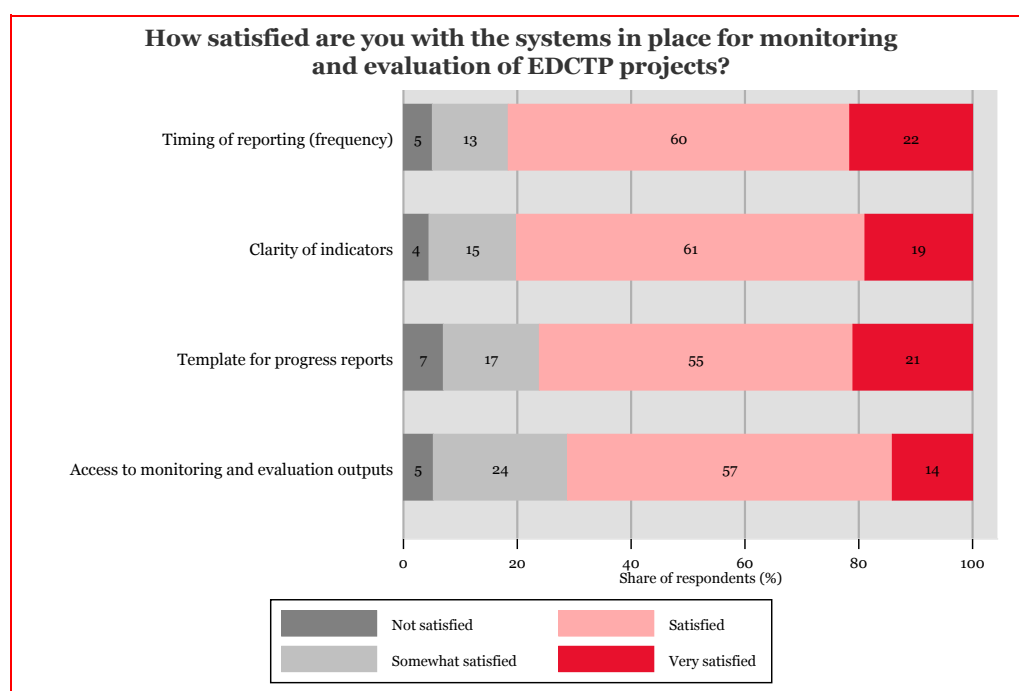
Source: Website of EDCTP (2014).

At the beginning of the programme there was a lack of a robust system, the intervention logic was not worked out properly. The Executive Secretariat does not have a dedicated unit or responsible person that deals with monitoring and evaluation on a regular basis. This led to the fact that the programme did not pay as much attention as intended and desired to monitoring and evaluating the achievements, longer-term results and impacts of the projects funded. Projects are followed by the Project Officers after they have finished, but monitoring and evaluation is something that could be taken up more

systematically in the second phase of the programme as an integral part. EDCTP2 already planned to adopt a Result Based Management Approach.

The following graph (Figure 30) shows that respondents are highly satisfied with the timing and template of the progress reports and clarity of the indicators. Respondents are slightly less unanimous about the access to the outputs of the monitoring and evaluations.

Figure 30 Satisfaction about monitoring and evaluation system (N=345)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

3.4 EDCTP's overall performance

There is wide acknowledgement that EDCTP, after a difficult start during the first years of the programme, turned itself into a well-tuned and effective funder of clinical trials on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa. The overall performance and effectiveness of the programme therefore has improved much over the years. The majority of the stakeholders that have been interviewed confirmed this by pointing out some positive developments such as the increased common understanding of EDCTP's mission and objectives and the improvements made in the governance and operational structures. At the current stage, EDCTP has become a more equal and transparent partnership in which African countries have a much stronger voice than in the early days. The programme has increased African engagement over the whole spectrum of clinical research and has helped to really achieve impacts in Africa, through developing products and building capacity based on good science.

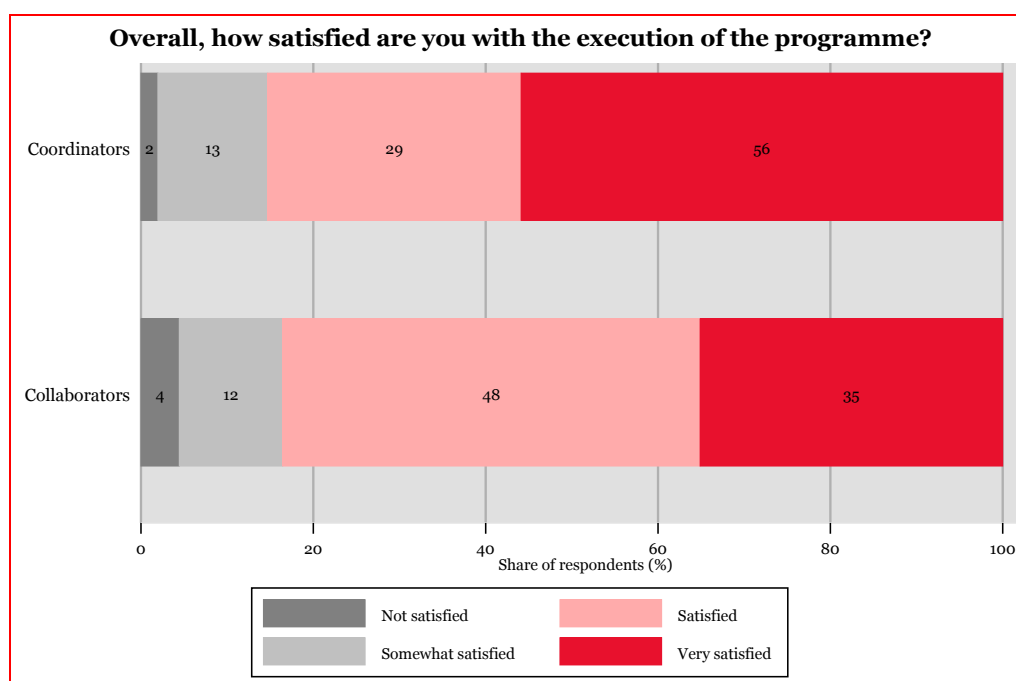
The combination of support for clinical trials with capacity building and networking (the 'holistic approach') is considered unique compared to the approach of other funders. Amongst others leading international actors such as the World Health Organization, the Bill & Melinda Gates Foundation, PDPs and researchers interviewed during the country visits EDCTP recognise it as a 'best practice' with regards to funding of clinical research in Africa. Through EDCTP, African researchers are given the opportunity to become principal investigators of projects and develop their own research questions based on local needs and challenges. As one stakeholder mentioned: "EDCTP gave Africa a way

to lead and design clinical trials and helped identifying the gaps for the studies that needed to be executed and in which way ethical committees should be organised”.

Stakeholders find it hard to judge the ‘value for money’ (especially in terms of quantification) as it will take years before the benefits can be reaped of the 100 clinical trials that were funded during its first programme, in terms of new products and long-term improvements in health outcomes. EDCTP is now at the point where the necessary infrastructure has been developed and strengthened in order to conduct clinical trials, and where people from different backgrounds and levels have been trained (see more on the impact on these aspects in the next chapters). The institutions might be in a better position to attract additional funding, but it is hard to say that this is already happening substantially.

The grantees are in general very positive about the execution of the programme (see Figure 31); around 85% of the respondents are (very) satisfied, of which the project coordinators report the highest scores.

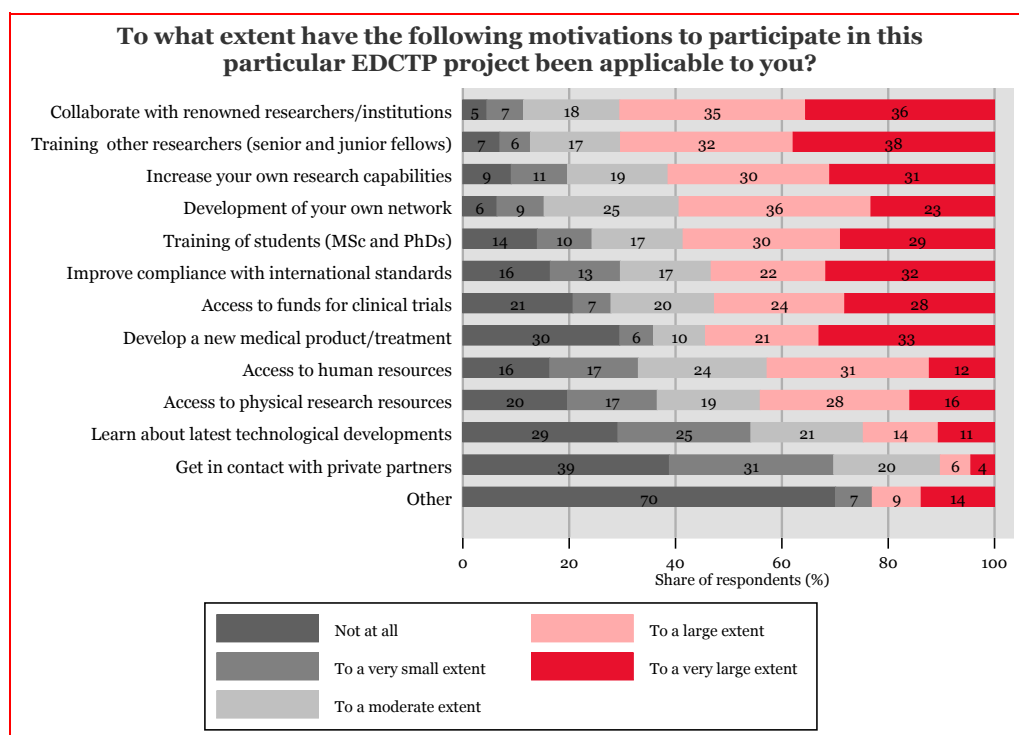
Figure 31 Satisfaction of the execution (N=103 (coordinators)/N=241 (collaborators))



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

Figure 32 shows a number of motivations for researchers to be involved in the EDCTP programme and the extent to which they apply to them. Networking and capacity building aspects have been the biggest motivational factor for researchers to apply for funding. These include the collaboration with renowned researchers/institutions, training of other researchers and students and the increase of research capabilities.

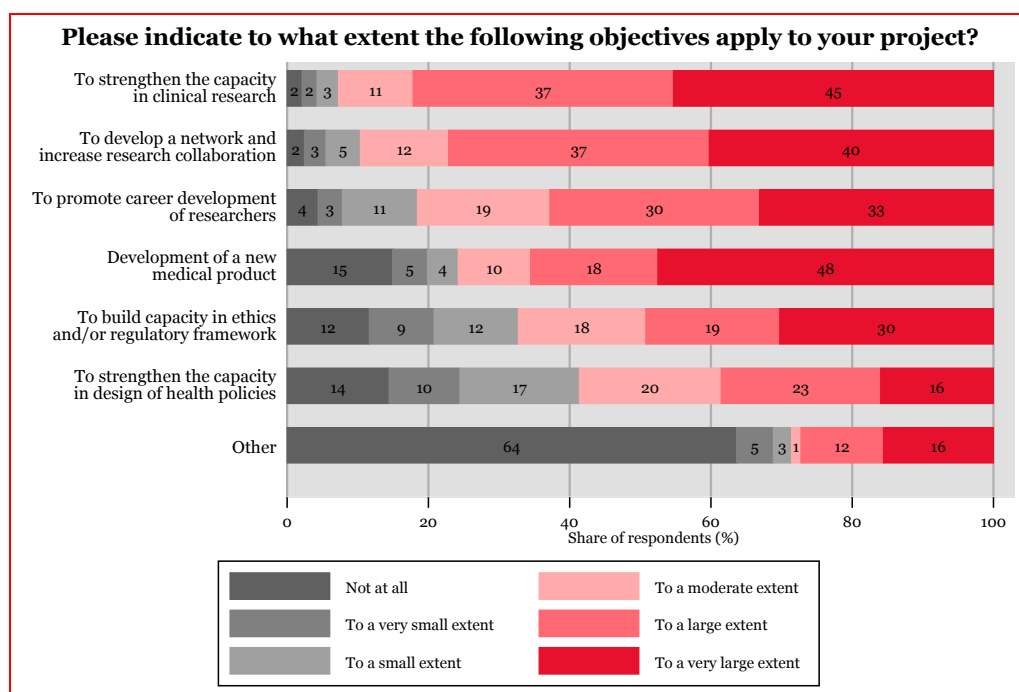
Figure 32 Overview of motivations to be involved in EDCTP (N=350)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

This also aligns with the project objectives as perceived by the grantees (Figure 33). Strengthening the capacity in clinical trials and developing networks to increase collaboration are to a very large extent applicable to the projects.

Figure 33 Project objectives according to respondents (N=345)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

4. Impact on clinical trials

This chapter addresses the impact of EDCTP funded activities on the execution of clinical trials and the broader health related impacts the funded clinical trials have realised to date.

4.1 Overview of clinical trials funded

As mentioned in Chapter 2 clinical trials are the main focus of the EDCTP funded projects. The majority of the clinical trials have been supported through the Clinical Trials and Integrated Projects grant scheme, however other grant scheme categories also supported clinical trials. These include some of the Strategic Primer Grants, fellowships and training grants and coordination and integration grants. In total 74 out of the 246 projects incorporated clinical trials, which is 30% of all grants funded. This however corresponds to a grant value of the clinical trial related projects of more than €154 million, which is almost 73% of the total grant value that has been disbursed by EDCTP. This shows the importance of clinical trials in EDCTP's project portfolio. The three disease areas are evenly addressed in these grants: 24 projects focus on HIV/AIDS, 22 on tuberculosis, 21 on malaria and 7 on HIV/TB co-infection. The table below shows the number of grants that supported clinical trials.

Figure 34 Overview of funded projects with clinical trials by grant scheme category

Grant scheme categories with clinical trials		Clinical Trials and Integrated Projects	Strategic Primer Grants	Fellowships and training grants	Coordination and integration	TOTAL	
HIV/AIDS	Treatment	11	1	3	1	16	24
	Vaccines	3	1		1	5	
	Microbicides	1	1			2	
	Other			1		1	
Tuberculosis	Treatment	5	1	2	1	9	22
	Vaccines	5				5	
	Diagnostics	3	2	2	1	8	
HIV/TB	Treatment	4	1	2		7	7
Malaria	Treatment	7		7	2	16	21
	Vaccines	2	3			5	
Number of projects including clinical trials		41	10	17	6	74	
Total number of projects		52	14	70	17	246	
As % of total # of grants		79%	71%	24%	35%	30%	

Source: Information EDCTP, analysis Technopolis Group (2014). * Within the grant scheme categories of ethics and regulatory framework and networking no clinical trials have been funded, for that reason these categories are excluded from this table.

The 74 grants have initiated a total of 100 clinical trials under EDCTP1, equally spread over the disease areas (as mentioned above following the grants that have been funded). This implies that some of the grants initiated more than one clinical trial. The majority of the trials (60 in total) is targeted at the development of new or improved treatments, followed by vaccines (25), diagnostics (11, only related to tuberculosis) and microbicides

(3, only related to HIV/AIDS). Currently 36% of the trials have been completed and one was terminated prematurely (the PROMPT trial). The next table presents the number of clinical trials per disease area and per type of development.

Figure 35 Total number of clinical trials per disease area

	Treatment	Vaccines	Diagnostics	Microbicides	Other	TOTAL	Completed
HIV/AIDS	18	8		3	1	30	13
Tuberculosis	11	5	11			27	8
HIV/TB	9					9	4
Malaria	22	12				34	11
TOTAL	60	25	11	3	1	100	36

Source: Information EDCTP, analysis Technopolis Group (2014). N.B. Some grants initiated more than one clinical trial.

The figure below shows the number of clinical trials for each of the phases of clinical development. The clinical trial phases are:

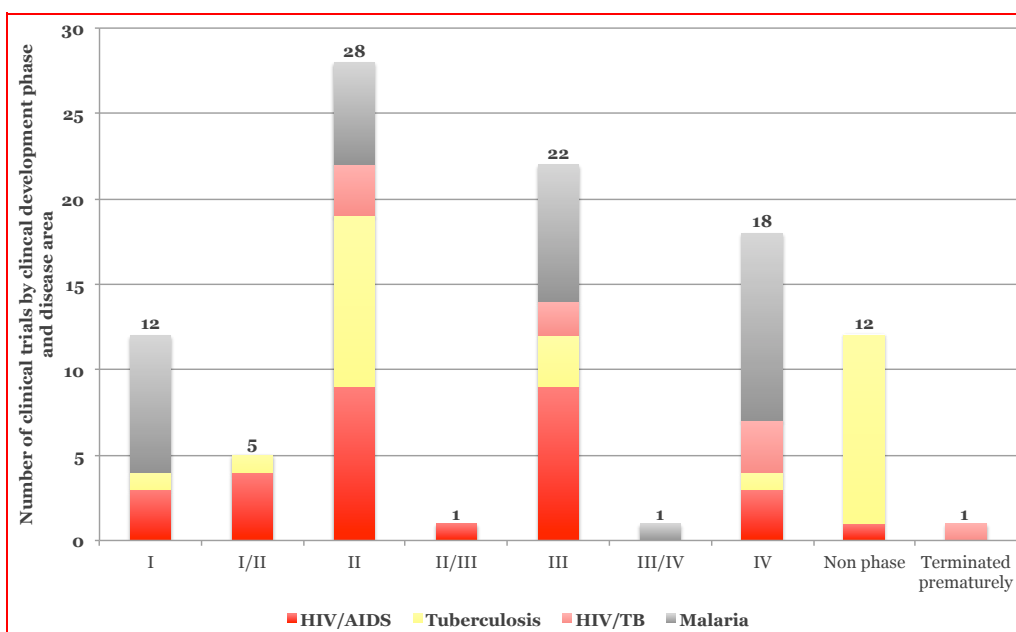
- Phase I: Testing of a new drug or vaccine on healthy volunteers (20 to 100 people) for dose-ranging to determine whether it is safe to check for efficacy;
- Phase II: Testing of drug or vaccine on patients (100 to 300 people) to assess efficacy and safety determining whether it can have any efficacy;
- Phase III: Testing of drug or vaccine on a large patient population (1,000 to 2,000 people) to assess efficacy and safety to determine the effect;
- Phase IV: Post marketing surveillance, investigation the long-term effects.

In some cases integrated phase trial designs implement the aspects of two subsequent phases into a single trial (this includes I/II, II/III and III/IV trials).

The EDCTP funded trials cover the whole range of these phases of clinical development, of which the largest number (50% of the trials funded) are currently in phase II (especially related to HIV/AIDS and tuberculosis trials) and III. This aligns with the focus of EDCTP's clinical trial activity. The projects with a focus on the development of diagnostics for tuberculosis are not captured in one of the four phases as diagnostics follow a different development path than drugs or vaccines. Although EDCTP was formally limited to support phase II and III clinical trials (as mentioned in Chapter 1) in certain situations the decision was made to support clinical phase I and IV studies as well. These reasons are:

- In some areas there are limited products in later phases of clinical development. This situation strategically urged EDCTP to support earlier phase I studies, in particular for the development of vaccines for HIV/AIDS, tuberculosis and malaria;
- As a result of disease area specific EDCTP stakeholders meetings EDCTP engaged to support phase IV studies when phase II and III studies were promising and taking into account the global portfolio of clinical developments;
- Finally due to differences in the way clinical trials are classified, there is a grey zone between phase IIIb and IV for specific studies (e.g. studies on very young children and pregnant women).

Figure 36 Number of clinical trials by clinical development phase



Source: Information provided by EDCTP, analysis Technopolis Group (2014).

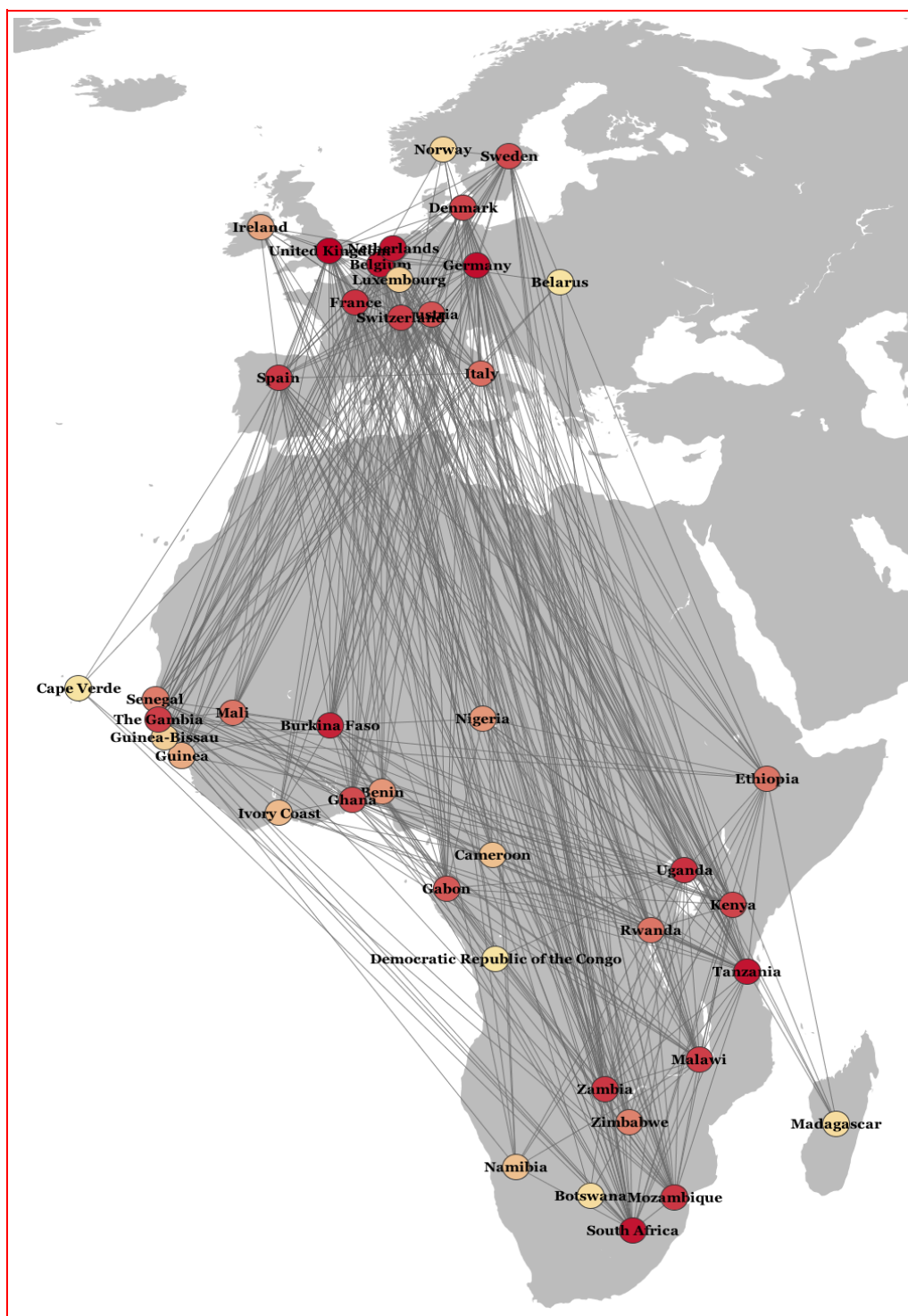
The network graph in Figure 38 shows all European and African countries that are involved in the clinical trials and the connections between the countries based on the participation data. In total 15 European Participating States and 27 African countries take part in the clinical trials. This means that 21 other African countries are not (yet) involved in EDCTP funded clinical trials. The intensity of the colours of the dots represents the degree of involvement in the clinical trials; countries that are represented by dark coloured red dots are involved in the highest number of clinical trial studies. The top-5 European and African countries in terms of involvement in clinical trials are presented in the table below (including the number of clinical trials in which these countries are involved).

Figure 37 Top-5 European and African countries involved in clinical trials

	Europe	Number of clinical trials involved in	Africa	Number of clinical trials involved in
1	United Kingdom	38	South Africa	26
2	The Netherlands	26	Tanzania	24
3	Germany	23	Uganda	17
4	Belgium	17	Kenya	14
5	Spain	10	Zambia	16

Source: Information provided by EDCTP, analysis Technopolis Group (2014).

Figure 38 Network of all countries involved in EDCTP initiated clinical trials



Source: Information provided by EDCTP, analysis Technopolis Group (2014).

4.2 Impact of clinical research activities

Tremendous progress has been made towards achieving EDCTP's objectives in setting a base for excellence in clinical trials across the African continent. However there is still a lot of work to be done, notably as the mutation of pathogen source of some poverty related diseases such as malaria is evolving so fast that new treatments have to be found,

that HIV continues being spread across Africa, HIV/TB co-infection poses drastic problems of inefficiency of existing treatments etc. As it was stated at the 7th EDCTP Forum in Berlin (30 June – 2 July 2014), “*business as usual is not an option*”.

Against this background, and even though it does not fall under the mandate of EDCTP, the need for Africa to achieve in parallel a better access to health care has been strongly highlighted by the interviewees. This issue is overall highly critical, as governments may tend to favour funding improvements of health care systems over research in health and as any potential developments subsequent to clinical trials will have no impact if the health care systems for prevention, vaccination or treatment are neither functional nor adequate.

In terms of clinical trial outputs, the majority of the stakeholders interviewed show optimism, while most of the clinical trials carried out under ECDTP1 are still in their early stages. This optimism is based on the fact that EDCTP created the ability to fund the whole spectrum of clinical development (from phase I to phase IV) and contribute to the pipeline of products. By closely interacting with the different PDPs, there will be more room for EDCTP2 to further strengthen and ensure this product pipeline.

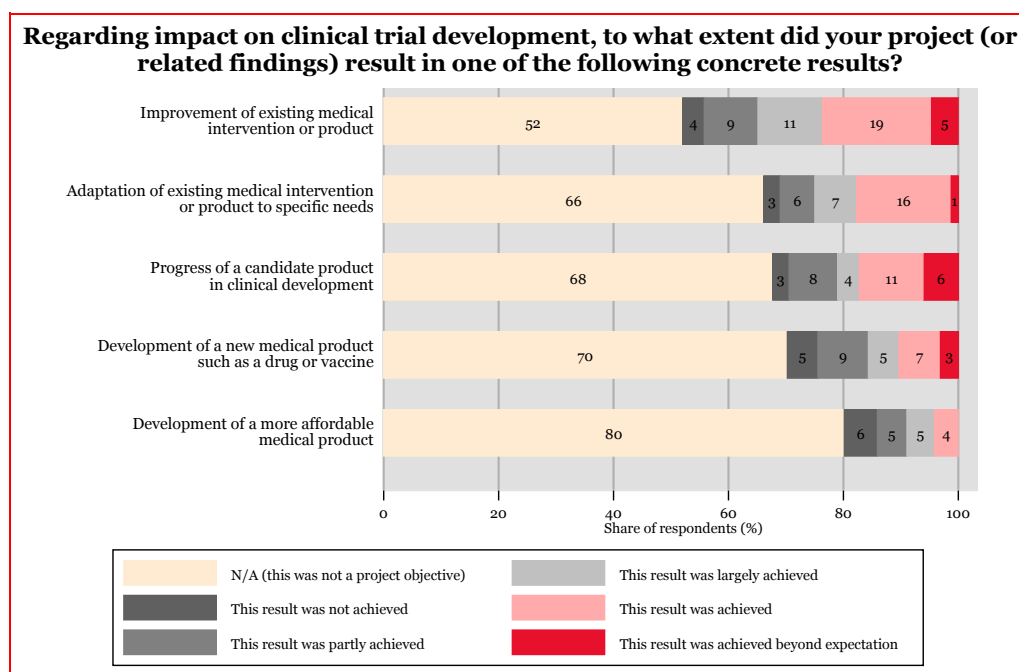
Even though EDCTP has been supporting clinical trials in sub-Saharan Africa during its first phase, it is still quite early to expect a large impact in terms of new products developed, as there were some preconditions to clinical trials, which had to be improved first. At the moment there are a few trial results that have led to new products or changes in treatment course (see section 4.2.2 for more details). Nevertheless, EDCTP1 supported preconditions for conducting quality trials, which ranged from training researchers, setting up research infrastructures and facilities, acquiring equipment to capacity building and creating the regional Networks of Excellence (see the following chapters for EDCTP’s achievements in these respective areas). However, many clinical trials already showed good results in terms of scientific outputs, but there is still a gap in phase IV trials especially related to vaccine for HIV/AIDS, tuberculosis (including HIV/TB) in sub-Saharan African countries.

The Strategic Primer Grants are very much appreciated by the grantees as a mechanism to stimulating research to develop innovative clinical research ideas that might lead to the development (through formal clinical trials) of new or improved clinical interventions.

In addition to be able to allow researchers to further investigate new (innovative) insights gained during current projects, opportunity can be provided for investigators to request for ‘add-on’ grants. For this reason EDCTP could reserve an amount of money that can be used to add interesting studies to the current projects or to respond to new research questions or opportunities that arose after the start of the core study.

The following graph (Figure 39) shows the impact on clinical trial development according to the grantees. Remarkable is that for the majority of the grantees these expected impacts are not considered to be objectives of the project. These are mainly grantees of non-clinical trials related projects (e.g. ethics and regulatory framework projects, networking grants), for which the answers are in align with the expectations. For those grantees that report that these impacts on clinical trial development are foreseen, the largest progress is shown in the improvement of existing medical interventions or products and the adaptations of existing interventions or products. The lowest impact is perceived in the development of more affordable medical products.

Figure 39 Impact on clinical trial development (N=329)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

One concern mentioned are the high responsibilities when sponsoring a clinical trial and the lack of institutions in Africa (except for some of the institutions in South Africa) that can bear the financial and managerial responsibilities associated with it. In the light of the future of the programme the potential risks associated with clinical trials should not be underestimated. It should be heard in mind that it is an obstacle for some institutions to risk involvement of partners with less capacity. A guarantee system to reduce the risk may be of appeal to EDCTP participating institutions.

4.2.1 Impact on research excellence

The outcome of the research conducted is overall positive, according to the stakeholders interviewed and the researchers that are working at institutions in the countries visited. These outcomes ranged from established guidelines based on the results from EDCTP funded projects, to improved networks and direct health impacts through improved treatments.

In addition, EDCTP has considerably changed the way clinical research is conducted in most of the sub-Saharan African countries as a result of the projects funded. According to interviewees, this is due to several reasons:

- First of all, participation in projects has fostered collaboration amongst universities across Africa and Europe, and thus has enhanced knowledge exchange and raised research standards in the less advanced laboratories and clinical research sites.
- The projects have supported capacity building of researchers and technical staff not only in conducting clinical trials by setting standards which became the norm, but also in writing research proposals which has led them to be more autonomous and possibly generate revenues from other funding sources.
- The projects have created and supported a critical mass of researchers in Africa, who previously had little access to funding for conducting clinical trials.
- And above all, the majority of the clinical studies funded by EDCTP would not have been carried out otherwise.

The selection of projects to be funded has been a critical issue to research excellence: according to a selection of interviewees the first steps of EDCTP were not optimal. The process of choosing research projects that could have an immediate impact on the health policies and the health of people in participating countries has significantly improved with the introduction of a system of review by external reviewers and a Scientific Review Committee. The number of successful clinical trials and the scientific publications that the programme has funded demonstrates in itself the impact of EDCTP on research excellence (see section 5.2.2 for more on the scientific impact). According to the stakeholders the achievements of the projects are really ground-breaking.

The Europe-Africa Research Network for Evaluation of Second Line Therapy (EARNEST) resulted in a feasible second-line therapy for HIV patients in Africa

The most frequent choice for initial treatment of HIV infected people is antiretroviral combination therapy consisting of 2 nucleoside reverse transcriptase inhibitors (NRTIs) and 1 non-nucleoside reverse transcriptase inhibitor (NNRTI). This combination therapy is effective in preventing or reversing the decline in immune function and dramatically decreasing the risk of opportunistic infections and thereby morbidity and mortality from HIV. However, even when using the most potent and best tolerated combination therapy available, HIV may become resistant to the antiretroviral drugs administered and virological failure may occur, thereby making it necessary to switch antiretroviral therapy. Most guidelines recommend that in that situation therapy with a boosted protease inhibitor (bPI) should be initiated, and the nucleoside backbone should be modified to 2 NRTIs predicted to be active on the basis of resistance testing. For Africa there are two challenges that might influence optimal drug combination for second-line therapy: late detection of failure and limited ability to individualise second-line therapy.

It is against this background that one of the largest clinical trials funded by EDCTP, co-funded by Spain, the United Kingdom, Ireland, Italy, Belgium and Sweden, has been initiated: the EARNEST trial. This trial compared several boosted protease inhibitor-containing second-line regimens in HIV patients in five African countries (14 clinical trial sites): Kenya, Malawi, Uganda, Zambia and Zimbabwe. This, three-arm open label randomised trial was the largest study of second-line therapy ever conducted in sub-Saharan Africa and resulted in the recruitment of a total of 1,277 HIV-infected adults and adolescents who failed first-line treatment. These patients received randomised:

1. Ritonavir-boosted protease inhibitor (lopinavir-ritonavir) plus clinician-selected nucleoside reverse transcriptase inhibitors (NRTI group, 426 patients);
2. A protease inhibitor plus raltegravir in a superiority comparison (raltegravir group, 433 patients);
3. A protease-inhibitor monotherapy after 12 weeks of induction therapy with raltegravir in a non-inferiority comparison (monotherapy group, 418 patients).

The trial demonstrated that the WHO-recommended regimen of a boosted protease inhibitor (option 1) combined with two NRTIs is effective and has an acceptable safety profile, with a 90% rate of survival free of WHO stage 4 events and an 86% rate of virologic suppression at 96 weeks. Importantly, the trial showed that combining a boosted protease inhibitor with raltegravir (options 2 and 3) to create a second-line regimen with two completely new drug classes was not superior to NRTIs. This regimen is significantly more expensive and therefore not suitable as a standard second-line regimen for large-scale use in low-income settings.

4.2.2 Impact on the acceleration and development of products/interventions

As there is still shortage of products or interventions in various areas, such as treatments and diagnostics for tuberculosis and HIV/TB co-infection and vaccines for malaria and tuberculosis, EDCTP funded projects are considered to be highly relevant as they specifically address these issues. EDCTP has been one of the few options for clinical trials in this field, where investments through other funding agencies have traditionally been sparse.

Due to the relatively recent character of its implementation, EDCTP did not yet had much impact on acceleration and development of new or improved products/interventions, including contribution of research data towards prequalification by regulatory authorities (e.g. WHO). At the moment there are a few trial results that have led to new products or changes in treatment course (see the various boxes with

information on clinical trials that have led to results). In any case, such an impact should be an explicit objective of EDCTP2 and should be translated within plans for prequalification by national regulatory authorities. For registration with Stringent Drug Regulatory Authorities (SRA) and WHO prequalification, phase II & III clinical trials need to be carried out following the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and the appropriate records need to be kept. For EDCTP there is a need to arrange financial provisions for monitoring, data storage, and safety reporting during and after the project. Also the need for strengthened collaboration between EDCTP and the European Medicines Agency (EMA) is stressed. Both are dependent on the European Union for their legal status and data obtained under EDCTP funded projects should be in a format and of a quality, which can be reported to the EMA without additional refinement.

In its second programme, EDCTP could focus on enhancing product development through a better involvement and early engagement of the regulatory groups, PDPs and industry partners in the research projects themselves.

4.2.3 Impact on health policies

Because of the long period between the actual clinical trial and the implementation of new clinical interventions, it is still too early to fully assess the impact of EDCTP on health policies and health services at a global level. Hence continuity matters, notably in funding trends, in order to allow continuity in capacity building and research conducted, as EDCTP remains the main, if not the sole, provider of funds for clinical trials in Africa.

Nevertheless, there are some examples of positive achievements. Through successfully conducted clinical trials, EDCTP has played an important role in the global portfolio of malaria vaccines. Another major result of EDCTP related to clinical trials is for instance the WHO guideline that has been developed on mother-to-child transmission of HIV during pregnancy and breastfeeding²⁷. Other funders in addition to EDCTP contributed to this trials, which are the Agence Nationale de Recherche sur le SIDA et les hépatites virales (ANRS) in France, the Wellcome Trust in the United Kingdom and WHO. This directly impacts the health of people in Africa. EDCTP has built relationships with Ministries of Health in Africa through which it can steer the agenda towards current African needs. Also, HIV is no longer acute but has become a chronic disease and there are some successful examples of specific trials in the regulation of drugs (children on HIV) through EDCTP funded projects.

The Kesho Bora study influences the WHO guidelines on prevention of mother-to-child transmission of HIV

In many developing countries, mothers with HIV have faced a difficult choice: either to breastfeed their babies with the risk of passing on the virus through their breast milk or to formula feed their babies with the risk of infants dying from diarrhoea, pneumonia and malnutrition because they are deprived of the nourishment, natural immunity and protection of breast milk. The Kesho Bora study (which means 'a better future' in Swahili), a partnership between international and national research agencies, coordinated by WHO's Department of Reproductive Health and Research, focused on the prevention HIV infection and death among infants in low-resource settings where many mothers with the virus breastfeed.

In addition to EDCTP, other major funders of this study are the French National Agency for Research on AIDS and Viral Hepatitis (ANRS), US Centers for Disease Control and Prevention (CDC) and the Institute of Child Health and Human Development (NICHD) of the National Institutes of Health.

The study consisted of a randomised controlled trial in antiretroviral-naïve pregnant woman infected with HIV-I conducted in five sites in Africa: one site in Burkina Faso, two in Kenya and two in South Africa. The study assessed the efficacy and safety of triple antiretroviral prophylaxis compared with

²⁷ <http://www.who.int/hiv/pub/mtct/antiretroviral2010/en/>.

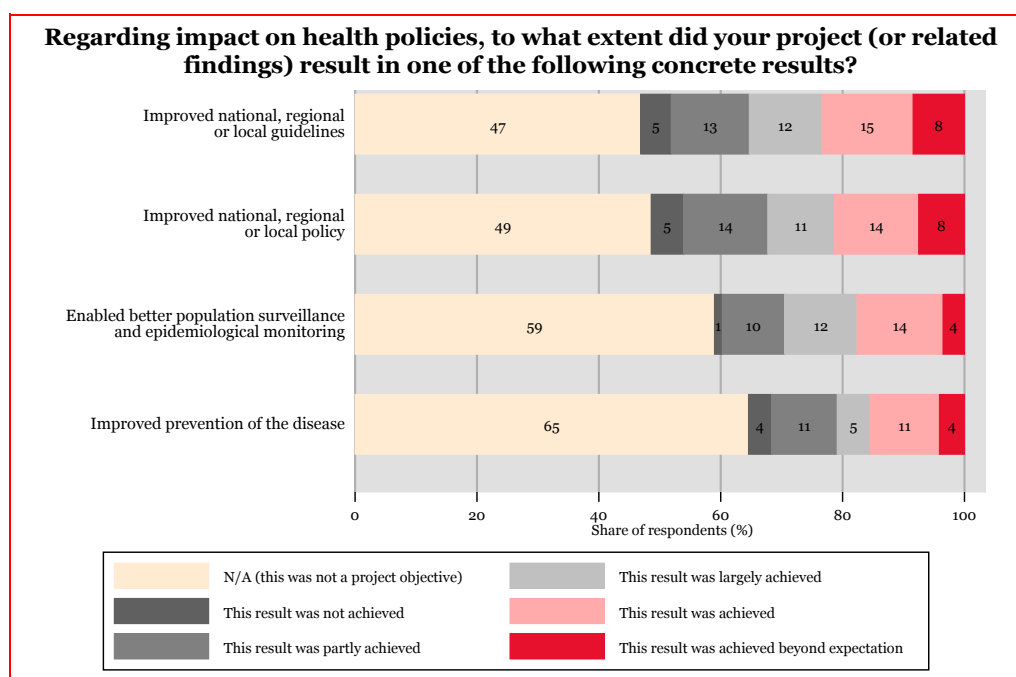
zidovudine and single-dose nevirapine prophylaxis (the standard regimen recommended by WHO from 2004) in pregnant women infected with HIV.

The results of the study, published in *The Lancet Infectious Diseases* in 2011²⁸, show that a combination of three antiretroviral (ARV) drugs to pregnant women with HIV infection from the last trimester, through delivery and six months of breastfeeding reduces the risk of transmitting HIV to the baby and improves survival. The triple-ARV regimen cuts HIV infections in infants by 43% compared with the control regimen, and reduces the risk of transmission during breastfeeding by more than half. This approach offers new hope for HIV infected mothers who cannot safely feed their babies with infant formula. It will improve the chances of infants remaining healthy and free of HIV infection as breast milk provides optimal nutrition and protects against other fatal childhood diseases such as pneumonia and diarrhoea. A revised WHO guideline (2010) now recommends antiretroviral prophylaxis (either to the mother or to the baby) during breastfeeding for all women with HIV and continued antiretroviral treatment for women with a CD4 count at or below 350 cells per μL .

Even though some of these examples are outstanding and concrete, substantial and global impact can only be seen on the longer term. Completing all phases of clinical research (from phase I to IV) needs at least two years per steps, and then impact on public health policies and public health can take at least 8 years (and sometimes even more). Despite the positive notes, the expectation is that the large part of the impact on the health situation of people will only become apparent in EDCTP2. Therefore it will be essential to closely monitor the progress made in the respective areas in order to have better insights in the impacts of the activities funded.

The following graph (Figure 40) shows the perceived impact on health policies by the grantees. Improved guidelines and policies are considered to be most likely to occur. The least impact is to be expected in the prevention of diseases.

Figure 40 The impact on health policies (N=325)

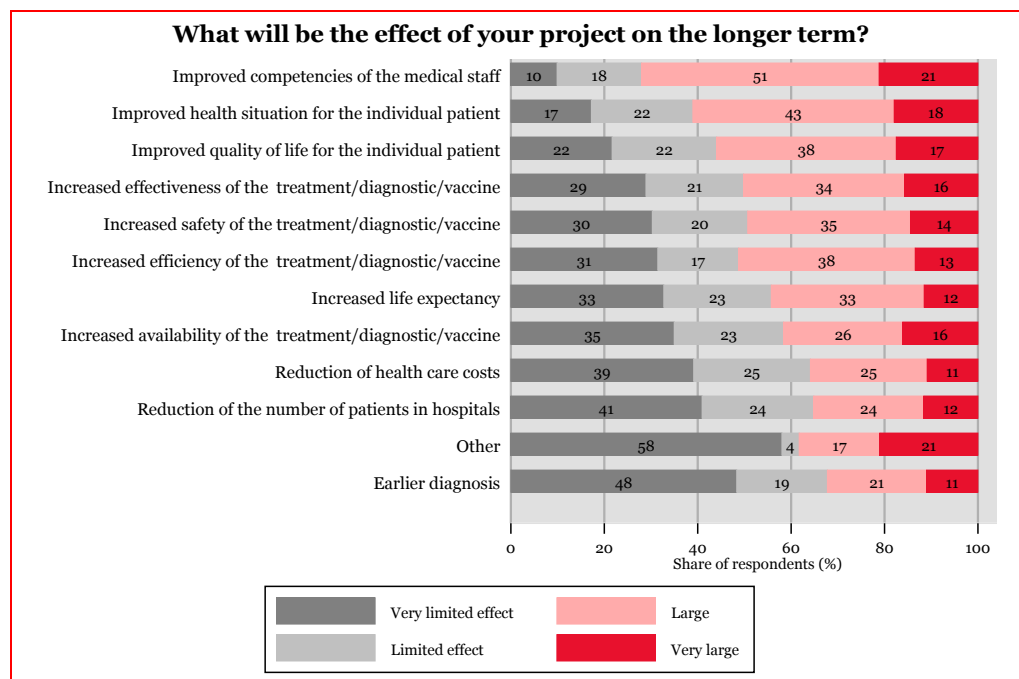


Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

²⁸ The Kesho Bora Study Group (2011). Triple antiretroviral compared with zidovudine and single-dose nevirapine prophylaxis during pregnancy and breastfeeding for prevention of mother-to-child transmission of HIV-1 (Kesho Bora study): a randomised controlled trial. *The Lancet Infectious Diseases*, 2011; 11.

The grantees have been asked to report on the effect of the project on the longer term. The effect is perceived largest in terms of improved competencies of medical staff, followed by improved health situation and quality of life for the individual patient (more than 50% of the respondents expect a (very) large effect). The least effects are expected in earlier diagnosis of diseases, reduction of hospitalisation and health care costs.

Figure 41 Perceived effect of project on the longer term (N=316)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

Insight from the country cases on the impact on clinical trials and research excellence

South Africa

EDCTP has funded a wide range of clinical trials and research activities in South Africa in the field of HIV/AIDS, tuberculosis and co-infection of these diseases and delivered some patents and publications.

No new tuberculosis vaccines have been developed yet. One clinical trial, the REMoxTB (Rapid Evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis) as one of the projects under the umbrella of the PanACEA consortium, allowed adjustment to the treatment course of tuberculosis (i.e. the dosage of drugs and length of treatment) and is expected to have an impact on the guidelines for the treatment of tuberculosis.

Concerning HIV, one of the major breakthroughs so far is on adolescent health through the SASHA project. Adolescent health was not well defined and described in Africa, while it is a key population affected by HIV and tuberculosis. Thanks to research conducted under EDCTP, the South African Minister of Health has put adolescent sexual and reproductive health higher on the research agenda. All aspects of clinical research have been taken on board (behavioural, legal aspects, et cetera) and the principal investigator is now consulted internationally for clinical research in this area.

Tanzania

Based on the progress made in the clinical trials in Tanzania, like those undertaken by the National Institute for Medical Research (NIMR), the Ifakara Health Institute (IHI), the Muhimbili University of Health and Allied Sciences (MUHAS), the Mbeya Medical Research Center (MMRC), the Kilimanjaro Clinical Research Centre (KCRI) there is an impact in reducing the burden of the three targeted diseases. There are some findings, which are immediately taken up by the Tanzanian Ministry of Health. In the past there were just a few locations to perform GCP trials, now there are many in the country. Another change in the way clinical trials are conducted is the fact more and more steps in the research process can be done in-house by the Tanzanian institutions. In the past (five to 10 years ago), after the clinical trials are finished, the collected samples were shipped to other countries for further analysis. Now the institutions are able to perform preparatory work, immunology and molecular biology.

Some of the projects in which interviewees participated also produced considerable scientific outputs. For instance, the innovative TAM-TB assay that has been developed as part of the TB CHILD project was subject of some scientific publications as it has become more promising for diagnosis of tuberculosis than other diagnostic tools. For MUHAS the experiences in the HIV trials have their spill-overs to other parts of the world as well since it is an idea that is widely acceptable. MMRC participated in the second vaccine trial in Tanzania, which led to a lot of misconception about the studies in the local community. During the establishment of the TaMaVac-01 project a specific board was set up in order to better connect the site and community to explain the aim of the project and to collect the rumours. The project helped in trying to reduce the number of rumours. During the follow-up project, TaMoVac II, there are frequent meetings and much more attention about the trial. This resulted in less rumours and made people more eager to get screened (the people have less questions and do not feel so worried anymore).

Republic of the Congo

Notably, a full laboratory at the Faculty of Medicine of the Université Marien Ngouabi in the Republic of the Congo was rehabilitated, equipped and staffed and is now operational as a result of grants made available through the Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM), one of the four Networks of Excellence established by EDCTP. The laboratory performs research activities in molecular biology for the first time in Congo. Two researchers are currently trained for clinical trials and the Fondation Congolaise pour la Recherche Médicale (FCRM) aims to conduct the first clinical trials in 2015.

Mali

Results in terms of clinical trials are considered to be on a good path in Mali. A project, led by Dr. Abdoulaye Djimdé, included 2,463 cases of malaria and concluded that combined therapy of artesunate plus amodiaquine or artesunate reduced malaria incidence more than arthemeter plus lumefantrine. Outputs include several international publications. These two artemisinin-combination therapies are now used concomitantly or simultaneously to treat malaria in Mali.

Through the West African Network for Clinical Trials of antimalarial drugs (WANECAM), a partnership has been set up with Medicines for Malaria Venture (MMV), Shin Poong (South Korea) and Sigma Tau (Italy) for the implementation of clinical trials (phase III and IV) in which 14,000 cases of Malaria were included over a period of 2 years. The study aimed to test new artemisinin based combination therapies (artesunate+pyronaridine and dihydro artemisinin+piperaquine) to add to and bypass resistance to current anti malaria treatments in Africa. The results are very encouraging; they are currently being submitted to the European Medicines Agency (EMA).

The complete country cases are included in Appendix I to Appendix L to this report.

5. Impact on capacity building in sub-Saharan Africa

This chapter focuses on the impact of the EDCTP funded projects on capacity building in sub-Saharan Africa, both on individual and institutional level. In addition to the broad spectrum of EDCTP capacity building activities, the chapter also pays attention to the Pan African Clinical Trial Registry (PACTR).

5.1 The number of people trained on EDCTP grants

One of the core elements of the capacity strengthening approach of EDCTP is the training of people through the projects grants that have been supported. In total 518 people have been trained on EDCTP funded projects.

The table below (Figure 42) shows the distribution of these trainees for the subsequent scientific career levels (from Bachelor students to Senior Fellows). The largest numbers of people trained are Master (233) and PhD students (173). The majority of these students have been trained on large integrated projects.

The overall male-female ratio is 59% (male) versus 41% (female). In the Senior Fellowship grants, male researchers are overrepresented (78% versus 22%).

In a total of 31 African countries people have been trained on EDCTP projects, the highest diversity of countries involved are in trained number of Master students. This automatically implies that not a single person from seventeen of the sub-Saharan partner countries has been trained. These countries are Angola, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Equatorial Guinea, Lesotho, Madagascar, Niger, Sao Tome and Principe, Seychelles, Sierra Leone, Somalia, South Sudan and Swaziland. It is worth investigating to what extent students and researchers from these countries can benefit from the training opportunities under EDCTP2.

Figure 42 Overview of trainees on EDCTP funded projects

Career level	Total number of people trained	Male - Female ratio	Number of African countries involved
Medical Diploma	7	57% - 43%	1
Bachelor student	8	37% - 63%	3
Master student	233	58% - 42%	27
PhD student	173	60% - 40%	22
Postdoctoral researcher	41	44% - 56%	11
Career Development Fellow	5	20% - 80%	5
Senior Fellow	51	78% - 22%	19
TOTAL	518	59% - 41	31

Source: Information provided by EDCTP, analysis Technopolis Group (2014).

In addition to these formal training programmes, EDCTP funded projects also include targeted short-term training schemes and workshops, which in most cases are part of the integrated projects.

Associate Professor Abdoulaye Djimdé: from Senior Fellow to coordinator of an Integrated Project

Abdoulaye Djimdé is an Associate Professor of Microbiology and Immunology and Chief of the Molecular Epidemiology and Drug Resistance Unit at the Malaria Research and Training Centre at the University of Bamako in Mali.

After obtaining his PhD in 2001, he had a research project but needed funds to conduct his research and would probably have moved to Europe if there was no opportunity to apply for an EDCTP Senior Fellowship grant in partnership with Sanofi Aventis (granted in 2004).

The Senior Fellowship was a great chance to consolidate his research activities in one project. Results were very encouraging and EDCTP accepted to fund a third year for the project.

The EDCTP Senior Fellowship helped him to build capacities and recruit and lead a dynamic research team at the MTRC. The primary focus of the research team is to understand how variations in the genomes of the malaria parasite, the human host, and the mosquito vector relate to disease outcomes like the spread of antimalarial drug resistance. His translational research programme uses molecular and genetic approaches to tackle important problems in malaria control.

In 2007 Dr. Djimdé has applied for an EDCTP Integrated Project. He succeeded and is now coordinator of the West African Network for Clinical Trials of Antimalarial Drugs (WANECAM) project who aims to conduct multicentre clinical trials in Mali, Burkina Faso and Guinea.

During his career he obtained the following prizes:

- Chevalier de l'Ordre National from the Government of Mali, presented by the President of Mali in 2001;
- Fighting Malaria Prize from the Federation of the European Societies for Tropical Medicine and International Health in 2002;
- Senior Fellowship from the European and Developing Countries Clinical Trials Partnership in 2004;
- International Scholar of the Howard Hughes Medical Institute in 2005;
- Prix de la Pharmacie Francophone from the National Academy of Pharmacy of France in 2009.

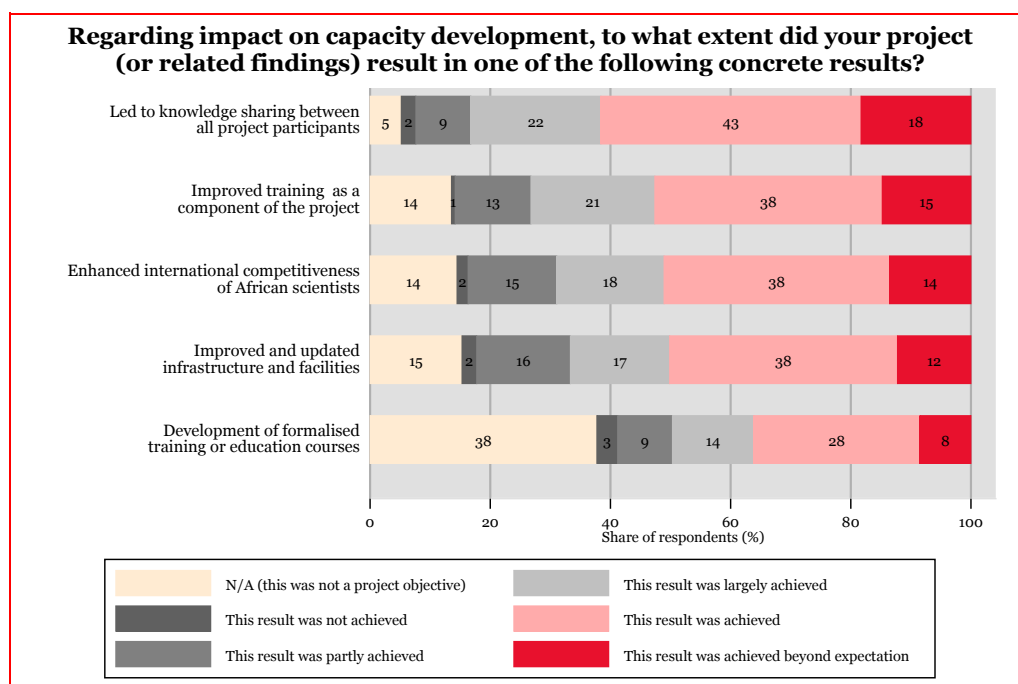
5.2 Capacity development in Africa

EDCTP's capacity building activities in sub-Saharan Africa are essential to the development of clinical research capacities in Africa. Overall, the interviewees mentioned that capacities in universities and research organisations have improved considerably by EDCTP. In addition, they were very positive about EDCTP's role in establishing and strengthening national ethics committees (NECs) and institutional review boards (IRBs) in the African institutions.

Nevertheless, many countries in sub-Saharan Africa are still lacking the basic know-how and infrastructure to conduct clinical trials that meet international standards in terms of scientific research quality and ethical conduct. EDCTP has certainly built capacities for individual researchers that have benefited from EDCTP funds and training but some of the stakeholders stated that institutional capacity has not been strengthened sufficiently through a proper regulatory environment. Stakeholders highlighted the fact that as capacity is strengthened the needs may change and should be evaluated again.

The different potential impacts on capacity development are in most cases formal objectives of the projects (more than the impacts on clinical trial development and health policies presented in the previous chapter). The largest impact has been perceived in terms of knowledge sharing between project participants, improved training, enhanced international competitiveness of the African scientists and improved and updated infrastructures. The development of training courses are perceived as the lowest impact achieved by the grantees (see Figure 43).

Figure 43 Impact on capacity development (N=335)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

5.2.1 Impact on the capacity to conduct clinical trials in sub-Saharan Africa

The impact of the EDCTP programme on the capacity to conduct clinical trials in sub-Saharan Africa through the development of laboratories and training of researchers and other staff is considered to be tangible in many countries. It can be observed through EDCTP's contribution to develop concrete clinical trial sites that can operate more or less autonomously now. Increasingly, African researchers can lead their own research projects and raise funding for new projects. Good examples are the Centre National de Recherche et de Formation sur le Paludisme (CNRFP) in Burkina Faso, the Uganda Virus Research Institute (UVRI)²⁹ and the Kilimanjaro Clinical Research Institute (KCRI)³⁰ in Tanzania. These centres initially have received small grants to develop a basic infrastructure then followed by larger grants from EDCTP and other funding organisations to extend these facilities (such as the Bill & Melinda Gates Foundation, National Institutes of Health and the Wellcome Trust). The centre in Burkina Faso now has established two public centres and created one private clinical trials centre (offering services similar to a CRO). The research centre in Uganda (the Uganda Virus Research Institute) is currently collaborating with the International AIDS Vaccine Initiative (IAVI).

Interviewees reported that institutions' capacities have been strengthened in terms of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Some laboratories also gained know-how on how to perform clinical trials according to international standards. However, still a large share of the clinical trials are led and/or supported by Europeans.

EDCTP has also invested in strengthening the physical infrastructures of these institutions. Given the regional context this is considered important to offer the

²⁹ <http://www.uvri.go.ug/>.

³⁰ <http://www.kcri.ac.tz/>.

necessary working conditions to researchers. Trained individuals are considered to be essential in raising the overall quality of clinical research in sub-Saharan countries

In addition to this, African countries are still lacking sufficient expertise in certain fields of clinical research and management and financial aspects of clinical research. This is important to take into account. Finally training of these people in the seventeen countries that did not participate yet in the training programmes is considered to be a point of attention for the second phase of the programme.

Considering the local difficulties and the immense needs in terms of human capital, EDCTP's investments and results in building human capacities in sub-Saharan Africa are considered as exceptional by external and internal stakeholders. Interviewees have pointed out that not many other funders have achieved the same impact.

Capacity building in Africa requires considerable investments and long-term engagement. Almost all stakeholders emphasise that EDCTP should build on the capacity that has been developed during its first phase. Money invested on capacity building in the first programme would be a waste of resources if the efforts are no longer to be continued. As continuation is currently not ensured after an EDCTP project is finished, the issue of sustainability is worrisome (but not different from other research conducted). Promising projects could be considered for continuous funding.

5.2.2 *The scientific impact of EDCTP associated papers*

In 2013 EDCTP commissioned a study to analyse the citation impact of its associated papers in the areas of HIV/AIDS, tuberculosis and malaria between 2003 and 2011³¹. This study was meant to support its preparations for the second phase of the programme. This study is supplementary to a broader bibliometric analysis of European and African research output within the scope of EDCTP2³². The main conclusion of the study is that the collaborative research papers are exceptionally highly cited, across its entire research portfolio.

In total, 144 papers were matched in HIV/AIDS, 99 in tuberculosis, 58 in malaria and 7 in research into neglected infectious diseases (within the broader scope of EDCTP2). There is a crossover in HIV/AIDS and tuberculosis research (62 papers) reflecting the HIV/AIDS and tuberculosis co-infection. Data on journal impact factor (JIF) from the Thomson Reuters *Journal Citation Report* 2011 shows that EDCTP research is in general published in high impact journals.

The citation impact of HIV/AIDS research is exceptionally high. Papers in this area are cited over three times the world average (3.24). Papers on tuberculosis research have a citation impact over four times the world average (4.08). Papers addressing HIV/AIDS and tuberculosis co-infection are cited over five times the world average (5.10). Papers on malaria research have a higher citation impact than the world average (1.70). The table below shows that for each area the citation impact of EDCTP-associated papers is higher than papers from other European collaborative research with sub-Saharan Africa (except for malaria, where the impact of these two publication sets are almost equal) and even higher than papers globally published in these areas (the last column of the table).

³¹ EDCTP (2013). Impact of EDCTP-associated research in HIV/AIDS, tuberculosis and malaria (including co-infection), 2003-11.

³² EDCTP (2013). Bibliometric analysis of European and African research output within the scope of EDCTP2.

Figure 44 Citation impact of EDCTP-associated publications (2003-2011) in comparison

	EDCTP-associated papers		European collaboration with sub-Saharan Africa		Global	
	n	Citation impact	n	Citation impact	n	Citation impact
HIV/AIDS	144	3.24	4,198	1.55	94,827	1.14
Tuberculosis	99	4.08	1,664	1.88	33,621	1.05
Malaria	58	1.70	3,893	1.72	29,714	1.24

Source: Impact of EDCTP-associated research in HIV/AIDS, tuberculosis and malaria 2003-2011.

Based on these figures (although the number of papers in the sample is relatively modest compared to the European and global number of papers published) the study concluded that the research supported by EDCTP is excellent, highly collaborative and world leading³³.

This conclusion was confirmed in the interviews. The interviewees in general state that the quality of research is good; the research has led to many high impact publications.

5.2.3 EDCTP Awards

As from 2009, every two years EDCTP confers awards for scientific excellence to African scientists. The awards aim to further stimulate and support the research activities of the winners and are awarded on the basis of a number of criteria: Innovation/Intellectual Property (IP); impact of research; publications; and advocacy for health. There are two different types of awards, depending on the career stage of the respective researcher:

- The EDCTP Outstanding African Scientist Award (recognition trophy and a cash prize of €20,000) for scientists who have made outstanding achievements in their field and who are recognised as research leaders in Africa;
- EDCTP Rising Star African Scientist Award (recognition trophy and a cash prize of €10,000) for scientists below the age of 45 who have made significant achievements in their field and who will continue to become leaders in their research field.

In addition to their scientific excellence, the scientists that are eligible for the award have made major contributions to the EDCTP objectives of strengthening clinical research capacity in Africa and supporting networking.

The following table (Figure 45) shows the names of the EDCTP Award winners, including the country of residence and the institution they were working for at the time of the award. Although four of the six previous award winners have been South African researchers, applicants are not predominantly from South Africa.

³³ EDCTP (2013), Impact of EDCTP-associated research in HIV/AIDS, Tuberculosis and malaria (2013).

Figure 45 Overview of EDCTP Award winners

Year	Name of researcher	Country	Institution
<i>Outstanding African Scientist Award (previously Outstanding Senior African Scientist Award)</i>			
2013	Prof Glenda Gray	South Africa	University of Witwatersrand and Medical Research Council
2011	Prof Salim Abdool Karim	South Africa	University of KwaZulu Natal
2009	Dr Alexis Nzila	Kenya	KEMRI Wellcome Trust Research Programme
<i>Rising Star African Scientist Award (previously Outstanding Junior African Scientist Award)</i>			
2013	Dr Graeme Meintjes	South Africa	University of Cape Town
2011	Mr Hannock Tweya	Malawi	Lighthouse Trust
2009	Dr Dominique Pepper	South Africa	University of Cape Town

Source: EDCTP annual reports (2009, 2011 and 2013).

5.2.4 The quality and quantity and retention of the researchers trained

The sustainability of the research capacities built through EDCTP investments depends on the institutions' capacities to retain and attract trainees and research fellows in Africa and to make sure that they continue their careers in research through clinical trials. There are examples of brain drain with negative effects on health services as people that are trained leave. The majority of the institutions or national governments do not have adequate financial resources to maintain the people. It is therefore difficult to retain EDCTP beneficiaries. On the contrary, there also cases where staff has been sustained by the institutions or governments (for instance in Tanzania). A large proportion of the PhDs and Senior Fellows that have been funded on EDCTP projects continue their scientific career in Africa and transfer their knowledge within their institutions. Some of them even have managed to set up their own laboratory facilities or research groups. In general, a situation in which incentives are put in place to retain people at least for a couple of years after the EDCTP projects has finished would be a preferable to be able to transfer the knowledge they have gained through the project to others.

EDCTP would benefit from monitoring the information on careers of people who were trained through its programme in particular beyond the duration of the projects. EDCTP could find techniques to incentivise people to report on where they are and to create an environment that would contribute to retention of the researchers in Africa. An EDCTP alumni association, something that is currently under development, is something that is supportive in the creation of this community. These researchers can act as real ambassadors of the programme. The *National Institutes of Health* (NIH) was mentioned as very successful in tracking the people that have been funded.

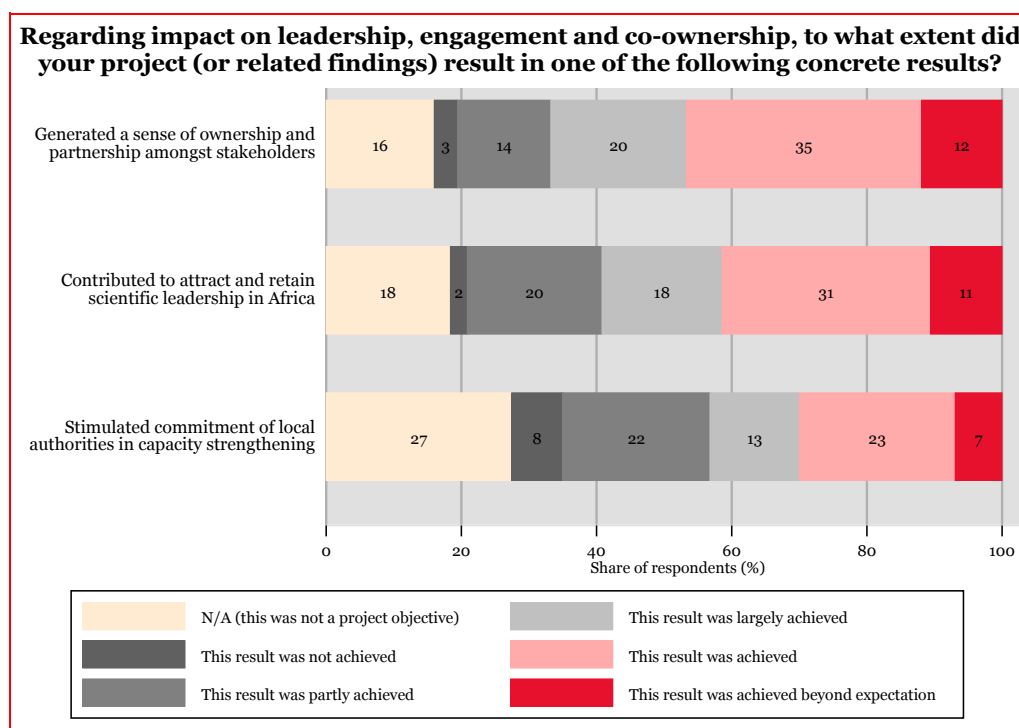
The issue of the sustainability of research capacities could also benefit from coordination with actions carried out by other organisations and coordination with African governments who should further invest in the programme's objectives. In the second phase of the programme African countries will have to show their commitments and contributions before becoming members of the programme.

5.2.5 African leadership

African leadership in the multinational projects was difficult at the beginning of the programme but Africans are now leading consortia. Overall, 74% of the projects were led by people working in African institutions. Specifically for the 74 projects that include clinical trials, 38 (51% of the projects) were led by researchers from African institutions, of which only a small proportion are in fact European researchers working at an African institution. For the second phase of the programme it is recommended that African scientists should continue taking over leadership roles.

The following graph (Figure 46) shows the perceived impact of the projects on African leadership, engagement and co-ownership according to the survey respondents.

Figure 46 Impact on African leadership, engagement and co-ownership (N=325)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

5.2.6 National Ethics Committees (NECs) and Institutional Review Boards (IRBs)

As part of the preparation for its second phase, EDCTP conducted an internal assessment on the ethics capacity development activities funded under its first programme³⁴. The assessment concluded that “EDCTP has contributed to developing ethics capacity in sub-Saharan Africa through establishing/strengthening Institutional Review Boards (IRBs) and National Ethics Committees (NECs), training ethics committee members and ensuring that the boards and committees are independent”. The assessment also found a clear relationship and complementarity between clinical trials supported and the capacity building ethics scheme.

However, the assessment also concluded that there is still a lot to be done in terms of developing capacity for research ethics in Africa as the ethics projects funded are mainly start-up grants. The major limitations of these type of grants are:

- The duration (mainly 18 months);
- The grant ceiling of €50,000;
- The sustainability of the activities after the end of the grant; and
- The lack of a clear mechanism for facilitating well deserving countries or ethics committees that are otherwise unable to submit high quality proposals.

³⁴ EDCTP (2013). Overview of achievements and internal evaluation of ethics capacity development activities funded under EDCTP1 programme.

At the end of 2013 an external evaluation of the Ethics Grants Programme has been performed³⁵, commissioned by EDCTP. This evaluation concluded that the ethics projects funded by EDCTP are a great success within the following three focus areas:

1. Supporting mapping of ethics review and trial regulatory capacity in sub-Saharan Africa – The Mapping African Research Ethics Review and Medicines Regulatory Capacity (MARC) project succeeded in mapping 166 IRBs in 34 African countries³⁶ and developing innovative tools for administration of the IRBs (see the box below on the RHInno Ethics platform). The project continues its development in a second phase.

RHInno Ethics: an online review platform for research ethics committees

The Mapping of research ethics review and trial regulatory capacity in sub-Saharan Africa (MARC) project has developed an online review tool for research ethics committees: the Research for Health and Innovation Organiser (RHInno)³⁷. The tool provides research ethics committees with a secure, web-based solution for tracking research applications throughout the entire life-cycle of the research project.

The rationale for developing this tool is due to the fact that many research ethics committees (RECs) in Africa lack the tools to efficiently coordinate the submission and review of protocols and timely communication to researchers. Also because the resources for these RECs are often limited there was an immense need to set up a tool that can be beneficial both in terms of effectiveness (by increasing the opportunity for knowledge exchange) and efficiency (to reduce the amount of paper work needed in review processes). Furthermore, international standards require that protocols of clinical research should be reviewed by an independent REC.

Of particular interest to RECs is the 'Ethics' version of RHInno, allowing RECs to streamline the ethics review, produce reports, track projects and produce annual reports.

The MARC project has been implemented by the Council on Health Research and Development (COHRED) in Switzerland and the University of KwaZulu-Natal in South Africa.

2. Promoting the establishment and strengthening of competent and independent NECs and IRBs – NECs and IRBs were established and strengthened through training, infrastructure development and networking. Overall, the functionality of NECs and IRBs was high, with most meeting the requirements to have a functional ethics committee. Funding provided to the ethics committee played an integral part in helping ethics committees address some of the infrastructural and human resource challenges they were experiencing. However with funding having come to an end, the issue of sustainability for the ethics committees is at question. Successes of NECs and IRBs are considered to be developing and implementing well-designed Standard Operating Procedures (SOPs) as well as the provision of training for ethics committees' members. This led to an increase in knowledge and efficiency around reviewing protocols. Challenges included sustaining the ethics committee after funding had concluded as well as retention of ethics committee members.
3. Supporting ethics training activities, including development of online training programmes – Approximately 6,700 beneficiaries were trained by EDCTP grantees involved in capacity building activities between 2005 and 2012. Online training reached the highest number of people trained (+/- 3,600), suggesting that online training is a favourable alternative to workshops as it is flexible, accessible to large amounts of beneficiaries and require relatively few resources once established. Capacity building through training in medical ethics has produced numerous

³⁵ Creative Consulting & Development Works (2014), Evaluation of the EDCTP Ethics Grants Programme.

³⁶ This website provides a complete overview of all Institution Review Boards (IRBs) mapped by the MARC project: <http://www.researchethicsweb.org/>.

³⁷ The RHInno can be found at: <http://rhinno.net/>.

achievements in the promotion of significant research procedures in Africa, specifically related to the ethical practice of researchers and improved functionality of IRBs.

According to the stakeholders that have been interviewed during the current evaluation, the programme's contribution to establish and strengthen ethics committees has been an important step forward. The progress in ethics and regulatory issues has been very significant. An important number of people were trained and many regulatory committees were established through the programme. EDCTP has also developed the capacity of these committees in reviewing clinical trial applications. EDCTP has played a leading role in raising capacities and awareness on ethical considerations.

Textbook Research Ethics in Africa: A Resource for Research Ethics Committees

One of the recent achievements of the ethics grant programme is the textbook on research ethics in Africa that has been published. The aim of this textbook is to provide members of the research ethics committees with a resource focusing on research ethics issues in Africa. The book is free of charge, will be available for downloading from the internet and is expected to be translated in French and Portuguese. This book presents for a very first time the African perspective on research ethics.

The book contains four sections, each dealing with different aspects of research ethics: (1) an overview and historical background of research ethics in Africa, (2) the functions of ethics committees guidance for the process of ethics review, (3) specific topics, including informed consent, vulnerable populations, participant remuneration and the handling of biological samples and (4) the resources needed by ethics review committee members and training opportunities for members.

5.3 The Pan-African Clinical Trials Registry (PACTR)

EDCTP, in partnership with the South African Cochrane Centre (SACC) and the Cochrane Infectious Disease Group, has established an international registry for all clinical trials conducted in Africa. Initially, this registry was not considered to be part of the capacity building activities of EDCTP, but initiated under the heading of information management (see the intervention logic of EDCTP in Figure 3).

The main motivation for setting up a registry is the fact that the WHO concluded that only a few trials that take place in Africa are registered. Such a registry was considered an opportunity to increase the trial registration locally. The registry was established in 2007 as the AIDS, Tuberculosis and Malaria Clinical Trials Registry (ATMCTR), but in 2009 its scope expanded to include all diseases of the African continent and renamed to the Pan African Clinical Trials Registry (PACTR)³⁸. PACTR is an African initiative to support regional clinical trial registration. The aims of the registry are to:

- Provide a repository for prospective registration of clinical trials conducted in Africa;
- Promote prospective clinical trial registration in the African region;
- Ensure the WHO-stipulated minimum dataset for registered trials is publicly and freely available to all users of the registry;
- Provide a searchable database of all clinical trials conducted in Africa.

PACTR aims to increase the number of trials in Africa that are registered prospectively. In the initial phase, the registry only registered trials in HIV/AIDS, tuberculosis and malaria to demonstrate proof of concept. At present, the registry is the only African member of the WHO Network of Primary Registers and transfers all trial information to the central WHO International Clinical Trials Registry Platform (ICTRP)³⁹, so that trials registered in the PACTR are represented in global searches. Primary registries in the

³⁸ <http://www.pactr.org>.

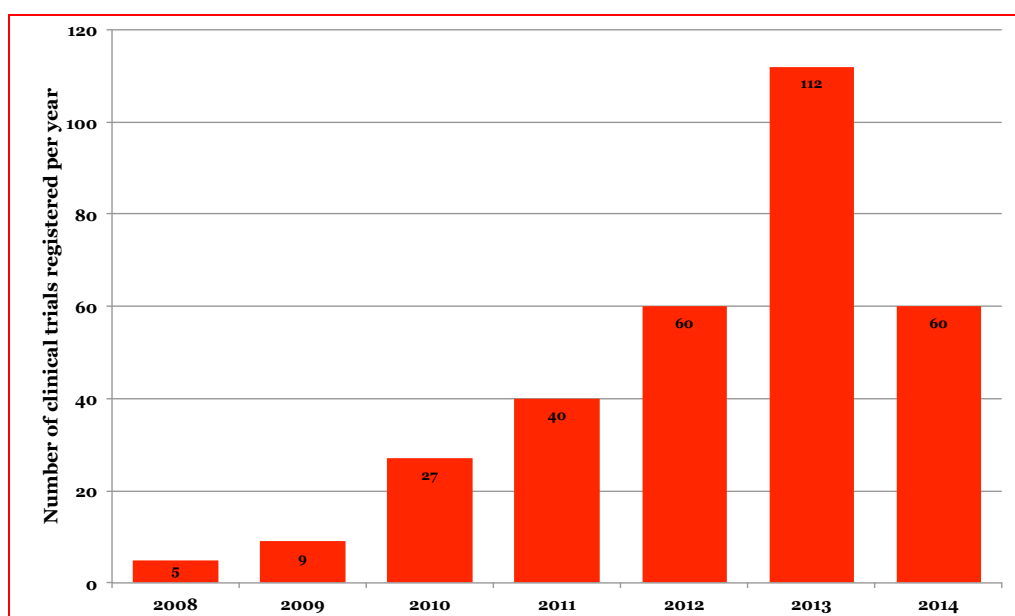
³⁹ <http://www.who.int/ictpr/en/>.

WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Currently fifteen registries meet these criteria⁴⁰.

PACTR is considered beneficial for a large variety of different stakeholders: it can provide policymakers a full overview of what clinical trials are being conducted in their respective countries and how these try to address health needs of the populations; health professionals may advise patients about appropriate trials to participate in; funders of clinical trials and development agencies can learn what research is being conducted where and by whom; and researchers are provided a way to identify gaps in the research landscape and better focus their research activities.

To date (Status June 2014), 313 clinical trials have been registered with PACTR, of which 48 on HIV/AIDS, 23 on tuberculosis, 37 on malaria and 17 on co-morbidities (HIV/tuberculosis, HIV/malaria and tuberculosis/malaria). The following graph (Figure 47) shows the number of registrations per year since its conception, which represents a steady annual increase.

Figure 47 Number of clinical trials registered with PACTR by year



Source: PACTR (2014), analysis Technopolis Group (2014).

In order to get an impression of the coverage of African clinical trials by PACTR, its number of registered clinical trials are compared with those registered with ClinicalTrials.gov⁴¹, a database on clinical trials provided by the National Institutes of Health in the United States. Within the same time frame (2008-2014) a total of 2,728

⁴⁰ Australian New Zealand Clinical Trials Registry (ANZCTR), Brazilian Clinical Trials Registry (ReBec), Chinese Clinical Trial Registry (ChiCTR), Clinical Research Information Service (CRiS), Republic of Korea. Clinical Trials Registry - India (CTRI), Cuban Public Registry of Clinical Trials (RPCEC), EU Clinical Trials Register (EU-CTR), German Clinical Trials Register (DRKS), Iranian Registry of Clinical Trials (IRCT), ISRCTN.org, Japan Primary Registries Network (JPRN), Thai Clinical Trials Registry (TCTR), The Netherlands National Trial Register (NTR), Pan African Clinical Trial Registry (PACTR), Sri Lanka Clinical Trials Registry (SLCTR).

⁴¹ ClinicalTrials.gov, established in 2000, as a Web-based resource that provides patients, their family members, health care professionals, researchers and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website can be accessed through <http://clinicaltrials.gov/>.

clinical trials from Africa have been registered with this service, which is more than nine times more than those registered with PACTR. Please note that PACTR initially only focused on HIV/AIDS, tuberculosis and malaria. When specially looking at the year 2013, ClinicalTrials.gov registered 495 clinical trials, while PACTR registered 112. From 2008 to 2013, ClinicalTrials.gov registered 496 HIV/AIDS trials in Africa, 127 tuberculosis trials and 248 malaria trials. This implies that there is potential for PACTR to cover more trials.

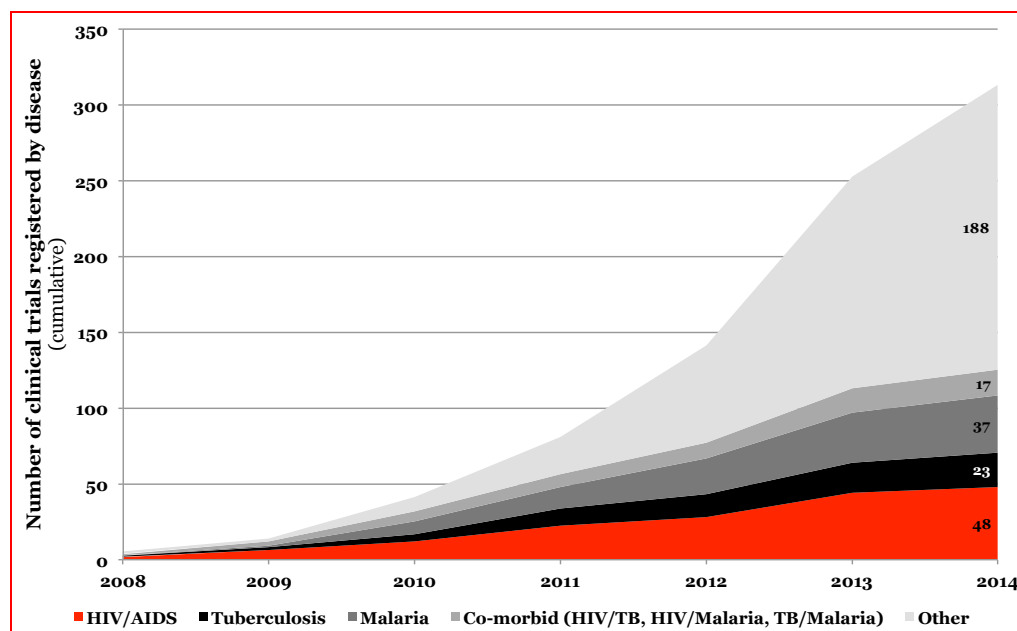
Figure 48 Number of HIV/AIDS, tuberculosis and malaria trials registered with PACTR

	2008	2009	2010	2011	2012	2013	2014	TOTAL
HIV/AIDS	2	4	6	10	6	16	4	48
Tuberculosis	1	1	3	7	3	5	3	23
Malaria	0	1	7	6	10	9	4	37
Co-morbid	1	2	4	1	2	6	1	17
TOTAL	4	8	20	24	21	36	12	125

Source: PACTR (2014), analysis Technopolis Group (2014).

Although there is a steady increase in the number of HIV/AIDS, tuberculosis and malaria trials registered (aligning with EDCTP's performance), the biggest increase is based on the number of other type of clinical trials. These include trials on other communicable diseases, non-communicable diseases and maternal & child health (see Figure 49).

Figure 49 Cumulative number of clinical trials registered with PACTR by disease group

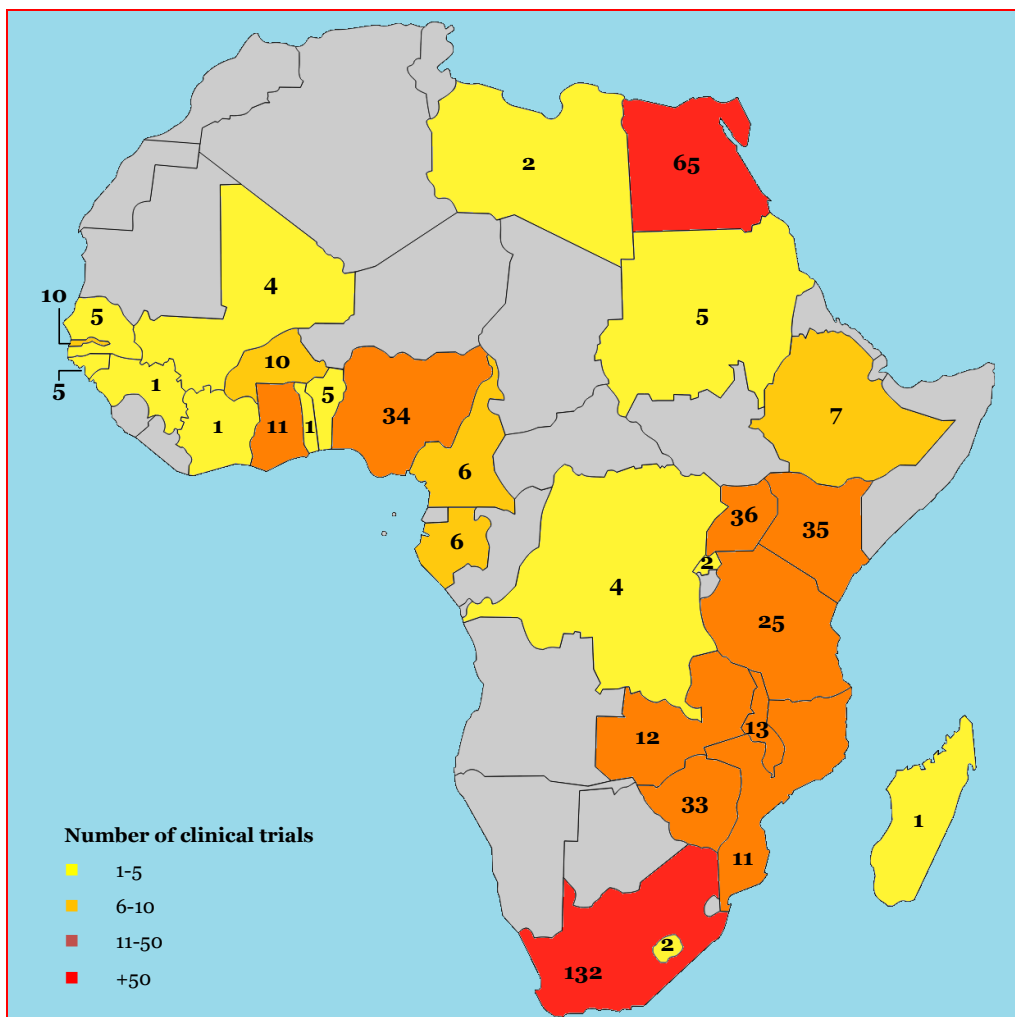


Source: PACTR (2014), analysis Technopolis Group (2014).

The figure below shows the number of clinical trial sites per country of those clinical trials that have been registered with PACTR. This shows a fair correlation with the EDCTP projects in which the different countries participate. Southern and East African countries are the most involved in EDCTP projects, which is in general reflected by the largest number of clinical trials registered through PACTR. South Africa, Uganda and

Kenya, in the top-5 of most active African countries in terms of project participation are the three leading countries in terms of clinical trial registration through PACTR. The only two exceptions are Egypt and Libya, which are not partner countries of EDCTP, but trials in these countries are included in PACTR.

Figure 50 Clinical trials per country registered through PACTR



Source: Information provided by PACTR (2014). NB. This is not a complete overview of all trials conducted in Africa, but rather trials that have been registered through PACTR. Note that several countries can register one trial.

5.3.1 The impact of the Pan African Clinical Trials Registry

Not all interviewees in the countries visited are familiar with the existence and aim of PACTR. Especially, communication about the intention and benefits of the registry is something that needs to be strengthened. Those that did know about PACTR considered it one of the highlights of the capacity building approach of EDCTP, created with African leadership. Also the WHO endorsed it as it complies with the standards required to be a Primary Registry. A couple of benefits have been mentioned: (1) the practical advantage of having a system in place to see what is happening in the area of clinical trials in Africa (*“if we cannot enumerate the clinical trials in Africa we cannot do anything”*), (2) it is instrumental in identifying potential collaboration partners, but (3) also for a mind-set, to build a mechanism to report on the results from a trial (both positive and negative) which influences the way we think about clinical trials.

Insight from the country cases on the impact on capacity building

South Africa

Impact on capacity development in South Africa is considered as tremendous as a high number of researchers (Master's students, PhD students and postdocs) and health professionals have been trained on EDCTP projects. Not only medical officers, but also nurses have developed clinical trial knowledge and are able to implement CT requirements. Even though the level of expertise and funding for researchers in South Africa is much higher than in other African countries, EDCTP still made a difference to the clinical trial field and trainees acknowledge that.

Ethical legal framework implementation is part of the whole capacity building as each clinical trial site had gone through a specific training programme, including an ethical legal component which has later become a best practice, later shared with other African countries such as Kenya for example.

Tanzania

For all of the institutions visited, the capacity building activities through EDCTP projects considerably helped in establishing a suitable research infrastructure and training people in performing clinical research. This specifically includes training of human resources: PhDs, technical staff on how to operate the equipment, ethical issues and GCP. Furthermore the procurement of certain laboratory equipment, computers, freezers and archive facilities have been made possible through the grants. This capacity can still be used in future research, which helps in attracting additional funding. This also comprises sustainability on the personal level as people have been able to stay at the institutions because of the EDCTP grant.

The situation in Tanzania is different from some of the other countries as there are only a few researchers in the top segment, however those that can apply for senior fellowships are lacking. There has been a period where there was no funding and interest in performing research. For that reasons there are no senior fellows participating in EDCTP. As a result there is a strong need for career development fellowships in Tanzania to bridge the gap. In addition, capacity for lower cadres (e.g. for nurse who needs training as well as data entry) is lacking. There are almost no capacity building opportunities to train these people, but they are essential in performing the research.

Another point that is important for institutions that perform clinical trials is to have an adequate clinical trial unit space. It is very challenging to perform a phase III study in a small room, because it implies the recruitment of hundreds of people. If institutions cannot attract substantial research funding they cannot maintain or strengthen the infrastructure. The capacity development then becomes very fragile. The Kilimanjaro Clinical Research Institute (KCRI) is considered as a good example of this evolution of grants building on the achievements of previous projects.

Republic of the Congo

Needs in terms of research capacities were critical in the Republic of the Congo. EDCTP has contributed to train laboratory technicians, biostatisticians and quality managers. The country still needs to strengthen its research competencies; there are for instance no epidemiologists in Congo. Data are very limited in the country and EDCTP has helped to establish baseline data on pathologies.

Public authorities do not fund research. There is a promise from the Minister of Research to mobilise a fund for medical research but this is still to be implemented. The Fondation Congolaise pour la Recherche Médicale (FCRM) has made great efforts to communicate on its activities and results with the aim to raise additional funds. It was successful in raising additional funds from private actors such as the oil company Total and other organisations in order to sustain its activities despite the lack of public funding.

EDCTP's investments for the development of ethics in Congo also have a great impact on research activities in the country. The Faculty of Medicine and the Faculty of Sciences have both integrated ethics lessons in their curriculum. A few years ago this would have been impossible.

Mali

The Malaria Research & Training Center (MRTC) in Mali counts about 70 beneficiaries of training through EDCTP funded projects which have contributed to develop their capacities in ethics, drafting of scientific articles, good clinical practices, data management, cellular biology, immunology and to raise the general quality of research at the MRTC. EDCTP has also supported the development of Mali's ethics committee considered as more dynamic thanks to the training received.

Dr. Djimé, started as EDCTP Senior Fellow but currently coordinating the large Integrated Project (WANECAM), helped to develop capacities for three students that have obtained their PhDs and to carry out several training sessions on good clinical practices and good ethical practice. All trained staff are still conducting research activities in his unit, twelve were offered permanent positions.

6. Impact on networking and research coordination

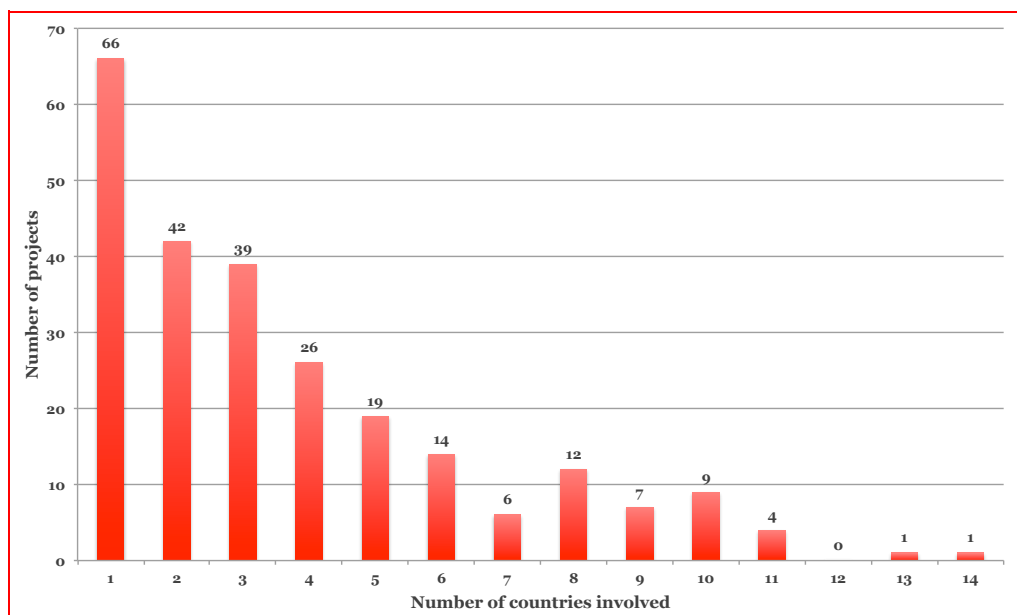
The last chapter regarding the impact of EDCTP focuses on the impact of the programme on networking and research coordination. This addresses networking between European institutions and countries (north-north networking), networking between African institutions and countries (south-south networking) and networking between the two continents (north-south networking). Also the engagement of EDCTP with PDPs and the pharmaceutical sector is assessed. The four Networks of Excellence (NoEs) that have been established through EDCTP are discussed in more detail.

6.1 Networking and research coordination

From the analysis of the networking on country level within the funded EDCTP projects, the following can be concluded: a total of 66 out of the 246 projects were performed by a single country, these are the Senior Fellowships and some of the ethics and regulatory framework projects. These projects in fact do not contribute much to the concept of networking on the higher programme level. There are 15 projects that involved more than ten countries; these projects include eight integrated projects (i.e. 4 on malaria, 3 on tuberculosis and 1 on HIV/AIDS), three ethics and regulatory framework projects, two Strategic Primer Grants and two networking grants. For the Clinical Trials and Integrated Projects two European countries are required as a minimum condition.

The complete distribution of number of projects presented based on the number of countries involved in presented in the next graph (Figure 51).

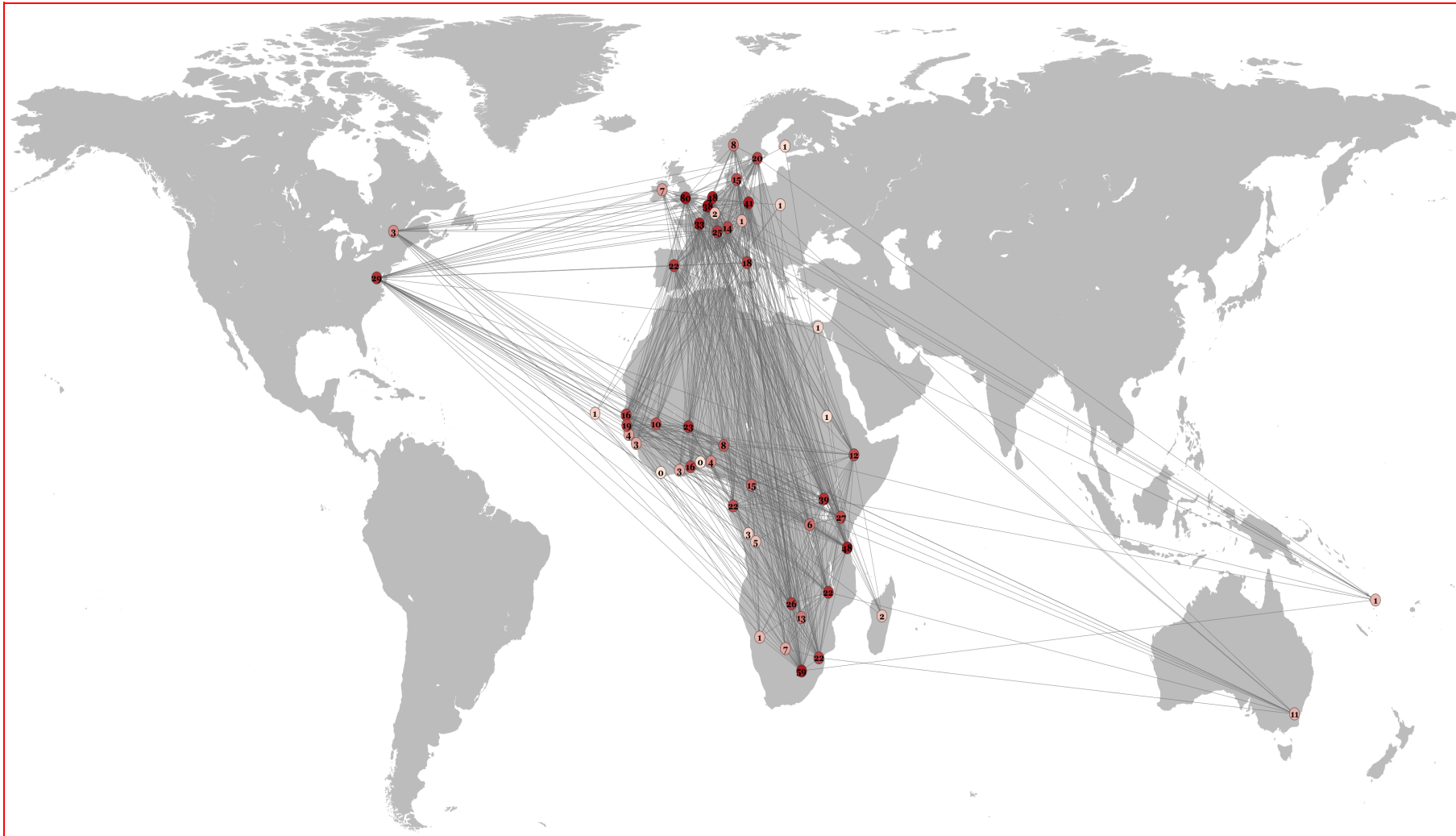
Figure 51 Number of projects based on the number of countries involved



Source: Information provided by EDCTP, analysis Technopolis Group (2014).

The network presented in the following figure shows all collaborations between countries based on the information on project participation (i.e. the complete database of funded projects). This clearly shows the links between Europe and Africa. The colour of the dots corresponds to the overall number of projects the countries are involved in. The actual number of project involvements are indicated by the number in the dot.

Figure 52 Network analysis of EDCTP grants



Source: Information provided by EDCTP, analysis Technopolis Group (2014).

6.1.1 North-north, south-south and north-south networking

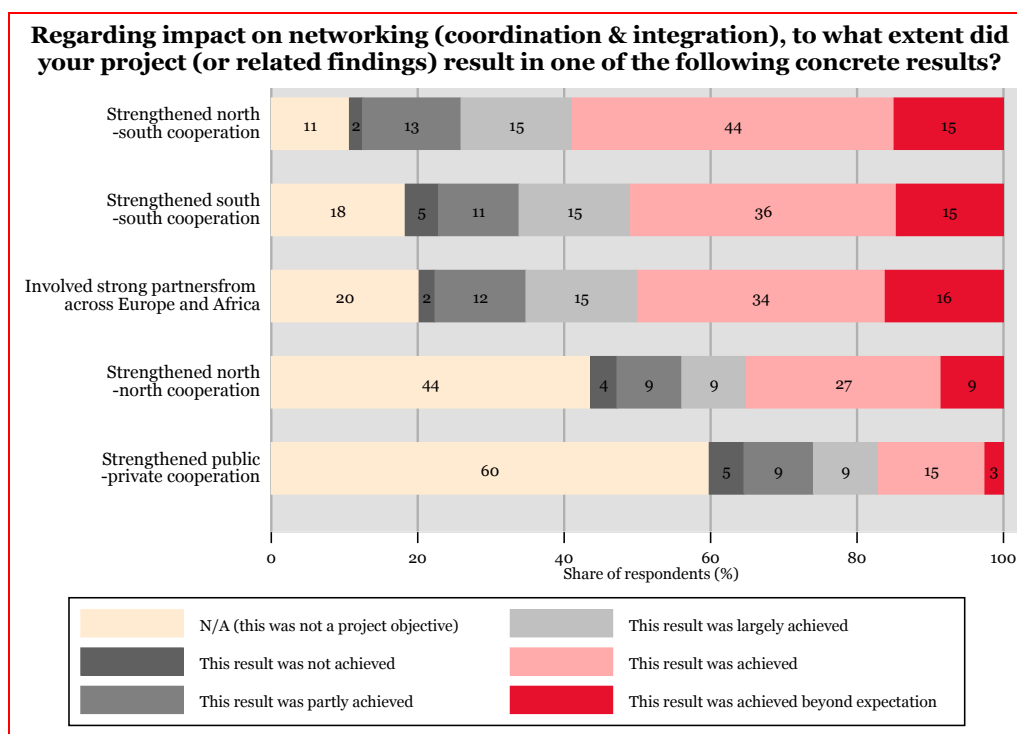
Networking and links between researchers and research institutions in Africa and those in Europe are one of the benefits achieved through the activities of EDCTP. The programme has created the right conditions (through a set requirements for research collaborations and networking) for establishing new relationships (both in Europe and Africa) and strengthening those relationships that already existed.

Both north-south and south-south networks are considered to be important. The north-south linkages are, perhaps, more useful as they widen the scope for African researchers to have the possibility to choose different partners from Europe. Having such an opportunity is crucial for building up research capacity in developing countries. The south-south networks have created opportunities for African scientists and institutions that did not have a chance to work together before. The stakeholders did not comment much on the north-north networks. This is not because these do not exist but probably mostly because the benefit for the European researchers is coming mostly from the new or strengthened old links with African institutions through the north-south links.

One weakness of the networking is around the network participants. The tendency in many cases was to build networks on already established relationships, i.e. between organisations and researchers in Europe and Africa who have already known each other from the past and between European and African countries, which have historical links due to common language (e.g. France with French-speaking African countries and the United Kingdom with English-speaking African countries). The challenge for EDCTP2 is to create conditions and go beyond the established historical relationships and create new networks by bringing new players into various collaborations.

Figure 53 shows the impacts on networking according to the grantees. This corresponds to the above mentioned. The highest impact has been achieved in strengthening north-south and south-south networking, the lowest in north-north and public-private cooperation (partly because this has not been an objective of the project).

Figure 53 Impact on networking (N=334)



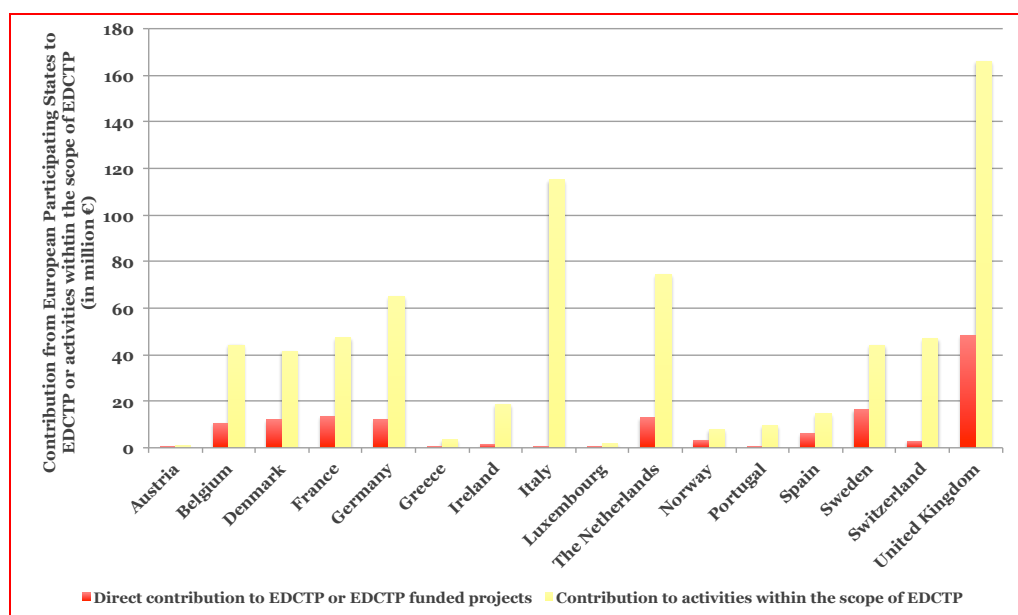
Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

6.1.2 Shared vision and alignment of research strategies in Europe

When looking at the benefits of networking for Europe (i.e. north-north networking), two main conclusions can be drawn from the interviews. First, that such collaborations were already in place and EDCTP did not add so much here. Second, in cases where collaboration was not yet in place, it was somewhat enforced. More so, the overall impact on EU collaboration is limited as only a small set of institutions participate in EDCTP – and usually these are the institutions which already had some connections/research activities in Africa before (i.e. historical ties).

In addition to the establishment of networks, it was aimed that EDCTP (and north-north collaborations) would have helped to establish a shared vision and encourage alignment of research strategies in Europe. In addition to the direct contribution to EDCTP or to EDCTP funded projects (the ‘real’ co-funding), European Participating States also support activities within the scope of the EDCTP joint programme (see section 2.3 and Figure 20 for the different routes to allocate the contribution). The total amount of co-funding to the EDCTP programme adds to a total of €842.10 million by the end of 2013; this includes the €141.44 million of direct contribution to EDCTP or to EDCTP funded projects. This means that European countries themselves have funded considerable amounts of activities (either clinical trials, capacity building or networking) that relate to the activities funded directly by EDCTP. The following graph shows the distribution of the contribution for each of the Participating States, by their direct contribution (red columns) and contribution to activities in the scope of the programme (the yellow columns). For all countries this second type of co-funding to EDCTP is significantly higher than the actual direct contribution to the programme.

Figure 54 Contributions from European Participating States

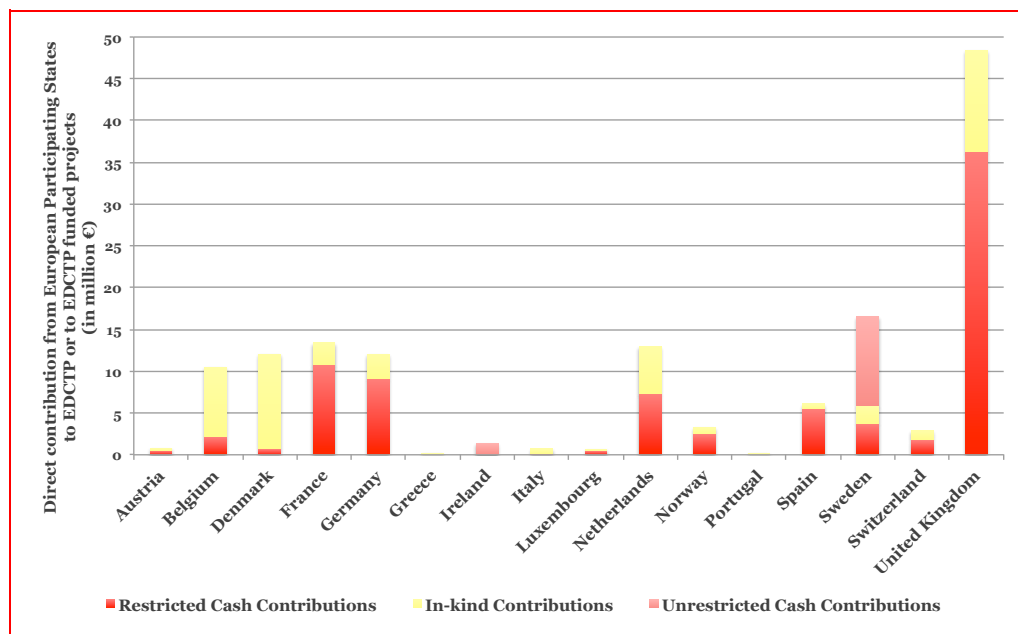


Source: Information provided by EDCTP (2014).

When looking more in detail into the direct contributions from European Participating States to EDCTP or EDCTP funded projects (i.e. the red columns from the graph above) the following graph is obtained (Figure 55). This graph shows the difference between cash (both unrestricted and restricted) and in-kind contributions. The majority of the cash contributions by the countries are restricted (57%) of which almost half provided by the United Kingdom. Ireland and Sweden are the only two countries that provided unrestricted cash contributions to EDCTP or EDCTP funded projects (in total 9% of the direct contributions). The main countries that provide in-kind contributions (34% in

total) are in decreasing order the United Kingdom, Denmark, Belgium and the Netherlands.

Figure 55 Direct contributions to EDCTP in terms of cash and in-kind contributions



Source: Information provided by EDCTP (2014).

The interviewees noted that EDCTP was considered too much a scientific programme thus missing (in many cases) alignment to the political agenda in various European countries. One way to address this could be through real joint programming, i.e. align existing activities in various countries and link them together. This way there is a chance that a shared European vision and alignment of research strategies will take place. Some interviewees, however, were more sceptical about this approach as it will be difficult to change behaviour of researchers – they know how to work together and how to apply for funding and will try to continue working under the conditions, which they find the most comfortable.

6.1.3 Increased coordination of research in Africa

The larger impact of networking resulted from EDCTP projects is observed in the south-south collaborations. To start with such networks in clinical trials in Africa was considered to be relatively new. They brought together people who did not work together before. EDCTP was the key success factor behind these south-south networks. The African countries are more aware of the fact that they are in the drivers seat. It is encouraging that the south-south networks have taken up. This is a big achievement, which needs to be maintained in EDCTP2. However, there is still some room for improvement. For instance, the capacity and resources for networking and motivation of researchers to network should be increased.

There were also some concerns about using networking as an indicator of EDCTP's success. Networking of institutions per se as an outcome of clinical trials is not always scientifically the best approach. Networking is not always the best way to support the multicentre clinical trials. Networking and clinical trial applications should not be mixed and be used as an indicator of success for each other.

6.1.4 Engagement with PDPs and the private sector

At the start of EDCTP it was envisioned that the funding by the European Commission and the European Participating States would be equally matched by private sources, both for-profit and not-for-profit. It is against this background that EDCTP developed a specific project plan to secure a sustainable partnership with the private sector⁴² as at the end of 2007 co-funding of EDCTP activities was still limited to around €2 million, by the end of 2013 this has increased to €8.24 million (see section 2.3 for a complete overview of the co-funding data). Although EDCTP projects have received considerable funds from the private sector (primarily PDPs, philanthropic organisations, big pharmaceutical companies and Small and Medium Enterprises (SMEs)), EDCTP considered there to be a need to expand and structure future engagement with the private sector. The approach that was proposed focused at the following four stages:

1. The development of a clear statement explaining why the private sector should partner with EDCTP;
2. The identification of members of the private sector that are most likely to respond to an appeal for partnering. This comprises that the needs of the private sector are met by choosing the most appropriate partnering approach;
3. The planning and coordination of the activities in more detail, taking into account any relevant internal and external factors (e.g. available staff);
4. The monitoring and evaluation of the approach to assess the success of the partnering activity.

To implement this plan a dedicated Private Sector Relations Coordinator was appointed, in 2011 and in 2012 more formally taken up by the current networking team of the Executive Secretariat. In addition, in 2013 a working document was developed to propose the General Assembly an outline of the rules of engagement with third-party organisations in respect to EDCTP⁴³. In this document a distinction is made between three types of third-party organisations: (1) non-European public sector (public funding agencies and international organisations), (2) not-for-profit private sector (charitable and philanthropic organisations and PDPs) and (3) for-profit private sector (multinational pharmaceutical companies and small and medium-sized enterprises). EDCTP2 aims to increase the collaboration with these organisations in order to leverage resources and share risk in major projects through partnerships with other funders. For each of the three types, the following table shows the organisations with which EDCTP is in contact or trying to establish contact. This overview is based on EDCTP's third party database (status end of 2013) and therefore might not be exhaustive.

Figure 56 Overview of third-party organisation in contact with EDCTP

Type of 3 rd party organisations	Sub-type	List of organisations
Non-European public sector	Public funding agencies	<ul style="list-style-type: none"> National Institutes of Health (NIH) United States Agency for International Development (USAID)
	International organisations	<ul style="list-style-type: none"> World Health Organization Council on Health Research for Development (COHRED) Médecins sans Frontières (MSF) UNITAID African Network for Drugs and Diagnostics Innovation (ANDI) African Society for Laboratory Medicine (ASLM) World Bank

⁴² EDCTP (2011). Updated project plan 'Encouraging the participation of the private sector.

⁴³ EDCTP (2013). Proposed EDCTP strategy for collaboration with third-party organisations in the second EDCTP programme.

Type of 3 rd party organisations	Sub-type	List of organisations
Not-for-profit private sector	European establishment	<ul style="list-style-type: none"> European Investment Bank
	Charitable and philanthropic organisations	<ul style="list-style-type: none"> Bill & Melinda Gates Foundation Wellcome Trust Calouste Gulbenkian Foundation
	PDPs	<p>PDPs involved in projects:</p> <ul style="list-style-type: none"> AREAS Global TB Vaccine Foundation Drugs for Neglected Diseases Initiative (DNDi) European Vaccine Initiative (EVI) Foundation for Innovative new diagnostics (FIND) International AIDS Vaccine Initiative (IAVI) International Partnership for Microbicides (IPM) Medicines for Malaria Venture (MMV) Global Alliance for TB Drug Development (TB Alliance) Tuberculosis Vaccine Initiative (TBVI) <p>PDPs not (yet) involved in projects, but in contact with:</p> <ul style="list-style-type: none"> PATH Malaria Vaccine Initiative Sabin Vaccine Institute IVI
For-profit private sector	Multinational pharmaceutical companies	<ul style="list-style-type: none"> Abbott Laboratories AstraZeneca Bayer Healthcare Boehringer-Ingelheim Bristol-Myers Squibb Crucell Eli Lilly Emergent BioSolutions Endo Pharmaceuticals Genzyme GlaxoSmithKline Janssen Pharmaceuticals Johnson & Johnson Merck & Co. Novartis Novo Nordisk Otsuka Pfizer Sanofi Vertex
	Small and medium-sized enterprises	<ul style="list-style-type: none"> Anacor Archivel Farma BD Diagnostics BIOFABRI BioMérieux Dafra Pharma R&D Delft Imaging System Eisai Europe Ltd Etna Biotech and Zydis EuroVacc Foundation Genus Pharmaceutical Jomaa Pharma Lionex Mymetics Nutriset S.A.S NVI-Vaccine Okairos s.r.l Partec Essential Healthcare Parteurop Pharma Quintiles Sanaria Sandoz
	Small and medium-sized enterprises	<ul style="list-style-type: none"> Gilead Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria (GBCHHealth) Guilin Pharmaceutical (Shanghai) IDT GmbH ImmunoClin Ltd Innovative Biotech USA Sequella Shinpoong Pharm. Co Sigma Tau Tibotec Triclinium Vecura Company ViivHealthcare

Source: EDCTP (2013), Strategy for collaboration with third-party organisations; and EDCTP's third-party database.

The engagement with these third-party organisations used to be mainly on the level of the individual projects. The last few years more emphasis has been put on engaging with these organisations at a more strategic or programmatic level. As the clinical trials that have been funded under EDCTP1 are showing progress engagement with these organisation will be more important in the second phase of the programme.

The interviewees who were able to share their thoughts on the aspect of EDCTP's engagement with third-party organisations commented that it is a missed opportunity that EDCTP did not realise to attract substantial funds from the private sector or did not use the experience of pharmaceutical companies. Under its first programme EDCTP could not give funding to private organisations. As such EDCTP was from a private sector point of view not a very attractive partner.

The question '*how to bring pharmaceutical and biotechnology partners on board?*' remains open and sooner or later will have to be addressed. In EDCTP2 some steps are already envisaged and taken to engage more with these third-party organisations. Under EDCTP2, compared to EDCTP1, private sector entities can also receive funding as long as the minimal eligibility requirements have been fulfilled, which makes the programme more attractive to the private sector.

6.2 The Regional Networks of Excellence (NoEs)

In 2007 EDCTP launched a call for proposals for the establishment of regional Networks of Excellence (NoEs) for conducting clinical trials and provide mentorship programmes in sub-Saharan Africa. The NoEs, which comprises at least three institutions from at least three different African countries, have the following objectives⁴⁴:

1. Organise mentorship programmes and training of staff members working at African institutions where clinical trials will be conducted;
2. Conduct epidemiological and demographic studies that facilitate the planning of trials; and
3. Support less established institutions with additional expertise that will enable them to participate in multicentre clinical trials. Such expertise shall include design of trials, data management, financial management and administration, quality assurance and required laboratory techniques.

In total four regional Networks of Excellence have been established, in each of the four different sub-Saharan African regions (see Figure 57 for the countries involved in each network):

- Central Africa: The Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM), with a total funding €2.8 million;
- East Africa: The East African Consortium for Clinical Research (EACCR), total funding €3.46 million;
- Southern Africa: The Trials of Excellence for Southern Africa (TESA), total funding €2.3 million;
- West Africa: The West African Network for TB, AIDS and Malaria (WANETAM), total funding €3.5 million.

⁴⁴ Call to support the establishment of regional networks of excellence for conducting clinical trials and provide mentorship programmes in sub-Saharan Africa.

Figure 57 Map of Networks of Excellence and country involvement



Source: Annual Report EDCTP 2013.

The following table presents some of the characteristics of the four NoEs, partly based on a publication about the NoEs that has been published in 2013⁴⁵.

Figure 58 Characteristics of the Networks of Excellence

NoE	Number of countries involved	Number of institutions involved	Number of people trained	Number of publications	Number of sites upgraded	Funding leveraged
CANTAM	3	7	101	8	4	1,152,360
EACCR	5	34 *	197	4	19	1,400,000
TESA	6	10	564	29	10	20,000,000
WANETAM	7	13	180	2	3	1,706,000
TOTAL	21	64	1,042	38	36	24,258,360

Source: Miro, *et al.* (2013) and additional information. * of which 17 are the established institutions.

⁴⁵ Miro, *et al.* (2013). EDCTP regional networks of excellence: initial merits for planned clinical trials in Africa, BMC Public Health 2013, 13:258.

This publication also provides some insights into the achievements of the NoEs. The main findings can be summarised as follows⁴⁶:

- The NoEs conducted baseline studies for two main reasons: (1) they are a practical prerequisite for conducting future clinical trials and (2) the studies are publishable aspects of the research activities for each NoE.
- The NoEs have invested substantially in clinical trial infrastructure and in short-term training, long-term training and/or field mentorships to produce networked high-skilled African researchers. Stronger research institutions have been connected to upcoming ones for on-going mentoring. The results however will take years to be measured, especially in Central Africa, where a critical mass of scientists is nascent and the culture of research is still lacking.
- The institutions within each NoE have learnt to collaborate in joint proposal development and project implementation. Also the NoEs have developed relationships among themselves. However, more initiatives engaging all four NoEs should be encouraged. Finally all NoEs have interacted with various networks, organisations or northern partners.

6.2.1 *The impact of the NoEs*

The regional Networks of Excellence (NoEs) had a special attention in this evaluation. The interviewees positively commented about NoEs and singled out WANETAM, CANTAM and EACCR highlighting them as a great success – not only in terms of capacity building and staff training but also in terms of some of the research studies that have come out of these NoEs. They also noted that the NoEs served as an excellent tool through which the stronger countries helped the weaker ones. However, the networks can still develop further. One concern was that perhaps not all networks have developed as planned, e.g. TESA as the network had problems in the cooperation between the different partners and faced some changes in leadership. Although a great stimulus for putting people together, some networks sometimes were too much dependent on certain individuals. Another concern was around the ‘excellence’ part of the network as stakeholder confirmed that networks were built but questioned whether these were really networks of excellence.

6.2.2 *Sustainability of the NoEs*

In order to get some true impact from these regional NoEs and increase capacity of various countries, the networks are important to be continued. Considerable efforts have already been put in place during EDCTP1 on developing capacity and training (i.e. lots of investments were made in training people). The question is how to make sure these networks thrive and are supported on the longer term. Ideally (partial) financial support for the NoEs should come from the African countries themselves as this is a way to show African contribution to EDCTP. However, not all countries (as mentioned before) have adequate financial resources to do so. This means that there is a role for EDCTP to maintain the networks in a second programme.

On-going support to already existing NoEs does not mean that no changes can be made to the current NoEs. For example, it will be important to open up the NoEs to include other countries in the same region (or at least give them the opportunity to become part of the networks), for example:

- CANTAM: Angola, The Democratic Republic of the Congo, the Central African Republic, Chad and Equatorial Guinea;
- EACCR: Somalia, Eritrea, Burundi and Rwanda;

⁴⁶ Miiro, *et al.* (2013). EDCTP regional networks of excellence: initial merits for planned clinical trials in Africa, BMC Public Health 2013, 13:258.

- TESA: Namibia, Lesotho and Swaziland;
- WANETAM: Niger, Togo, Benin, Côte d'Ivoire, Mauritania, Guinea-Bissau, Sierra Leone and Liberia.

Each network has to be dynamic and allow and encourage new partners to join. For African countries to become more eager to invest into the NoEs, efforts need to be made to make these regional networks locally attractive. Partially, this can be done by disseminating results of the NoEs more widely, e.g. through the African Academy of Sciences (as currently dissemination of the results from the NoEs is not done widely enough). Another suggestion is to make the NoEs more institutionalised at a higher level, not at a level of the researchers or institutions.

Whatever solution for the future, people and strong leadership will play an important role in the popularity, success and dynamism of the networks. This human factor should not be taken lightly and be one of the important factors on the agenda for the future of NoEs.

6.3 Policy and political level participation

The question of African leadership, engagement and co-ownership is not only important on the level of the regional NoEs, but also on the whole policy and political level. The increase of African leadership is a prerequisite to develop EDCTP into a real partnership. Therefore it is essential for African researchers to take a lead in scientific projects (i.e. to be principal investigators). This has gradually become reality during the first phase of the programme, but the momentum should be maintained. In the future, measuring the cash and in-kind contributions from African countries more systematically would potentially give more credits to the African share and ownership of the partnership. To remain successful, EDCTP needs continuity of investments and this money should only come not from European but also from African countries. Concerted political action is needed to make sure that these contributions are increased. The current move for African countries to become full member of the EDCTP partnership is considered a step in the right direction. EDCTP should keep the long term funding commitment, vision and engagement with African partners and aim for an increase of resources.

Involving as many African countries into the partnership and network is important for the long-term impact of EDCTP. However, not all countries can be true partners. One way to involve them is to do this via initiatives/organisations, which unite several countries. This will bring a number of countries into the partnership at the same time and on equal rights.

6.3.1 Interaction with other (intergovernmental) initiatives in Africa

To answer the question about policy and political level participation within EDCTP interviewees (both internal and external) confirmed that there is mutual exchange with (intergovernmental) initiatives in Africa, such as Regional Economic Communities, the New Partnership for Africa's Development (NEPAD), the African Union, WHO/AFRO and Health Ministries. These contacts are helpful in identifying the regional gaps related to clinical research in Africa.

These linkages also contributed to the establishment of the current situation in which African countries are becoming real partners of EDCTP.

It can also be considered a success that African ministries and co-funding organisations have shown an increasing interest in participating in EDCTP. Also the fact that EDCTP succeeded to prove itself for a second phase (this was not expected in the beginning) is a great achievement.

Communication and interaction are important in trying to increase the level of involvement (and interest of various African countries/partners to be involved) with EDCTP. This has increased substantially during the past years and especially towards

EDCTP2. The conferences, site visits and EDCTP's engagement with high representatives are also strong. Knowing that EDCTP is secured for a longer period of time will keep the level of African stakeholders involvement high; they will not be encouraged to participate if the initiative were to stop at some point in the near future.

Insight from the country cases on the networking

South Africa

The Trials of Excellence in Southern Africa (TESA), one of the four EDCTP Networks of Excellence, has been set up as a response to several identified gaps in the sub-region, i.e. capacity building in laboratory and in clinical trials, notably in tuberculosis (whilst HIV was quite established), networking the trials, bridging gaps between several research projects and infrastructure support. The network was initially lead by the South African Medical Research Council but was later on transferred to the University of Stellenbosch.

The network has had difficulties in implementing activities, due to weaknesses in communication and actual engagement of project leaders in several of the partnering countries. Some of the interviewees concur that TESA did not achieve much and that partners did not manage to cooperate with each other. However, the added value of the TESA network for South African researchers could have been mainly of two quite different natures:

1. The first one being that it feeds the passion of researchers for health issues they tackle, as they transfer their knowledge to other researchers whom they train thanks to TESA; and
2. The second one being that it allows funds collection.

Tanzania

EDCTP was very instrumental in supporting the south-south networking. Through the partners they have established a great network of close relationships with information sharing and spill-over effects. Working with other local sites enhanced standardisation of practice (south-south) and enabled the lab staff to go to Europe and participate in the analysis phase that is done over there (north-south).

The East Africa Consortium for Clinical Research (EACCR), another EDCTP Network of Excellence, is perceived as good by the institutions visited. There is an overlap between the participating organisations in the different projects, which is instrumental in networking and sharing of information. EACCR is a platform for exchanging research findings, building up further research capacity and stimulating institutions finding the right partners. The focus on south-south cooperation ensures that the countries in the South think of each other.

Republic of the Congo

Professor Ntoumi took the leadership of the Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM), another EDCTP Network of Excellence. Many institutions were present at the launch of the project but many have not been active and today only three African countries are part of CANTAM (Congo, Cameroun and Gabon) and one European (Germany). However CANTAM is said to be very active in terms of number of collaborative projects but also for knowledge and information sharing between its members.

Some interviewees identified a few weaknesses with regards to networking pointing that regional Networks of Excellence (NoEs) are very individual focused and that the mentor/mentee component needs to be closely assessed.

Mali

EDCTP has also supported the creation of the West African Network of Excellence for TB, Aids and Malaria (WANETAM). WANETAM aims the creation of a multi-disciplinary network for regional scientific collaborations (on the three diseases) with multi-site clinical trials.

Interviewees consider that WANETAM's development is very positive. It has succeeded in developing capacities to perform clinical trials in participating countries and to create synergies between Lusophone, English and French speaking African countries.

7. SWOT-analysis of EDCTP

The table below lists the strengths, weaknesses of EDCTP and opportunities and threats for EDCTP regarding the future as identified during the evaluation (the SWOT-analysis of EDCTP). This overview is based on the interviews conducted (both with internal and external stakeholders), the survey amongst project grantees, the country case studies and own interpretations by the evaluation team members. For each dimension of the SWOT, the elements are clustered into four categories in order to align with the focus of the evaluation: the organisation of the programme, clinical trials, capacity building and networking.

Figure 59 SWOT-analysis of EDCTP

Strengths	Weaknesses
Organisation <ul style="list-style-type: none"> The complete programme has been built from scratch; the first years were very challenging while the expectations might have been too high. Finally the programme turned out to be a success. Its clear strategy and long-term thinking (and funding commitment) on building research capacity, strengthening of networking and performing clinical trials in Africa (the holistic approach), starting from local research needs, capacity challenges and priorities (i.e. not defined in Europe). EDCTP is considered to be an important partner for clinical research in sub-Saharan Africa. The combination of both fellowship grants and large integrated projects. The focus of the programme on a limited number of diseases. EDCTP learned from the lessons of the past and the challenging first years of the programme (i.e. a shift in management, change of governance structure, hiring more qualified staff). Having a local presence in Africa through a dedicated office and a High Representative provided the necessary connections with African stakeholders and created high-level involvement and engagement. The engagement with African countries has been an important aspect of the decision-making process. The job done by the current Executive Director in moving EDCTP in the right future direction. The organisation (by means of the Executive Secretariat) is very flexible, approachable, committed, competent and supportive (a friendly environment and good institutional culture). The organisation's ability to be self-critical and self-evaluative. Easy, transparent and user-friendly application process, including clear eligibility criteria. Clear and concise reporting requirements (templates). The physical site visits by relevant EDCTP staff members are very much appreciated to monitor the actual progress of the projects. 	Organisation <ul style="list-style-type: none"> The lack of African partners formally involved in the governance structure of EDCTP1 (no real partnership). The political outreach and alignment to political agendas and alignment of European programmes is not very strongly developed. In the beginning the programme lacked standard operating procedures. The governance arrangements have not been always clear (i.e. the roles and mandate of the General Assembly and the different advisory boards since there were overlaps and to some extent duplications e.g. between PB and DCCC). The Executive Secretariat is understaffed to perform all the necessary tasks (and has a high turnover in the beginning). The long proposal review process, time-to-contract and project amendments. Bureaucracy (too many bureaucratic procedures and administrative demands). The challenging relationship with the European Commission and the European member states. The challenging co-funding arrangements (in particular the co-funding per project and securing in-cash contributions from African countries was not an easy task). Lack of flexibility with finance (including exchange deficits, spending within specific categories and withholding the last 10% of the grant) and timelines for complex clinical trials that reduces the chance of fully capitalising on the investments made. The budget-reporting template is very complicated and user-unfriendly. Limited follow-up of projects beyond funding period. The current monitoring and evaluation system in place of the activity and implementation (especially to assess the impact of the projects funded). The limited communication of successes and advocacy. The static character of the website.

Strengths (continued)	Weaknesses (continued)
<p>Clinical trials</p> <ul style="list-style-type: none"> • EDCTP is the first programme that combines clinical trials focusing on the development of new interventions (treatment, vaccines, diagnostics and microbicides) for HIV/AIDS, tuberculosis and malaria with capacity building and networking. • The Strategic Primer Grants for stimulating innovative clinical research. • The provision of funding for health-policy and health-care relevant clinical trials of medical interventions. <p>Capacity building</p> <ul style="list-style-type: none"> • Clinical trials are very demanding; they require specific expertise. EDCTP developed and strengthened this local capacity both in terms of human resources, trial sites and infrastructure. • The opportunities for (young) African researchers to develop themselves in the area of clinical research, to generate their own research questions and to become principal investigators for projects (African leadership has increased). • Focus on “on the job” capacity building in Africa (both on researcher and institutional level) in the context of performing clinical trials. • The establishment/strengthening of local research sites in Africa to perform clinical research. • Clear outcomes in capacity building (i.e. number of people trained, infrastructures developed and national ethics committees and institutional review boards established/strengthened) which otherwise would not have happened. • Great awareness of the importance of research ethics and ethics strengthening. It influenced other funders to increase their attention to ethics. • The Pan African Clinical Trials Registry (PACTR) providing an overview of all clinical research conducted on the African continent in compliance with WHO requirements. <p>Networking</p> <ul style="list-style-type: none"> • Shaping a framework for European member states to work together on research in Africa (encouraging the development of new interventions that will address poverty related diseases); EDCTP has pushed a collaborative research agenda even for countries that did not have a focus on the three diseases targeted. • Fostering north-south and south-south cooperation that contributes to transfer of skills and knowledge that will impact on performance of staff and institutions. • The initiation of the regional Networks of Excellence (NoEs) and the increased south-south collaboration it has resulted in. 	<p>Clinical trials</p> <ul style="list-style-type: none"> • Clinical trials are expensive, finding co-funding was a challenging task for researchers, which sometimes led to frustration. • Insufficient funding for large phase 3 trials. <p>Capacity building</p> <ul style="list-style-type: none"> • African scientists are not always trained as independent researchers, sometimes too much dependency of institutions in the North. • The gap between recent graduate and senior researchers (career development or postdoctoral fellowships). • The links between clinical researchers and medical doctors, nurses and other health professionals are still weak. • The lack of opportunities to fund physical infrastructure (e.g. building, laboratory facilities). • The lack of sufficient expertise in data management, data analysis (including biostatistics), clinical management at clinical sites. • There is lack of sustainability and retention of trainees within the countries after the grant has finished. • The limited awareness of the existence of PACTR amongst stakeholders. <p>Networking</p> <ul style="list-style-type: none"> • The interaction with third-party organisations (especially the industry) was not worked out well in the beginning. • Networking did not get as much as attention as required. • The restricted access to the Networks of Excellence by new organisations. • The lack of a database for project coordinators to share experiences and challenges that might be relevant for other projects in different countries.

Opportunities	Threats
Organisation <ul style="list-style-type: none"> A new 10-year programme with a bigger budget and broader scope (other diseases) is the ingredient for a successful future of the programme and creates opportunities. Strategic planning based on current project portfolio. The involvement of African countries to make EDCTP a real partnership. Further increase the commitment on national levels. Increase of the flexibility for the researchers taking into account the overall goals of the programme. The introduction of a grant management system will help in easier administration, monitoring and evaluation purposes. Clinical trials <ul style="list-style-type: none"> Expansion towards neglected infectious diseases. Maintaining a focus on finding interventions that will improve the lives of people in places/countries where the diseases disproportionate affect the poor. Ensure that research results are translated into policy actions in the respective countries. Linking phase II and III trials to the standards of the European Medicines Agency (EMA). Capacity building <ul style="list-style-type: none"> Continuation of capacity building as it is not finished yet. Stimulating researchers to look at research as a profession. Training of lower cadres in addition to clinical researchers (e.g. laboratory technicians, nurses, medical doctors). Networking <ul style="list-style-type: none"> Continuation of the partnerships that have already been established. Engaging more with new third-party organisations like pharmaceutical companies and charitable foundations. 	Organisation <ul style="list-style-type: none"> The organisation is vulnerable in case the current Executive Director will be leaving the organisation. It is a challenge to find someone with the right background in clinical trials and administration skills. Countries that will leave out either because they cannot get the target for the membership contribution (cash or in-kind) or due to political reasons. The possible imbalance of the partnership between European and African partners and the relationship with the European Commission. The lack of public funds available in the participating countries. The sustainability of the initiative in the long run. French speaking countries do not always have the capacity to write competitive proposals in English. Clinical trials <ul style="list-style-type: none"> Drug and vaccine development is long and unpredictable process (flexibility to adapt milestones and deadlines is necessary). Capacity building <ul style="list-style-type: none"> If institutions are left without additional funding there is a fair chance that the sites will collapse. Researchers that have been trained on EDCTP projects who leave Africa. Networking <ul style="list-style-type: none"> New type of partners might also cause new rules and conditions that need to take into account. The success of the Networks of Excellence is highly dependent of the dynamism and capacities of a few individuals.

Source: Technopolis Group (2014).

8. Main findings, conclusions and recommendations

8.1 Main findings

8.1.1 EDCTP funded activities

A total of 65 calls for proposals led to 246 awarded grants (situation by December 2013), with an overall success rate of 31%. In absolute numbers the majority of the supported grants are related to ethics and regulatory frameworks (32%). In terms of grant value Clinical Trials and Integrated Projects account for more than 78%. The number of awarded grants for the three main disease areas – HIV/AIDS, tuberculosis and malaria – are distributed evenly over the years

Under the Clinical Trials and Integrated Projects grant scheme category, European Institutions coordinate the majority of projects. Nevertheless, overall participation of African countries under this category is slightly higher than in other categories.

Around 74% of the coordinators of the 246 awarded projects are working in an African country and 72% are male.

In total, 259 different institutions across Africa and Europe have participated in EDCTP grants and have received funding: 188 from Sub-Saharan and 71 from Europe. Four of the European Participating States and eighteen of the sub-Saharan African countries have not yet participated in any projects (i.e. have not received funds from EDCTP).

The signed grant value disbursed by EDCTP to the 246 projects is €212.1 million; overall funding associated with these projects is €382.7 million. The ten institutions that received the largest amount of EDCTP funding together are responsible for just over 25% of the total value of EDCTP grants. Four African countries (South Africa, Tanzania, Uganda and Kenya) have received 56% of the total grant value received by all African countries. Three European countries (the United Kingdom, the Netherlands and Germany) received 67% of the total grant value received by all European countries.

Sub-Saharan African co-funding is relatively limited: South Africa, Tanzania and Uganda account for almost 70% of African co-funding. A few Private Development Partnerships (PDPs), charitable and philanthropic organisations and a few industry partners provide the majority of third party co-funding. The Global Alliance for TB Drug Development (TB Alliance), the Bill & Melinda Gates Foundation and Aeras Global TB Vaccine Foundation together account for more than 60% of third party co-funding.

8.1.2 The execution of the programme

Governance and management

Recent changes in the governance structure of EDCTP (from a European Economic Interest Group to an Association under Dutch law, to allow membership of African countries) have been greatly welcomed. This as a result of the fact that the first programme was not considered a real partnership in which African countries could become full members. To date, a total of eleven sub-Saharan countries have completed their membership process and are now full members of the EDCTP partnership, namely Cameroon, Republic of the Congo, the Gambia, Ghana, Mozambique, Niger, South Africa, Senegal, Tanzania, Uganda, and Zambia.

During the first phase of EDCTP the roles of the different governance and advisory boards have not been optimal: there have been overlaps in terms of decision-making power and the advisory role, and to some extent duplications between the PB and the DCCC. This has resulted in a lack of real strategic vision based on the current portfolio of funded projects. This has been changed in EDCTP2 as the PB and the DCCC have been merged into the SAC.

The current capacity and professionalism of the Executive Secretariat is assessed very positively. It shows an immense improvement compared to the start of EDCTP and has contributed significantly to EDCTP's overall success. The current staff at the Executive Secretariat, both in The Hague and Cape Town (Africa office), are considered very approachable, dedicated, competent and supportive. The officers have a good understanding of the projects and the local context in which they are embedded. In addition, the current Executive Director is considered an important contributing and decisive factor in the actual performance of EDCTP. A major point of concern is the fact that the Executive Secretariat has a relatively high turnover and staff appear to be significantly overloaded.

The average overhead percentage of EDCTP for the period 2004-2013 has been calculated at 9.2%. For a funding programme of the scale and complexity of EDCTP, this is a reasonable overhead percentage and it falls within the common range of 5 to 15%. EDCTP2 must operate with an overhead of just 6%, which is very modest and could limit its activities.

In addition to the more common and most frequently used open calls for proposals, EDCTP has applied two more innovative funding approaches: a brokered approach and a single-source approach. The PanaCEA consortium, an example of the brokered approach, has been valued very positively and is considered to be a best practice of clinical trial funding that could be expanded in more directions and disease areas in the future. The WHO provision of capacity building activities, single-sourced, has proved a very positive experience.

The Executive Secretariat has invested considerable time and efforts to train participating African institutions (research organisations and universities) on the (financial) management of their research projects. The lack of proper management procedures was one of the reasons why contract negotiations were delayed in the early years of EDCTP. Due diligence needed to be completed before advance payments could be released to all partners. This has now improved considerably due to training and guidelines.

From 2004 to 2012 the time-to-contract has been significantly reduced from 19 to 3.6 months.

The level of detail requested for the proposals, in particular related to the budget overview, is perceived as too high. By definition research is unpredictable, which implies that a certain level of flexibility is needed. Furthermore, the financial report templates are considered too complicated.

Finding the right people, without a potential conflict of interest, for the review of proposals is very challenging, as in the field of HIV/AIDS, tuberculosis and malaria almost all people know each other.

The co-funding arrangements in place during the first phase of the programme were complex for the Participating States. It was also confusing and tedious for grantees to find project-based matching through negotiations with the respective national agencies and governments. This has been changed for EDCTP2, where it is no longer necessary to raise co-funding on a project-by-project level.

Communication and advocacy

EDCTP has managed to create and maintain awareness and visibility for EDCTP and its mission and goals towards those who have been involved in its activities, keeping all stakeholders regularly informed on the funded grants and the programme in general.

Since 2011 EDCTP reports on its media appearances to showcase its performance, mainly in terms of online news articles, blogs, publications and press releases. The number of unique visitors to EDCTP's website – its main platform to share information about the programme – shows an increase from 28,142 in 2012 to 39,289 in 2013. Additionally, EDCTP distributes an electronic newsletter in three languages (English,

French and Portuguese) currently to approximately 1,047 contacts. EDCTP has also become active on social media through Twitter and a YouTube channel.

EDCTP Awards are widely advertised on the EDCTP website, newsletter, news alerts and social media. Selection of candidates is based on excellence and level of achievements. Although four of the six previous award winners have been South African researchers, applicants are not predominantly from South Africa.

Nonetheless, EDCTP does not yet make enough use of its communication and public relations approach to make EDCTP known to the world by showcasing best practices and key successes to the media. In addition, only parts of its web content are currently published in French and Portuguese.

Dr. Pascoal Mocumbi, the former High Representative for EDCTP has raised the visibility of EDCTP and has advocated for the EDCTP in Africa.

Monitoring and evaluation

At the beginning of the programme the intervention logic was not worked out properly, which resulted in the development of Key Performance Indicators that did not really focus on the impact of the programme. The monitoring and evaluation system has positively evolved over the past years, but should be further institutionalised, as envisaged under EDCTP2.

8.1.3 Impact on clinical trials

EDCTP awarded 74 projects that incorporated clinical trials, which corresponds to 30% of all grants awarded. Out of these projects a total of 100 clinical trials have been initiated, equally spread over the disease areas: 24 on HIV/AIDS, 22 on tuberculosis, 21 on malaria and 7 on HIV/TB co-infection. The majority (60%) of these trials is targeted at the development of new treatments, followed by vaccines (25%), diagnostics (11% on related to tuberculosis) and microbicides (3% on related to HIV/AIDS). Currently, 35% of the trials have been completed. The trials cover the whole range of clinical development phases, with the majority in phase II. The later phase III and IV studies mainly relate to HIV/AIDS and malaria. In total 15 European Participating States and 27 African countries take part in the clinical trials. This implies that still 21 other African countries are not (yet) involved in EDCTP funded clinical trials.

Tremendous progress has been made towards achieving EDCTP's objectives in setting a base for excellence in clinical trials across the African continent. Most of the clinical trials already show (scientific) outputs, and preconditions to conduct clinical trials are now set in countries which were not carrying out any before EDCTP intervention (i.e. training of researchers, setting up infrastructure and facilities and creating of networks). EDCTP has predominantly funded phase II and III trials, but it appears that there is still a gap in phase IV trials related to HIV/AIDS, tuberculosis and HIV/TB in sub-Saharan African countries.

EDCTP has considerably changed the way clinical research is conducted in most sub-Saharan African countries as a result of the funded projects. This is due to several reasons:

- Participation in projects has fostered collaboration amongst universities across Africa and Europe, and thus has enhanced knowledge exchange and raised research standards in less advanced laboratories and clinical research sites;
- The projects have supported capacity building of researchers and technical staff, not only in conducting clinical trials by setting standards, but also in writing research proposals which has led them to be more autonomous and possibly generate revenues from other funding sources;

- The projects have created and supported a critical mass of researchers in Africa, who previously had little access to funding for conducting clinical trials;
- And above all, the majority of the clinical studies funded by EDCTP would not have been carried out otherwise.

As there is still shortage of products or interventions in various areas, such as treatments and diagnostics for tuberculosis and HIV/TB co-infection and vaccines for malaria and tuberculosis, EDCTP funded projects are considered highly relevant as they specifically address these issues. EDCTP has been one of the few funding options for clinical trials in this field.

Due to the relatively recent character of its implementation, EDCTP has not yet had much impact on acceleration and development of new or improved products/interventions, including contribution of research data towards prequalification by regulatory authorities (e.g. WHO). Because of the long period between the actual clinical trial and the implementation of new clinical interventions, it is still too early to fully assess the impact of EDCTP on health policies at a global level. Nevertheless, there are some examples of positive achievements that directly impact the health of people in Africa:

- Through successfully conducted clinical trials, EDCTP has played an important role in the global portfolio of malaria vaccines.
- The results of an EDCTP funded clinical trial have contributed to a WHO guideline on mother-to-child transmission of HIV during pregnancy and breastfeeding.
- EDCTP funded clinical trials in the regulation of HIV treatments (e.g. for children infected with HIV).

8.1.4 Impact on capacity building in sub-Saharan Africa

In general, capacities in sub-Saharan African universities and research organisations have been improved considerably by EDCTP. This has been achieved through staff training, establishing and strengthening infrastructure and facilities, and establishing or strengthening national ethics committees (NECs) and institutional review boards (IRBs). Nevertheless, many countries in sub-Saharan Africa are still lacking the basic know-how and infrastructure to conduct clinical trials that meet international standards in terms of scientific research quality and ethical conduct.

In total 518 people in 31 different African countries have been trained on EDCTP funded projects. The largest numbers of people trained are Master's (233) and PhD students (173), of which the majority has been trained on large integrated projects. The overall male-female ratio is 59% (male) versus 41% (female). In the Senior Fellowship grants, male researchers are overrepresented (78% versus 22%). In seventeen Sub-Saharan countries, of which the majority was not involved in the initiated clinical trials, no people were trained. In addition to these formal training programmes, EDCTP funded projects also include targeted short-term training schemes and workshops.

Through EDCTP's contribution, clinical trial sites have been developed that can now operate more or less autonomously. Increasingly, African researchers can lead their own research projects and raise funding for new projects.

EDCTP has contributed to developing ethics capacity in sub-Saharan Africa through establishing or strengthening IRBs and NECs, training ethics committee members and ensuring that the boards and committees are independent.

A separate bibliometric study concluded that the papers that resulted from the EDCTP funded projects are exceptionally highly cited, across its entire research portfolio. This implies that the research supported by EDCTP is excellent, highly collaborative and world leading.

From 2009, EDCTP has awarded six African researchers for their scientific excellence through the Outstanding and the Rising Star African Scientist Awards.

Overall, 74% of the projects were led by people working in African institutions. Specifically for the 74 projects that included clinical trials, 38 (51% of the projects) were led by researchers from African institutions.

The Pan-African Clinical Trials Registry (PACTR)

EDCTP, in partnership with the South African Cochrane Centre (SACC) and the Cochrane Infectious Disease Group, has established an international registry for all clinical trials conducted in Africa, the Pan African Clinical Trials Registry (PACTR). This registry is the only WHO Primary Registry covering the entire African continent.

PACTR is considered beneficial for a large variety of stakeholders: it can provide policymakers a full overview of what clinical trials are being conducted in their respective countries and how these try to address health needs of the population; health professionals may advise patients about appropriate trials to participate in; funders of clinical trials and development agencies can learn what research is being conducted where and by whom; and researchers are provided a way to identify gaps in the research landscape and better focus their research activities.

To date 313 clinical trials have been registered with PACTR, of which 48 on HIV/AIDS, 23 on tuberculosis, 37 on malaria and 17 on co-morbidity (HIV/tuberculosis, HIV/malaria and tuberculosis/malaria).

Not all interviewees in the countries visited are familiar with the existence of PACTR and its benefits. Those that did know about PACTR considered it one of the highlights of the capacity building approach of EDCTP, created with African leadership.

8.1.5 Impact on networking and research coordination

Of the 246 projects 66 (27%) were performed by institutions from just a single country. Around 60% of the projects did not contain more than three countries. Consortia of institutions from more than ten countries applied to fifteen projects in total.

Networking and links between researchers and research institutions in Africa and those in Europe are one of the benefits achieved through the activities of EDCTP. The programme has created the right conditions for establishing new relationships and strengthening those relationships that already existed.

The south-south networks have created opportunities for African scientists and institutions that did not have a chance to work together before. The north-south networks have widened the scope for African researchers to work with renowned institutions in Europe. There is a tendency to build networks on already established relationships. The north-north networks were not considered highly important for European researchers, as they did not lead to the establishment of completely new collaborations. The main benefit stems from new or strengthened links with African institutions. However, at country level the north-north networking approach has resulted in countries not previously involved in poverty-related and neglected diseases developing research programmes in these areas.

The total amount of co-funding from the European Participating States to EDCTP adds to a total of €842.10 million by the end of 2013; this includes the €141.62 million of direct contribution to EDCTP or to the EDCTP funded projects. This implies that European countries themselves have funded considerable amounts of activities (either clinical trials, capacity building or networking) that relate to the activities funded directly by EDCTP. For all countries this second type of co-funding is significantly higher than the actual direct contribution to the programme.

The engagement with third-party organisations (PDPs, charitable and philanthropic organisations, pharmaceutical companies and small and medium sized enterprises) used to be mainly on the level of the individual projects. The last few years more emphasis has been put on engaging with these organisations at a more strategic or programmatic level.

It can be considered a success that African ministries and co-funding organisations have shown an increasing interest in participating in EDCTP. Also the fact that EDCTP succeeded to prove itself for a second phase is a great achievement in itself.

The regional Networks of Excellence

In 2007 EDCTP established four regional Networks of Excellence (NoEs): WANETAM (West Africa), CANTAM (Central Africa), EACCR (East Africa) and TESA (Southern Africa). WANETAM, CANTAM and EACCR showed great success, while TESA – although showing good results on paper – should be reorganised to achieve better value and requires capacity building of the weaker institutions. In general the NoEs have led to the following main achievements:

- Conducted baseline burden of disease studies as a prerequisite for conducting future clinical trials.
- Invested substantially in clinical trial infrastructure and in crosscutting short-term training, long-term training and/or field mentorships to produce networked high-skilled African researchers.
- Institutions within each NoE have learnt to collaborate in joint proposal development and project implementation.

8.2 Conclusions

In general, there is wide acknowledgement that EDCTP, after a difficult start during the first years of the programme, turned itself into a well-tuned and effective funder of clinical trials on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa.

During its first programme EDCTP distributed a total of 246 projects amounting to €212.12 million from EDCTP (situation by December 2013), balanced across the three disease areas and 16 different grant schemes that complement each other. There is a relative balance in the geographical coverage between European and African countries and institutions participating in the programme. However, four African countries (South Africa, Tanzania, Uganda and Kenya) and three European countries (UK, Germany and the Netherlands) are responsible for the largest number of project participations.

EDCTP has become a more equal and transparent partnership in which African countries have a much stronger voice than in the early days. The programme has increased African engagement over the whole spectrum of clinical research and has helped structure clinical research capacity in Africa. The planned integration with national activities under EDCTP2 is a step towards simplification and clarification, and shall generate higher engagement of Participating States.

The combination of support for clinical trials with capacity building and networking (the ‘holistic approach’) is considered unique and a best practice in funding clinical research activities in Africa. Through EDCTP, African researchers are given the opportunity to become principal investigators of projects and develop their own research questions based on local needs and challenges.

However, it is as yet hard to judge the ‘value for money’ as it will take years before the benefits can be reaped of the 100 clinical trials that were funded during the first programme, in terms of new products and long-term improvements in health outcomes. Even though EDCTP’s financial contribution remains small compared to that of institutions such as the Wellcome Trust and the Bill & Melinda Gates Foundation,

EDCTP is one of the only clinical trial funders who also engage in capacity building and networking activities. As such, it has found a niche where its intervention is absolutely relevant.

EDCTP is now at a point where the necessary infrastructure has been developed and strengthened in order to conduct clinical trials, and where people from different backgrounds and levels have been trained. Further impact of funded projects on product development can therefore be expected in the years to come.

8.3 Recommendations for the future of EDCTP

Based on the main findings and conclusions of the evaluation as presented in the previous chapter, the following recommendations for the future of EDCTP are made.

General

- It is strongly recommended that EDCTP continues its 'holistic approach' of supporting clinical trials, combined with capacity building and networking activities. In addition to broadening its scope to include neglected infectious diseases and all phases of clinical development, it is recommended to build on the projects that have been funded so far in order to bring them one step further.
- EDCTP should keep the long term funding commitment, vision and engagement with African partners and aim for an increase of resources.

Governance and management

- The challenge for the future of the programme is to sustain African countries' contribution and engagement and the actual financial means provided by these countries.
- The definition of a strategic vision and direction based on portfolio management of the results from EDCTP1 is something that could be strengthened under EDCTP2. The SAC is considered responsible for the development of such a strategy, including an implementation plan.
- A specific point of attention for the future of the programme is the continuity of the composition of the SAC. The rate of renewal of SAC members can be adjusted by prolonging the duration of members' mandate and/or phasing new appointments in thirds or halves.
- It will be essential for the EDCTP to maintain good leadership through its Executive Director, particularly as the Executive Secretariat is likely to grow.
- Based on the progress of the clinical trials funded and the strategic and scientific opportunities for each disease area, a brokered approach could be implemented, similar to the establishment of the PanACEA consortium. The SAC could play a role in defining the specific areas, based on the portfolio of projects funded and scientific challenges.
- As the experiences with WHO on strengthening regulatory activities via a single-source approach proved very positive, there is no drawback to following this same route for supporting capacity building activities in the future.
- As the project proposals have been perceived as too detailed and the financial report templates as too complicated by the project participants, it is recommended to add more flexibility to timelines of the projects, budgets and activities and to reconsider the structure and complexity of the information to be provided in the financial templates.

- It is also suggested to reconsider the mechanisms in place for final payments, since for institutions that are largely publicly funded it can be very challenging to fund the final stages of a project in case the payment from EDCTP is withheld.
- It is further recommend that EDCTP considers the scientific review procedures of other funding organisations to ensure that the best research is funded, and to view how they deal with potential conflicts of interest.

Communication and advocacy

- With regard to the communication and advocacy approach of EDCTP, it is recommended that electronic newsletters be distributed to all project participants and, where possible – due to privacy regulations –, to other contacts, to adopt a more proactive way of disseminating the results of EDCTP funded projects and of the programme in general. In addition to the current electronic newsletter, specific information could be provided through electronic communication to dedicated target groups (e.g. Senior Fellows, Master and PhD students, but also African and European researchers) about aspects that are of particular interest to these groups.
- As more clinical trials funded under EDCTP1 have finished or are about to finish, it is important to highlight the programme's impact and key successes. Therefore the following suggestions are made to improve the communication and advocacy approach of EDCTP:
 - The website should contain more information on project outcomes;
 - A list of five to ten top successes from projects should be listed that can be taken up by, for instance, health ministries and politicians;
 - It is a good approach to have the homepage in three languages (English, French and Portuguese). However not all parts of the website are comparable in size and level of detail. This is something that should be improved;
 - There should be more direct contact with the press and other media to showcase key successes;
- In order to maintain the visibility of EDCTP as a scientific and a political initiative, it is important to find a new candidate for the position of High Representative.

Monitoring and evaluation

- There is room for EDCTP to better demonstrate its achievements through a more systematic and integrated monitoring and evaluation system that is based on the following elements:
 - Creation of a dedicated unit or responsible person that deals with monitoring and evaluation on a regular basis, not incidentally.
 - The monitoring and evaluation process should focus more on the follow up of the projects: referred to what has been designed in the protocol, what has been achieved in the project and how the results affected health policy development and situation of the countries involved. In other words, the monitoring and evaluation should focus more on the longer-term results and impacts of the projects funded. This could include more systematic follow-up of the projects three years after the grant has been finished (through an impact report).
 - Regular (annual) satisfaction surveys among the grantees giving them the opportunity to comment on the programme in general and the project performance in particular. The results can be used to continuously improve, monitor and assess the programme.

- Site visits by members of the Executive Secretariat to the institutions that have been funded are considered to be another mechanism to collect opinions and suggestions on the programme from grantees. This will also provide insights into the effects and impacts of the projects funded.
- The organisation of events to share results and discuss critical issues. The biennial EDCTP Forum however is considered to be very informative and a good platform for researchers to gather and share their experiences and discuss future opportunities.

Clinical trials

- To strive for better alignment and integration of research efforts, it is recommended not to fund too many small projects in too many different areas. This implies a focus on projects with a larger budget, based on the portfolio of projects funded, potentially through a brokered approach like the PanACEA consortium.
- It is strongly recommended to continue the support of Strategic Primer Grants as the innovative angle of the programme. Additionally, to allow researchers to further investigate new insights gained during current projects, opportunities could be provided to investigators to request ‘add-on’ grants. For this reason EDCTP could reserve funds for adding interesting studies to current projects or for responding to new research questions or opportunities that arise after the start of the core study. This can also be combined with a mechanism to retain human capacity.
- In its second programme, EDCTP could focus on enhancing product development through better involvement and earlier engagement of regulatory groups, Product Development Partnerships (PDPs) and industry partners.
- A financial guarantee system for participating institutions should be explored to minimise the risk taken when partnering in clinical trials with weaker institutions (in financial terms). One potential system to be investigated is the European Commission’s Guarantee Fund for External Actions implemented by the European Investment Bank.
- As it is likely that health impacts of the funded activities will only become apparent under EDCTP2, it will be essential to closely monitor the progress made in the respective areas.

Capacity building

- As a considerable number of sub-Saharan countries have not been involved in the initiated clinical trials, in seventeen of these countries no formal training has taken place. It is worth investigating to what extent students and researchers from these countries could benefit from training opportunities, even if their institutions do not take part in integrated projects or clinical trials.
- As trained individuals are essential in raising the overall quality of clinical research in sub-Saharan countries, EDCTP should continue its approach towards investing in all scientific career levels (Bachelor’s, Master’s and PhD students, postdoctoral researchers and senior fellows). Especially reintroducing career development fellowships for postdoctoral researchers will complete funding opportunities for all career levels.
- Furthermore, it is recommended to train other staff (in the lower cadres) as well as those who are involved in clinical research (e.g. medical doctors, nurses, epidemiologists, laboratory technicians and biostatisticians), management and financial aspects of clinical research. However, as it is not directly the remit of EDCTP, this could be achieved through advocating for inclusion of modules on conducting clinical trials and research ethics in medical education.

- Capacity building in Africa requires considerable investments and long-term engagement. EDCTP should therefore build on the capacity that has been developed during its first phase. A situation in which incentives are put in place to retain people for at least a couple of years after the EDCTP projects have finished would be preferable to secure transfer of knowledge they have gained. A post-project grant to conduct another related project could be a good incentive. To avoid distortion of competition, this should not be systematic but based on performance, output and achievements of the other previous projects.
- An EDCTP alumni association, which is currently under development, will support the creation of a community of researchers and will be beneficial in monitoring career development of those who have received training. These researchers can act as real ambassadors of the programme.
- For the second phase of the programme, it is recommended that African scientists continue taking up leadership roles.
- As only a limited number of people are familiar with the existence and aim of the Pan African Clinical Trials Registry (PACTR), communication about the intention and benefits of the registry is something that needs to be strengthened. The Pan African Clinical Trials Alliance (PACTA) is another initiative that aims to integrate clinical trial registration, such as PACTR, with clinical trials regulation and ethical approval through national ethics committees and institutional review boards. Efforts can be put towards aligning these two initiatives to explore synergies and increasing their visibility.

Networking

- It will be important for a second programme to try to engage countries in sub-Saharan Africa that did not participate in the first programme, and to fund capacity building activities to develop a basis for clinical research.
- As the south-south networking approach is a big achievement, it is strongly recommended to maintain this in the second programme. To further increase its results, the capacity and resources for networking and motivation of researchers to network should be increased.
- Although EDCTP projects have received considerable contributions from the private sector (primarily from PDPs, philanthropic organisations, big pharmaceutical companies, and Small and Medium Enterprises), it is considered necessary to expand and structure future engagement with the private sector on a more strategic level. The question *‘how to bring pharmaceutical and biotechnology partners on board?’* remains open and will have to be addressed.
- As not all countries involved in the Networks of Excellence (NoEs) have adequate financial resources to contribute significantly and guarantee their sustainability, it is strongly recommended that EDCTP renew its NoE scheme. It will be important to open up the NoEs to include other countries in the region, as well as other institutions in the already participating countries. More initiatives should also be encouraged to engage all partners of the four NoEs. Lastly, the NoEs should be institutionalised at a higher level, rather than at the level of researchers or institutions. Regardless of their composition, people and strong leadership will play an important role in the popularity, success and dynamism of the NoE.
- In the future, measuring in-kind and cash contributions from African countries more systematically could give more credit to the African share and ownership of the partnership. To remain successful, EDCTP needs continuity of investments and this money should not only come from European, but also from African countries. Concerted political action is needed to make sure that these contributions are increased. The current move for African countries to become full member of the EDCTP partnership is a step in the right direction.

In the table on the following pages the evolution of the recommendations over time is shown including the recommendation from this evaluation that just have been presented. This table is based on the table that has already been presented in section 1.5 (see Figure 5).

Figure 60 Recommendations made by the independent external evaluations

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Activities	Capacity Development	n.a.	+	<ul style="list-style-type: none"> • Recommends involvement of Northern and Southern partners in all aspects of capacity strengthening of African research institutions. 	+	<ul style="list-style-type: none"> • EDCTP is strengthening capacity development through various efforts e.g. senior fellowships, training of PhDs, MScs, et cetera; • Focus on training shall not let down other capacity building components such as logistical support to institutions, motivation of researchers, improving behaviours, action on national research systems. 	<ul style="list-style-type: none"> • Survey respondents highly appreciate the capacity building efforts of the EDCTP. 	+	<ul style="list-style-type: none"> • Investigate ways to involve the seventeen of sub-Saharan countries which have not benefited yet from the capacity building activities; • Reintroducing the career development fellowship grant scheme for postdoctoral researchers; • Train lower cadre staff and advocate for introducing modules clinical trials and ethics courses in medical curricula; • Introduce a post project follow-up scheme with incentives to retain staff in institutions.
Activities	Networking	n.a.	n.a.	n.a.	+	<ul style="list-style-type: none"> • EDCTP has improved networking (South-South, North-South, North-North); • Brings a new model of international research cooperation, promoting African ownership and Africa/EU networking; • Underrepresentation of non-English speaking countries but CANTAM NoE recently set up. 	<ul style="list-style-type: none"> • Respondents believe that the promotion of partnerships and networks between EU and African institutions for project application and implementation has significantly increased collaboration opportunities between European and African institutions (North-South) and between African institutions (South-South); • North-North collaboration has not been particularly mentioned by the survey respondents, neither in positive nor in negative sense; • The Networks of Excellence are highly valued. 	+	<ul style="list-style-type: none"> • Engage all sub-Saharan countries; • Engage further with the private sector and like-minded organisations (such as PDPs and charitable and philanthropic organisations). • Continue supporting the four Networks of Excellence, while opening them to new countries and participating institutions and institutionalising them at a higher level.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Activities	Clinical trial strengthening	n.a.	+	<ul style="list-style-type: none"> • Recommends involvement of Northern and Southern partners in all aspects of product development (product specification/design of clinical phase); • Encourages EDCTP to associate with likeminded and comparable actors to assure up-to-date know-how, capacity development and expertise. 	+	<ul style="list-style-type: none"> • It is the core activity of EDCTP and EDCTP is continuously investing in staying updated on new developments and seeks collaboration with important likeminded actors; • Equity in participation of African researchers; • 43 % are preparedness studies; 38 countries are participating with UK participating to 70%; • Good representation of specific groups; • Few epidemiological studies were initially conducted to determine incidence or prevalence; • Slow progress in cohort recruitment; • No outcome evaluation measures as final indicators; • Many researchers participate to 3 projects or more at a time. 	<ul style="list-style-type: none"> • Survey respondents believe that EDCTP is filling an important gap in clinical trial conduct for the three poverty related diseases. 	+	<ul style="list-style-type: none"> • Focus on projects with a larger budget i.e. through a brokered approach similar to the set up of the PanACEA consortium; • Continue the support to the Strategic Primer Grants as the innovative angle of the programme; • Create an “add-on grant” with simplified procedure to allow responsiveness to arising questions during a research; • Engage regulatory groups early, as well as PDPs and industry partners.
Activities	Regulatory environment and ethics	n.a.	n.a.	n.a.	+	<ul style="list-style-type: none"> • EDCTP is strengthening the regulatory environment and ethical standards e.g. through the establishment of an African public clinical trial registry. 	<ul style="list-style-type: none"> • The majority of comments are rather positive; • Survey respondents highly appreciate EDCTP's efforts in this field. 	+	<ul style="list-style-type: none"> • Continue financing the Pan African Clinical Trials Registry (PACTR) • Communicate widely on the aim and benefits of PACTR; • Integrate the national ethics committee and institutional review boards in PACTR.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Activities	African ownership	n.a.	+	<ul style="list-style-type: none"> Broaden DCCC membership to increase engagement of African governments and organisations. 	+	<ul style="list-style-type: none"> African ownership has been improved as is shown by the increased involvement of African countries and increasing numbers of African project coordinators. 	<ul style="list-style-type: none"> The level of African EDCTP project ownership is either rated as average (40%) or high (31%) by the majority of survey respondents, acknowledging the fact that it might well vary between projects. Compared to other similar mechanisms, if similarities do exist, 45% of stakeholders believe that African ownership is “higher than” average or at least “average” (33%). 	+	<ul style="list-style-type: none"> n.a.
Activities	Sustainability	n.a.	n.a.	n.a.	+/-	<ul style="list-style-type: none"> The major challenge is the long term sustainability of the positive impacts; Would be beneficial if EDCTP would implement an impact evaluation process to allow prospective analysis of EDCTP achievements and consider advances in research by other funders. 	<ul style="list-style-type: none"> Respondents repeatedly voice their concern regarding the sustainability of existing EDCTP projects in case EDCTP funding should come to an end. 	+/-	<ul style="list-style-type: none"> Provide train opportunities for institutions in funding research and create incentives to look for additional funding from other partners.
Activities	Integrating national programmes	n.a.	n.a.	n.a.	n.a.	<ul style="list-style-type: none"> Progressing too slowly; Member States national programme integration and financial commitment does not follow a realistic strategy and common shared vision (only 40% integration indicator). 	<ul style="list-style-type: none"> n.a. 	-	<ul style="list-style-type: none"> Seek further alignment of the national activities with EDCTP.
Governance	African presence in General Assembly	n.a.	+	<ul style="list-style-type: none"> The African presence in the General Assembly should be reinforced. 	+/-	<ul style="list-style-type: none"> A decision has already been made to increase African representation on the General Assembly. It will be implemented. 	<ul style="list-style-type: none"> In general, survey respondents tended to rate African representation at decision-making level with an “average” (28%) to “high” rating (24%) with quite a few stakeholders (26%) not really knowing how to evaluate this question at all. 	+	<ul style="list-style-type: none"> This has been realised through the change in the legal structure of EDCTP to an Association under Dutch law for African countries to become full members of the partnership. To date nine countries already became full members.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Governance	More Political representation of GA	n.a.	+/-	<ul style="list-style-type: none"> Make the General Assembly more political and create and Executive Steering Committee. 	o	<ul style="list-style-type: none"> A steering committee has been composed; A number of Member States have taken steps to improve political representation and engagement with EDCTP e.g. Netherlands, Belgium and UK. 	<ul style="list-style-type: none"> The majority of survey participants (55%) are not aware of an improved political representation of the EDCTP programme as recommended in the 2007 external review. They refer to a lack of visibility, which does not really allow them to make a valid assessment of this issue. 	+	<ul style="list-style-type: none"> n.a.
Governance	Scientific excellence	n.a.	+	<ul style="list-style-type: none"> Install adequate firewall protection from political and other external pressures for scientific independence and at Partnership Board level. 	n.a.	n.a.	n.a.	n.a.	n.a.
Governance	EDCTP Mandate	n.a.	+	<ul style="list-style-type: none"> Agree on EDCTP component mandates and clarify dialogue between components. 	n.a.	n.a.	n.a.	n.a.	n.a.
Operations	PDP/ Private sector engagement	n.a.	+/-	<ul style="list-style-type: none"> Expand association with major PDPs/private partnerships to encourage participation and mobilisation. 	+/-	<ul style="list-style-type: none"> Engagement with PDPs has grown and EDCTP projects have received considerable funds from the private sector. A working group of experts has been initiated by EDCTP to prepare a strategy document and business plan on how to effectively engage with the private sector. 	<ul style="list-style-type: none"> The majority of survey respondents are not aware of improved engagement with the private sector focusing on product development. 	+/-	<ul style="list-style-type: none"> Use a brokered approach i.e. PanACEA or single source approach and increase engagement of third party organisations and PDPs.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Operations	Streamline co-funding	<ul style="list-style-type: none"> Develop an overview of Member State funding mechanisms. 	+/-	<ul style="list-style-type: none"> Simplify and streamline co-funding from virtual to an actual common pot by 2009 and renewal of vows to finance EDCTP. 	o	<ul style="list-style-type: none"> EDCTP is still engaging in discussions with Member States on this issue to identify ways to streamline co-funding. Some members are in the process of making changes and EDCTP is continuously working on improving the co-funding arrangements. It is a burden on the researchers. 	<ul style="list-style-type: none"> Funding and co-funding is one of the two topic areas receiving most criticism from survey respondents. 40% stakeholders did not know how to evaluate the interest of major funders to invest in EDCTP and 40% noted only “some” or “average interest from funders. Many are not aware of efforts to establish a common funding pot. 	+/-	<ul style="list-style-type: none"> Further alignment of the national activities with EDCTP (i.e. the contracting/budgetary calendars) might contribute to a further reduction of the time-to-contract.
Operations	Information Management/Visibility	<ul style="list-style-type: none"> Recommends developing a communication plan and guidelines on how to have a more direct contact with the research community. 	+	<ul style="list-style-type: none"> Recommends publishing a web page with KPI, minutes, annual reports and official key documents, ethical judgements on projects, EDCTP Intellectual Property policy; Implement a communication plan to make EDCTP an attractive and visible player. 	+	<ul style="list-style-type: none"> EDCTP has introduced various mechanisms to increase visibility e.g. website, quarterly newsletters in 3 languages, et cetera; Recommends publishing on the website how it verifies compliance with international ethical principles and IP rights. 	<ul style="list-style-type: none"> The majority of survey respondents highly appreciate and are aware of the various visibility measures initiated by the EDCTP e.g. webpage, quarterly newsletter, et cetera. 	+	<ul style="list-style-type: none"> As more clinical trials funded under EDCTP1 have been finished or are about to finish, it is important to show the impact and key successes.
Operations	Call procedures	<ul style="list-style-type: none"> Improve process of call initiation has damaged EDCTP reputation (the 2nd call was cancelled). Inconsistencies in proposal evaluations exist. Standard Operating Procedures (SOPs) need to be developed. 	+	<ul style="list-style-type: none"> Implement quality assurance of call process; Renew calls for appropriate projects to be submitted rapidly to attract the best public/private partnership and to participate in major R&D initiatives. 	+/-	<ul style="list-style-type: none"> Review how proposal are handled and revise procedural guidelines; EDCTP increased the number of calls launched. In order to be more effective with regards to interested private and public parties, it has implemented stakeholder meetings before launching new clinical trials. 	<ul style="list-style-type: none"> Varying opinions exist: 47% believe the call system is effective, while 33% claim it to be only partially effective. 	+/-	<ul style="list-style-type: none"> Simplify proposals and financial report templates; Allow more flexibility to timelines of the projects, budgets and activities.
Operations	Scientific and ethical evaluation	n.a.	+/-	<ul style="list-style-type: none"> Accept one single integrated scientific and ethical evaluation utilising a pool of the best national experts. 	n.a.	<ul style="list-style-type: none"> n.a. 	<ul style="list-style-type: none"> n.a. 	n.a.	<ul style="list-style-type: none"> Benchmark other funders proposal review procedures and modify the current procedure to ensure that best research is funded.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Operations	Operational Structure	<ul style="list-style-type: none"> Employ an experienced Executive Director; Improve communication between EDCTP constituent bodies through joint meetings and information exchange as misconceptions of roles and responsibilities exist; Develop Standard Operating Procedures for roles and responsibilities. Familiarise with EC funding system. 	+	<ul style="list-style-type: none"> Draw lessons from past Executive Director instability and management weaknesses at Executive Secretariat level. 	+/-	<ul style="list-style-type: none"> n.a. 	<ul style="list-style-type: none"> The slow start-up phase of the EDCTP, also marked by many managerial and strategy changes, was mentioned as the most detrimental factor limiting EDCTP's progress in the first few years of existence. However, many respondents now acknowledge that the initial hurdles have been overcome and that EDCTP has flourished in the past 3 years and is achieving and in some cases even exceeding its objectives, thanks to the current Executive Director. However, criticism of various aspects persists. 	+/-	<ul style="list-style-type: none"> Secure the replacement of Executive Director with great leadership and diplomatic skills ahead of deadline.
Operations	Strategy and Monitoring and Evaluation	n.a.	+/-	<ul style="list-style-type: none"> Regroup the various activities around clinical trials, capacity building and Networks of Excellence; Define a strategy, action plan with financial targets and deliverables, KPI and external benchmarks. 	+/-	<ul style="list-style-type: none"> KPI are so far a good start but should be narrowed; Need for a needs assessment approach; Absence of any a priori formulated measurable indicator for the expected outcome set at the start of the EDCTP programme; It is difficult to assess EDCTP's economic and societal impact. Monitoring and auditing of projects shall be done by an external contract organisation 	<ul style="list-style-type: none"> n.a. 	+/-	<ul style="list-style-type: none"> The SAC shall define a strategic vision and direction based on portfolio management of the results of EDCTP1; Ensure continuity in the SAC composition; Set up a dedicated unit for Monitoring and Evaluation; Monitoring and evaluation shall focus on longer-term results and impacts as well as follow-up of projects 3 years later; Distribute satisfaction surveys among the grantees; Organise events to share results.

Topic	Issue	Self-assessment 2005	Δ	Independent External Review 2007	Δ	Independent External Evaluation 2009	Internal Assessment 2009	Δ	Independent External Evaluation 2014
Operations	Coherence	n.a.	+	<ul style="list-style-type: none"> The need for EDCTP activities to be part of a broader international research agenda; Ensure coherence with EC public health strategy; Ensure coherence with priorities of African governments; Ensure coherence with existing conditions required for the supply of accessible and affordable essential medicines; Systematic review of all clinical trials developments and clinical capacity for poverty related diseases; Comprehensive needs assessment of the requirements for capacity building for clinical research and health systems. 	+	<ul style="list-style-type: none"> Compels EDCTP to find its strategic niche to similar research funding initiatives working in Africa; Engage with European Commissions Directorate General on Development and Cooperation (DG DEVCO) and EU delegations. 	n.a.	+	n.a.

Source: Various previous assessments of EDCTP and external evaluation of EDCTP by the Technopolis Group (2014).

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Appendix A References

In this evaluation the following documents are used:

- EDCTP Annual Reports (2005 – 2013)
- EDCTP constituency members contact lists
 - Developing Countries Coordinating Committee (2004 – 2012)
 - European Network of National Programmes (2006 and 2009)
 - General Assembly representatives (2006 – 2014)
 - Interim Strategic Advisory Committee (2013)
 - Partnership Board (2007 – 2012)
 - Strategic Advisory Committee (2014)
- EDCTP joint Program of the Action A (2003, 2007 and public version)
- EDCTP Joint Program of Action B (work plan, period 1 – half period 12)
- EDCTP Meeting reports
 - EDCTP Forum reports
 - High-level Conference on EDCTP2 report
 - EDCTP current and prospective partner countries meeting
 - EDCTP pharmaceutical industry workshop
 - EDCTP Stakeholders meeting on Neglected Infectious Diseases
 - First EDCTP investigators' meeting
 - Connecting the Chain II: Linking research and development
 - Post-registration medicinal products safety monitoring in Africa meeting
- Strategic documents
 - Updated project plan: Encouraging the participation of the private sector
 - Revised Communication Strategy 2010-2015
- EDCTP-funded projects summaries
 - EDCTP funded Senior Fellowships: 2004-2011
 - SWOT Analysis for West African Network for TB, AIDS and Malaria (WANETAM)
- Mapping analysis
 - Bibliometric analysis of European and African research output within the scope of EDCTP2 (2013).
 - Supplementary Analysis – Impact of EDCTP-associated research in HIV/AIDS, tuberculosis and malaria, 2003-11 (2013).
 - Supplementary Analysis – Intra-European research collaboration in HIV/AIDS, tuberculosis, malaria and neglected infectious diseases, 2003-11 (2013).

- Networks of Excellence (publications)
 - EDCTP regional networks of excellence: initial merits for planned clinical trials in Africa
 - African networks launch to boost clinical trial capacity
 - The Ant Who Learned to Be an Elephant
 - Strengthening capacity, collaboration and quality of clinical research in Africa: EDCTP Networks of Excellence
 - International health research monitoring: exploring a scientific and a cooperative approach using participatory action research
- EDCTP review and evaluation
 - EC Mid-term Independent External Evaluation on EDCTP Report (2007)
 - Independent external evaluation report of EDCTP (2009)
 - Internal Assessment of the 2003-2009 EDCTP Programme (2009)
 - EDCTP Impact assessment by the European Commission – Summary (2013)
 - EDCTP Impact assessment by the European Commission – Full report (2013)
 - Results of the EC public consultation on EDCTP (July 2012)
- Ethics and regulatory
 - EDCTP support to regulatory affairs in sub-Saharan Africa final version
 - Evaluation of the EDCTP Ethics Grants Programme (January 2014)
 - Overview of achievements and internal evaluation of ethics capacity development activities funded under EDCTP1 programme (January 2014).
 - Publication: Joint reviews and inspections: Strategic forms of collaboration for strengthening the regulatory oversight of vaccine clinical trials in Africa
 - Publication: Regulatory oversight of clinical trials in Africa - Progress over the past 5 years
 - Recommendations from the previous EDCTP Stakeholder Meeting on Regulatory Affairs
- Launched call for proposals
 - 2004
 - Call for proposals EDCTP Code 2004.02
 - Senior Fellowship Programme EDCTP Code 2004.2.C.f1
 - Call text first EDCTP calls
 - 2005
 - Call text Capacity building and site development for the conduct of phase III trials of TB vaccines in high risk populations
 - Call text Capacity building and site development for the conduct of phase III trials of TB vaccines in children under 1 year of age
 - Call text Capacity building for the conduct of phase I/II and Phase III trials of vaginal microbicides against sexual transmission of HIV
 - Call text Development of an MSc course in clinical trials methodology

- Call text Identification of safe and efficacious ARV in combination with tuberculosis drugs in tuberculosis patients with HIV infection
- Call text MSc Studentship
- Call text PhD Scholarship
- Call text Senior Fellowship
- Call text Support to national networking of African scientists working on HIV/AIDS, Malaria and Tuberculosis in Africa
- Career Development fellowship
- Coordination and Networking of research activities in Africa
- Promotion of networks of training facilities for clinical monitors in Europe and Developing Countries
- Providing incentives for joint capacity building programmes in Africa with 2 or more European institutes
- Sponsorship of meetings or workshops of sustainable networks on an EDCTP relevant subject
- Support of an African coordinating office for ethics
- Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards
- Support for Courses and Seminars on Ethics
- 2006
 - Capacity building in preparation for the conduct of preventive HIV vaccine trials
 - Support of studies for the Prevention of Mother To Child Transmission (PMTCT) of HIV, including prevention of transmission during breast feeding
- 2007
 - Call for the support of clinical trials, capacity building and networking for HIV/AIDS treatment
 - Call for the support of clinical trials, capacity building and networking in HIV/AIDS vaccines development
 - Call for the support of clinical studies, capacity building and networking for HIV/AIDS Microbicides
 - Support of phase I, II and III clinical trials on new drugs and improved drug combinations for the treatment of tuberculosis
 - Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards
 - Call for the support of clinical trials, capacity building and networking in malaria vaccines development
 - Call for the support of clinical trials, capacity building and networking in tuberculosis vaccines development
 - Call for the support of clinical trials, capacity building and networking in malaria in pregnancy
 - Call for the support of clinical trials, capacity building and networking in malaria treatment

- Call to support the establishment of regional networks of excellence for conducting clinical trials and provide mentorship programmes in sub-Saharan Africa
- Senior Fellowship
- 2008
 - Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards
 - Call for Identification and Strengthening of Joint Programme Activities
 - Call for the support of clinical trials, capacity building and networking in malaria treatment
 - Call for the support of clinical trials, capacity building and networking in malaria vaccines development
 - Senior Fellowship
- 2009
 - Call for the support of clinical trials, capacity building and networking on treatment of HIV/AIDS
 - Call for support of member states initiated projects within the scope of EDCTP activity areas
 - Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards
 - Senior Fellowship
 - Call for applications to support clinical trials, capacity building and networking in new and improved diagnostics for tuberculosis (TB)
 - Call for the support of clinical trials, capacity building and networking in tuberculosis vaccines development
- 2010
 - Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards
 - Call for support of member states initiated projects within the scope of EDCTP activity areas
 - Evaluating the impact of clinical trials in Africa
 - Senior Fellowship
 - Senior Fellowship with affiliations or linkage to EDCTP Networks of Excellence
- 2011
 - Support for the establishment and the strengthening of African National Ethics Committees and Institutional Review Boards (February 2011)
 - Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards (August 2011)
- 2013
 - EDCTP Master's Fellowship in Epidemiology and Medical Statistics
 - EDCTP small grant programme

- Reports of South-South contacts
 - Report on EDCTP attendance at the AU/AAVP regional consultation on HIV vaccine research and development in Africa, Addis Ababa, Ethiopia, 25-26 October 2006
 - AU/AAVP regional consultation on HIV vaccine research and development in Africa, Addis Ababa, Ethiopia, 25-26 October 2006
 - Minutes of the meeting between the African Union Commission (AUC) - Department of Social Affairs (DSA) and the European & Developing Countries Trials Partnership (EDCTP)
 - Feedback on the Fifth Session of the African Union Conference of Ministers of Health (CAMH5)
 - Report on the attendance at the Second Conference of African Ministers of Health (CAMH2) in Gaborone, Botswana, from 10 to 14 October 2005
 - Report of Advocacy visit to Botswana – 27 to 28 March 2008
 - Brief report on visit of Dr P Mocumbi to the Chinese Embassy, Pretoria – South Africa; 8 April 2009
 - EDCTP participates in the 54th ECSA Health Ministers' Conference
 - Report on participation of Drs Mocumbi and Nyirenda at the 48th Conference of Ministers of Health from East, Central and Southern African Health Community (ECSA HC) – 16 to 20 March 2009, Swaziland
 - Tackling Africa's poverty related diseases through partnership - The Commonwealth Health Ministers Reference Book 2006
 - HR report on WHO/AFRO 55th Regional Committee, August 22-26, 2005, Maputo, Mozambique
 - NEPAD workshop on harmonisation of drug registration in Africa – Johannesburg, South Africa
 - Minutes of Meeting on NEPAD-EDCTP MOU renewal – 24 July 2007
 - Joint HIV meeting of Research Working Group and Prevention Working Group
 - AAVP/COMESA sub-regional consultation on HIV vaccines research and development in Africa
 - Proceedings of meetings of HR – Dr Pascoal Mocumbi and Dr Thomas Nyirenda in Pretoria: 4-10 May 2005
 - Report of the SADC HIV research working group meeting
 - SADC secretariat/EDCTP points of action following comments from senior officials of member states
 - First National Workshop considering creation of a strategic framework in support of HIV vaccine development and clinical trials in Mozambique
 - WHO letter - post-visit response
- Other documents
 - EDCTP project portfolio
 - EDCTP Interim Technical Report 2012
 - Project highlights summary – October 2011

- Lists
 - EDCTP Associated publications
 - EDCTP Contacts list - February 2014
 - EDCTP grantees (former and current) - contact list
 - EDCTP grantees - project coordinators and collaborators
 - EDCTP media mentions
 - Third party database – Networking 2013
 - Contact details of WHO deputy DG and deputy RD Africa region
 - Contact details of health sector focal points in African Regional Economic Communities

Appendix B Terms of Reference of the evaluation

Terms of Reference for a Consultancy to assess the performance and impact of the first Programme of EDCTP

Background

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a not-for-profit organisation, which was created in 2003 under the Sixth Framework Programme (FP6) for research as a response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria.

The mission of EDCTP is to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria through a partnership of European national research programmes on PRDs with their African counterparts in collaboration with like-minded organisations.

The EDCTP programme (2003-2013) has supported various projects under the following funding schemes:

- Integrated clinical trial projects on HIV/AIDS, tuberculosis, malaria (mainly phase II and III) that include project management, capacity building and networking activities
- Training awards including Masters, PhD and Fellowships
- Ethics and regulatory capacity strengthening
- General networking grants
- Regional Networks of Excellence
- Member States' Initiated projects
- Strategic primer grants.

Preparations are currently underway for a second EDCTP Programme (EDCTP2), which is expected to start in January 2014 under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

In preparation for the new programme, EDCTP wishes to hire the services of a firm to conduct a comprehensive evaluation of its performance and effectiveness to date in the carrying out of the current programme, which is now coming to an end.

Rationale and purpose of this assignment

This evaluation is aimed to provide EDCTP and its constituents [(EDCTP-EEIG General Assembly (GA), the Secretariat, and the Strategic Advisory Committee (SAC)] and stakeholders with the necessary information on the performance and impact of the programme from 2003 to date. The expected outcome of this assignment is the evaluation of the contribution of the programme to conducting of clinical research, strengthening of clinical research capacity and networking among researchers and institutions, especially in sub-Saharan Africa. Additionally, the assignment should also provide case reports of lessons learned and give recommendations that will contribute to the planning of EDCTP2 to ensure successful implementation of work plans as set out in the Strategic Business Plan.

Specific objectives

- Determine whether the different funding schemes have met their objectives
- Assess the output and outcome of the programme highlighting specific case studies documenting any outstanding successes or notable failures
- Assess the effectiveness, efficiency, relevance and potential sustainability of projects for each funding scheme
- Review the funding mechanisms, grant awarding and management process delineating any specific constraints and make recommendations where necessary.

Scope of work

The assignment will include undertaking the following:

(A) Evaluation of the performance in the execution of the programme

1. Review the EDCTP Joint Programme of Action (2003 version and 2007 revised version) and the corresponding 18 monthly Joint Programmes of Action B to verify whether the undertaken activities were according to the plan and the chosen key performance indicators were appropriate
2. Assess the progress made towards achieving the objectives set out in the EDCTP Joint Programme of Action. This will include a detailed review of the funding scheme objectives and what has actually been delivered in the following areas:
 - Clinical research activities
 - Regional Networks of Excellence
 - Capacity building
 - Networking and research integration efforts in Europe and Africa
3. Review of overall programme including project documentation, processes and actual projects implemented
4. Report on the efficiency of implementation of the programme by the EDCTP Executive Secretariat
5. Document specific success stories, opportunities, challenges and failures
6. Engage key EDCTP stakeholders including grantees, representatives of current and phased out EDCTP constituencies, research funding agencies, PDPs, pharmaceutical industry, regional bodies involved in health and research, government representatives within geographical area covered by EDCTP and the broader scientific community

(B) Impact of the programme on conducting of clinical trials

7. Assess the impact of the programme in the conducting of clinical trials in sub-Saharan Africa taking into account the investments made on personnel training and career development, infrastructure improvement and ethics and regulatory capacity strengthening
8. Evaluate the effect of the programme in the establishment and strengthening of south-south, north-north and north-south collaborations and partnerships
9. Assess the impact of the programme in inculcating African leadership and co-ownership
10. Assess the impact of the programme on health services at centres where clinical trials are conducted.

The final report should be sufficiently detailed to allow users to form a clear view on EDCTP's achievements and impact so far as well as lessons learnt and must cover the following areas:

Programme outcome and effectiveness on interventional areas

Policy and political level participation in the programme

- Political commitment of European and African governments
- Engagement with and buy-in from European and African policy makers
- Interaction with intergovernmental African initiatives e.g. Regional Economic Communities, NEPAD, African Union and WHO/AFRO.

Research activities especially clinical trials

The efficiency and effectiveness in terms of:

- Impact of project outcomes in demonstrating scientific/research excellence
- Impact of project results on informing of health policies at national, regional and global levels
- Impact of EDCTP on the acceleration and development of new or improved products or interventions, including contribution of research data towards prequalification by WHO and regulatory registration of products by African National Regulatory Authorities, European Medicines Agency (EMA) and United States Food and Drug Authority
- Anticipation and timely management of risk for projects that have failed to progress due to scientific, administrative, financial and managerial issues that may provide valuable insights for future course corrections
- Handling of projects which showed evidence of governance or management problems and assessment of how the important lessons learnt will inform future EDCTP guidelines and projects' oversight
- Relevance of the research to the health of people in the countries in which the research is undertaken
- Value for money.

Regional Networks of Excellence

The efficiency, effectiveness and sustainability of the networks of excellence in:

- Implementing network management with independent advisory structures
- Organising mentorship programmes and training of personnel working at African institutions where clinical trials are conducted
- Conducting epidemiological and demographic studies that facilitate the planning of trials
- Supporting less established institutions with additional expertise that enables them to participate in multi-centre clinical trials such as designing of trials, data management, financial management and administration, quality assurance and required laboratory techniques
- Attracting resources beyond EDCTP funding for the network
- Planning for sustainability of the established networks.

Capacity development in Africa

The efficiency and effectiveness of the capacity development initiatives in terms of:

- Impact of preparatory grants and site infrastructure development projects in promoting conduct of high quality clinical trials in Africa
- Quantitative and qualitative assessment of training supported under EDCTP through short-term training and long-term such as Masters, PhD, postdoctoral and Senior Fellowship schemes
- Retention and attraction of trainees and research fellows back to Africa (electronic tracer study to be used)
- Strengthening of African scientific leadership in international partnerships
- Promotion of scientific excellence of grantees with ability to produce high impact scientific publications and to acquire prestigious recognition awards for their contribution to the respective fields of research
- Establishment, strengthening and impact of the Pan-African Clinical Trials Registry
- Ethics review strengthening
- National Regulatory strengthening.

Networking and research coordination

The efficiency and effectiveness of the networking and research integration initiatives in terms of:

- Strengthening of research collaborations, partnerships, shared vision and alignment of research strategies in Europe (North-North)
- Strengthening of research collaborations, partnerships and coordination of research in Africa (South-South)
- Strengthening of research collaborations and partnerships between Europe and African scientists and institutions (North-South)
- Engagement of product development partners.

Programme execution, management and control

The efficiency and effectiveness of the programme execution, management and control in terms of:

Programme management and strategy

- European and African countries participation in the programme
- Governance and management structures
- Operational and financial planning of the programme
- Co-funding arrangements
- Mobilisation and involvement of third parties (like-minded public and private product development partners and funding agencies).

Programme implementation and activities

- Project delivery on core business of funding clinical trials in HIV/AIDS, tuberculosis and malaria
- Capacity building in African countries (qualitative and quantitative assessment of training and infrastructure development)
- Networking of European and African Programmes
- Advocacy for the EDCTP partnership
- Communication of the EDCTP partnership
- Resource mobilisation including engagement with like-minded organisations and the private sector
- Funding approaches used through open calls for proposals and brokering following stakeholder meetings
- Proposal review processes, process of costing activities and budget allocations and budget negotiation process.

Programme monitoring and evaluation

- Use of key performance indicators and their possible improvement
- Review of Project monitoring & evaluation systems
- Site visit activities, planning, reporting and follow-up
- Interaction process and sharing of information among EDCTP Executive Secretariat, EDCTP grantees, clinical trial sponsors and other partners actively involved in EDCTP funded projects
- Unplanned positive spin offs and negative side effects.

Output

The final output of the evaluation will be a comprehensive report clearly showing the progress made by EDCTP so far towards achieving the objectives set out in the EDCTP Joint Programme A and identify areas for improvement.

Timing

Should commence in December 2013 and be concluded by May 2014.

Qualifications of the evaluators

The evaluators must have the appropriate international experience and specific expertise necessary to conduct this assignment. Applications will be considered from consultants who have the necessary expertise to evaluate all aspects of the programme. The evaluators must have proven track record of programme evaluation including expertise in organisational management and scientific output evaluations. Experience of evaluating programme performance and impact in developed and developing countries will be advantageous.

Appendix C Evaluation questions and methodologies used

Topic	Evaluation questions	General desk research	LFA	Activity mapping	Financial/governance	Internal interviews	External interviews	E-survey	Case studies
Implementation of activities	What actions have been undertaken since 2003 to 2013, and were these according to the plan (Joint Programme of Action)?	✓	✓	✓		✓			
	What progress has been made towards achieving the objectives? What has been delivered in the different funding schemes in terms of outputs and outcomes? (clinical research activities, regional networks of excellence, capacity building, networking and research integration efforts in Europe and Africa)	✓	✓	✓		✓			
	What were unintended outcomes? (positive and negative?)	✓				✓	✓	✓	✓
	How effective and efficient was the implementation of the activities? Was it good 'value for money'?			✓		✓		✓	✓
	How relevant was the research undertaken to the health of people in the countries in which the research is undertaken?		✓					✓	✓
	What success stories and 'failures' can be identified? How were failures anticipated? What lessons can be learnt?	✓							✓
	What are the strengths, weaknesses, opportunities and threats of and for the programme?	✓				✓	✓	✓	
	What is the distribution of European and African countries involved in the programme (both in terms of funding contribution and project participation)?			✓	✓				
	To what extent are third parties reached and involved in the programme (both public and private product development partners and funding agencies)?			✓	✓				
Governance and management	Is the current governance and management structure of EDCTP effective and efficient?				✓	✓	✓		
	To what extent is the operational and financial planning of the programme accurate and optimal? What is the annual budget of EDCTP and how is it being allocated to the different activities? (projects, training, infrastructure, capacity building)			✓	✓	✓			
	How can the funding approach(es) be assessed? How effective and efficient are these processes? (proposal review, costing, budget allocations, budget negotiation)				✓	✓		✓	
	What are the co-funding arrangements made and have they been successful?			✓	✓	✓	✓		
	How were failures anticipated in particular (research) projects, for instance those that showed evidence of governance and management problems? What lessons can be learnt?				✓	✓		✓	
Communication and advocacy	What did EDCTP do to communicate to its stakeholders and a wider public about its programme and achievements? How can this be further improved?	✓		✓		✓	✓	✓	
	What has been done in terms of advocacy, and what were the effects? Can this be improved?	✓		✓		✓		✓	
	What can be learned from the internal communication interaction process and information sharing (including to partners, sponsors, grantees et cetera)	✓				✓	✓		

Topic	Evaluation questions	General desk research	LFA	Activity mapping	Financial/governance	Internal interviews	External interviews	Survey	Case studies
Monitoring and evaluation	Are the current Key Performance Indicators chosen appropriately? What can be improved?	√	√			√	√		
	What systems are in place regarding monitoring and evaluation of the projects including planning, reporting and follow-up? What can be improved?	√				√	√	√	
Policy and political level participation	What is the impact of the programme on African leadership, engagement and co-ownership? (African leadership can be referred to as scientific leadership)			√		√	√		√
	To what extent is there interaction between EDCTP and other (intergovernmental) initiatives in Africa? (e.g. Regional Economic Communities, NEPAD, African Union and WHO/AFRO).			√		√	√		
Research activities especially clinical trials	What is the impact in demonstrating research excellence?	√						√	√
	What impact has the programme on the acceleration and development of new or improved products/interventions, including contribution of research data towards prequalification by regulatory authorities?					√	√	√	√
	What impact has the programme on health policies at different levels, and health services at centres where clinical trials are conducted?					√	√	√	√
Regional Networks of Excellence	What is the impact: <ul style="list-style-type: none"> - On personnel working at African institutions where clinical trials are conducted? - Of studies conducted in the NoEs on the planning of clinical trials? - Of the NoEs on improving South-South collaboration among researchers and institutions? - Of the NoE on less established institutions? - On the availability of resources of the activities for the NoE? 	√				√	√	√	√
	How sustainable are the NoEs and their respective activities?					√	√	√	
Capacity development in Africa	What is the impact of the programme on the capacity to conduct clinical trials in sub-Saharan Africa? <ul style="list-style-type: none"> - On the quality of the research, e.g. publications in (high-impact) journals and scientific awards - On the quality and quantity of the training - On retention and attraction of trainees and research fellows - Strengthening of African leadership in international partnerships (e.g. participation and role in these partnerships) - Strengthening ethics review 	√				√	√	√	√
	What is the impact (added value) of the EDCTP funded Pan-African Clinical Trials Registry on registering clinical trials in Africa?	√				√	√	√	
Networking and research coordination	How effective and efficient are the networking and research integration activities based on the: <ul style="list-style-type: none"> - Strengthening of research collaboration and partnerships between scientists/institutions (north-north, south-south and north-south); - Establishment of a shared vision and alignment of research strategies in Europe (North-North); - Increased coordination of research in Africa (South-South); - Engagement of product development partners. - Resource mobilisation and engagement with like-minded organisations and the private sector 	√				√	√	√	√
	What can be learnt from best practices and worst cases for the implementation of the future strategy?	√				√	√	√	√
	What recommendations can be made based on the evaluation to EDCTP?	√				√	√	√	√

Appendix D EDCTP partner countries

D.1 European Participating States

Countries	EDCTP1	EDCTP2	Countries	EDCTP1	EDCTP2
Austria	✓	✓	Latvia		
Belgium	✓		Luxembourg	✓	✓
Denmark	✓	✓	The Netherlands	✓	✓
Finland		✓	Norway	✓	✓
France	✓	✓	Portugal	✓	✓
Germany	✓	✓	Spain	✓	✓
Greece	✓		Sweden	✓	
Ireland	✓	✓	Switzerland	✓	✓ aspirant
Italy	✓	✓	The United Kingdom	✓	✓

D.2 Sub-Saharan African countries

Countries	EDCTP2	Countries	EDCTP2
Angola		Madagascar	
Benin		Malawi	
Botswana		Mali	✓ aspirant
Burkina Faso	✓ aspirant	Mauritania	
Burundi		Mauritius	
Cameroon	✓	Mozambique	✓
Cape Verde		Namibia	
Central African Republic		Niger	✓
Chad		Nigeria	
Comoros		Rwanda	
Democratic Republic of Congo		Sao Tome and Principe	
Republic of the Congo	✓	Senegal	✓
Côte d'Ivoire		Seychelles	
Equatorial Guinea		Sierra Leone	
Eritrea		Somalia	
Ethiopia		South Africa	✓
Gabon		South Sudan	
The Gambia	✓	Sudan	
Ghana	✓	Swaziland	
Guinea		Tanzania	✓
Guinea-Bissau		Togo	
Kenya		Uganda	✓
Lesotho		Zambia	✓
Liberia		Zimbabwe	

Appendix E List of interviewees

E.1 Executive Secretariat EDCTP

Name	Position
Prof Charles Mgone	Executive Director
Mr Aboulie Barry	Director of Finance and Administration
Dr Michael Makanga	Director South-South Cooperation & Head of Africa Office
Dr Ole Oleson	Director of North-North Cooperation
Dr Thomas Nyirenda	South-South Networking Officer & Capacity Development Manager
Dr Gabrielle Breugelmans	North-North Networking Manager
Dr Pauline Beattie	Operations Manager
Dr Monique Rijks-Surette	Project Officer
Ms Nruaan Fakier	Project Officer
Dr Montserrat Blázquez Domingo	Project Officer
Ms Michelle Nderu	Project Officer
Ms Ana Lúcia Cardoso	North-North Networking Officer
Ms Lara Pandya	North-North Networking Officer
Mr Gert Onne van de Klashorst	Communication Officer
Ms Daniela Pereira-Lengkeek	Assistant Communications & IT Officer
Ms Chris Bruinings	Financial Officer
Ms Mary Jane Coloma-Egelink	Grants Financial Assistant

E.2 General Assembly (GA)

Organisation	Name	Position
Medical Research Council (UK)	Dr Mark Palmer	GA member United Kingdom (chair)
Instituto Superiore Di Sanita (IT)	Dr Stefano Vella	GA member Italy (vice-chair)
Deutschen Zentrum für Luft- und Raumfahrt e.V. (DE)	Dr Detlef Böcking	GA member Germany (vice-chair)
Institute for Tropical Medicine (BE)	Prof Bruno Gryseels	GA member Belgium (former vice-chair)
Swedish International Development Agency (SIDA) (SE)	Prof Hannah Akuffo	GA member Sweden (former chair)
Ministry of Health Welfare and Sports (NL)	Dr Marja Esveld	Former GA member The Netherlands (former vice-chair)
Instituto de Salud Carlos III (SE)	Dr Rafael de Andrés Medina	GA member Spain
Academy of Finland (FI)	Dr Sirpa Nuotio	GA observer Finland
East African Community (EAC)	Dr Stanley Sanoiya	Observer to the GA
WHO Regional Office for Africa (AFRO)	Dr Martin Ota	Observer to the SAB
Aspiring African Country (Zambia)	Prof Nkandu P Luo	Former DCCC member

E.3 Strategic Advisory Committee (SAC)

Organisation	Name	Position
London School of Hygiene and Tropical Medicine	Prof Shabbar Jaffar	Former chair interim SAC & former chair PB
Medical Research Council The Gambia	Prof Corrah	Chair SAC, former DCCC & PB member
University of Southampton	Prof Marie-Louise Newell	Member of SAC and interim SAC

E.4 European Commission

Organisation	Name	Position
European Commission - DG Development and Cooperation	Dr Eric Sattin	Observer to the GA

E.5 Other stakeholders (co-funding partners and host organisations)

Organisation	Name	Position
World Health Organization	Dr Vasee Moorthy	Technical Officer Initiative for Vaccine Research, Department of Immunization, Vaccines and Biologicals & Observer to the GA
Bill & Melinda Gates Foundation	Dr Siobhan Malone	Program Officer in the Global Health Program
Global TB Alliance	Dr Melvin Spigelman	President and Chief Executive Officer
Medicines for Malaria Venture (MMV)	Dr Tim Wells	Chief Scientific Officer
Wellcome Trust	Dr Val Snewin	International Activities Manager
European Vaccine Initiative (EVI)	Dr Odile Leroy	Executive Director & former EDCTP Executive Director
Internal Aids Vaccine Initiative (IAVI)	Dr Jill Gilmour	Executive Director Human Immunology Laboratory
NWO (host institution of the EDCTP Executive Secretariat in The Hague)	Dr ir Coenraad Krijger	Director Policy Development
Medical Research Council South Africa (host institution of the EDCTP Executive Secretariat in Cape Town)	Prof Glenda Gray	President

Appendix F Interview topics

Introduction

The European and Developing Countries Clinical Trials Partnership (EDCTP) invited the Technopolis Group to perform an evaluation of its entire first programme covering the period from 2003 to 2013. The evaluation takes place during the first half of 2014 and focuses on the three main components:

- A comprehensive evaluation of EDCTP's first programme's performance and effectiveness;
- The provision of case reports of lessons learned;
- Recommendations that will contribute to the planning and implementation of the second phase of EDCTP.

Individual responses will remain confidential and only reported on aggregated level. Only in case concrete examples are considered to be of added value to the overall evaluation, the evaluation team will explicitly ask for permission to use.

The interview is structured around a number of themes each consisting of a number of more in-depth questions. The themes are:

1. Implementation of the activities;
2. Governance and management;
3. Communication and advocacy;
4. Monitoring and evaluation;
5. Policy and political level participation
6. Impacts on each of the following levels;
 - Research activities especially clinical trials
 - Capacity development in Africa
 - Networking and research coordination
7. General opinion on EDCTP's performance;
8. Recommendations for improvement

Involvement of the interviewee with EDCTP

Could you briefly explain your involvement in EDCTP in terms of:

- Your background (current position, main duties and since when involved in EDCTP)
- The degree and focus of your involvement (more strategic or more operational)?

Implementation of the activities

EDCTP has a large variety of different activities (with a focus on clinical research activities, capacity building, regional networks of excellence, networking and research integration efforts in Europe and Africa)

- How do you assess the outcomes of these activities during the first phase of EDCTP (both positive and negative)?
 - How relevant was the research undertaken to the health of people in the countries in which the research is undertaken?
 - What success stories and ‘failures’ can be identified?
- How effective and efficient do you consider the implementation of the activities to be? Was it good ‘value for money’ or is there room for improvement?
- What would be your suggestions for improvement?

Governance and management

- Do you consider the current governance and management structure of EDCTP effective and efficient? Could you please explain?
 - Have the changes over time (in merging the different advisory boards – Partnership Board, Developing Countries Coordinating Committee to form the (Interim) Strategic Advisory Committee) led a better organised governance structure?
- Are the different co-funding arrangements clear to you/clear to work with and have they been successful in terms of budget allocation to EDCTP or its activities?
- What would be your suggestions for improvement?

Communication and advocacy

- How do you assess EDCTP’s communication approach to its stakeholders and wider public about its programme and achievements?
 - How can this be further improved?
- What has EDCTP done in terms of advocacy that you are aware of and what were the effects?
 - Do you think the advocacy can be improved?
- What can be learned from the internal communication interaction process and information sharing?

Monitoring and evaluation

- Are you familiar with the monitoring and evaluation approach of EDCTP (Key Performance Indicators)?
- What do you think of the current systems in place to monitor the progress of EDCTP (both on project and programme level)?
- What would be your suggestions for improvement?

Policy and political level participation

- To what extent is there interaction between EDCTP and other (intergovernmental) initiatives in Africa (e.g. the health arms of the Regional Economic Communities, the New Partnership for Africa's Development (NEPAD) Agency, African Union, African Governments and WHO/AFRO)?
 - Do you see any room for improvement in the involvement of African stakeholders? (which stakeholders)?

Impacts on research activities especially clinical trials

- From your point of view, what is the impact of EDCTP programme on the acceleration and development of new or improved products/interventions (including contribution of research data towards registration of new products or prequalification by WHO)?
- What impact has the programme on health policies and guidelines at different levels, and health services at centres where clinical trials are conducted?
- What would be your suggestions for improvement?

Impacts on capacity development in Africa

- From your point of view, what is the impact of EDCTP programme on the strengthening the capacity to conduct clinical trials in sub-Saharan Africa and how sustainable is it?
 - On the quality of the research, e.g. publications in (high- impact) journals and scientific awards
 - On the quality and quantity of the training
 - On retention and attraction of trainees and research fellows back to Africa
 - Strengthening of African leadership in international partnerships (e.g. participation and role in these partnerships)
 - Strengthening ethics review
- What is the impact (added value) of the EDCTP funded Pan-African Clinical Trials Registry (PACTR) on registration of clinical trials in Africa?
- What would be your suggestions for improvement?

Impacts on networking and coordination

- How effective and efficient are the networking and research integration activities based on the:
 - Strengthening of research collaboration and partnerships between scientists and institutions (North-North, South-South and North-South)
 - Establishment of a shared vision and alignment of research strategies in Europe (North-North)
 - Increased coordination of research in Africa (South-South)

- Resource mobilisation and engagement with like-minded organisations and private sector (non-profit organisations, foundations, philanthropic organisations, product development partners, pharmaceutical companies and SMEs)
- What would be your suggestions for improvement?

Regional Networks of Excellence (NoEs)

- Regarding the four regional networks of excellence (WANETAM, TESA, EACCR and CANTAM), what you think about EDCTP programme impact:
 - on personnel working at African institutions where clinical trials are conducted?
 - of studies conducted in the NoEs on the planning of clinical trials?
 - of the NoE on less established institutions?
 - on the availability of financial resources of the activities for the NoE?
 - on research infrastructures of the institutions involved (including equipment and systems)?
- In your opinion, how sustainable are the NoEs and their respective activities?
- What would be your suggestions for improvement?

General opinion on EDCTP's performance

- What is your general opinion on the effectiveness and performance of the first programme of EDCTP?
- What do you consider the Strengths, Weaknesses, Opportunities and Threats of and for EDCTP?

Concluding remarks

- Do you have any other remarks that you think are relevant and add value to this evaluation?

Appendix G Survey methodology and respondent characterisation

G.1 Survey methodology

As part of the evaluation of the first programme of EDCTP an electronic survey amongst both project coordinators and collaborators has been distributed. The survey has been accessible from the end of April till mid-June 2014. In this period all grantees has been invited by e-mail to participate in this evaluation by completing the survey. The survey has been available in two languages: English and French. In addition to the invitation that has been on 25 April, three reminders have been sent (5 May, 19 May and 28 May) in order to try to increase the response rate and collect as much information as possible.

Assessment of the performance and impact of EDCTP

Technopolis Group is an independent research and consultancy firm, which has been assigned by the European and Developing Countries Clinical Trials Partnership (EDCTP) to carry out the evaluation of the performance and impact of it's first programme that ran from 2003 to 2013.

You have been identified as a coordinator or participant to project [title of project]. As part of the evaluation, we kindly ask you to complete the following questionnaire regarding the project, its achievements and impacts and the EDCTP programme in general. A letter of recommendation signed by the Executive Director of EDCTP, Prof. Charles S. Mgone, is available through this link: http://www.technopolis-group.com/downloads/EDCTP_letter/. If you have been involved in more than one project we choose to keep the oldest one, to have more results on impacts.

To access the questionnaire please click on the following link or copy the link into the address bar of your internet browser: [link to the survey]

The questionnaire will take about 15 minutes of your time and will be online until mid-June 2014.

If you have any questions about the questionnaire or in case you encounter problems when filling it in please do not hesitate to contact the evaluation team at the Technopolis Group.

Thank you very much for taking the time to provide us with your input. We really appreciate your cooperation.

Yours sincerely,

Technopolis Group

The table below shows the response characteristics of both types of respondents (in absolute and relative figures). The overall response of the survey is 43.6% ($N=432$), for the coordinators the response is 59.5% ($N=101$), for the collaborators slightly lower with 39.9% ($N=138$). These response rates are above average based on experiences in other evaluations. In total 172 out of the 246 funded projects (close to 70%) are represented in the survey either by responses from the coordinators or collaborators.

Figure 61 Response characteristics of the survey

Type of respondent	Total number of invitations sent	Number of bounced invitations	Number of successful invitations sent	Response		# of projects represented
				#	%	
Coordinator	201	6	195	116	59.5%	101
Collaborator	873	78	795	317	39.9%	138
Total	1,074	84	990	432	43.6%	172

Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

G.2 Respondent characterisation

The majority of the responses (270 in total, which represents 63% of the overall responses) are derived from Africa (i.e. researchers working on EDCTP projects in African institutions). The country representation for the three country groupings (i.e. Africa, Europe and other) is listed in the following table.

Figure 62 Country representation in survey

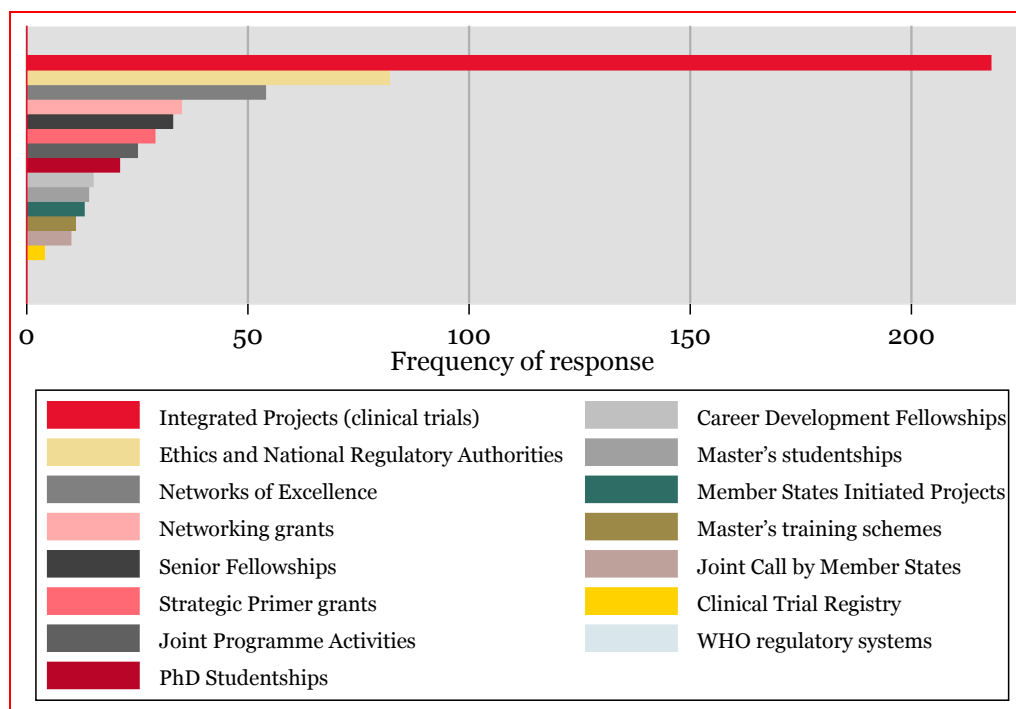
African countries	# of responses	European countries	# of responses	Other countries	# of responses
South Africa	37	United Kingdom	39	United States	11
Tanzania	32	Germany	20	Australia	1
Uganda	21	Belgium	15	TOTAL	12
Nigeria	20	France	13		
Ghana	13	Sweden	13		
The Gambia	13	Denmark	12		
Zimbabwe	13	Netherlands	10		
Kenya	12	Spain	9		
Cameroon	11	Switzerland	8		
Mali	11	Italy	6		
Burkina Faso	9	Ireland	2		
Ethiopia	9	Luxembourg	1		
Zambia	9	Norway	1		
Senegal	8	Slovakia	1		
Gabon	7	TOTAL	150		
Malawi	7				
Mozambique	6				
Benin	4				
Republic of the Congo	4				
Guinea	4				
Guinea-Bissau	4				
Democratic Republic of the Congo	3				
Rwanda	3				
Botswana	2				
Liberia	2				
Togo	2				
Egypt	1				
Madagascar	1				
Namibia	1				
Sudan	1				
TOTAL	270				

Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

Figure 63 below shows the involvement of the respondents in the different funding schemes of EDCTP. The large representation of the integrated projects is not surprising

given the large amount of researchers working on clinical trials. Overall all of the funding schemes are represented in the survey sample, which increases the reliability of the results.

Figure 63 Funding scheme involvement of respondents (multiple answers possible)



Source: Electronic survey amongst EDCTP grantees, analysis Technopolis Group (2014).

Appendix H Survey questionnaire

Introduction

This questionnaire is part of an independent evaluation of the performance and impact of the first programme of the **European and Developing Countries Clinical Trials Partnership (EDCTP)**. The evaluation should lead to recommendations about the future direction of the programme.

Technopolis Group, an independent research and consultancy firm, has been commissioned by EDCTP to carry out this study.

The success of this evaluation is to a large extent dependent upon data, information and feedback we are able to gather among stakeholders of the EDCTP programme. You have been identified by EDCTP as you were a one of the participants to the project entitled '[project title]'. Your input and opinion is of great value to the project and the future of EDCTP, therefore we would be very grateful if you could take some time to fill in this short questionnaire. A letter of recommendation signed by the Executive Director of EDCTP, Prof. Charles S. Mgone, is available through this link [link to letter].

The information provided through this questionnaire will be treated anonymously and presented on an aggregate level only. Your individual information will not be shared outside the independent study team for this evaluation. The aggregated results will be made available in a report to EDCTP.

The survey takes about 15 minutes and includes the following sections:

- Background information
- Characterisation of the project
- Motivation for the project
- Results and impacts from the project
- The EDCTP programme
- Communication and advocacy
- SWOT of the programme
- Recommendations to improve performance of the programme
- Final remarks

More information?

If you have any questions regarding the survey please do not hesitate to contact the questionnaire team at agathe.buffet@technopolis-group.com. In case you have any questions regarding the evaluation in general please contact Ms Soheir Dani (soheir.dani@technopolis-group.com) or Mr Bastian Mostert (bastian.mostert@technopolis-group.com).

Background information

Personal background of the respondent

- What is your age category?
 - Under 25
 - 25-34
 - 35-44
 - 45-54
 - 55-64
 - Over 65

- What is your highest finished level of education?
 - College/High School
 - Bachelor-level (tertiary education, first phase)
 - Master-level / MPH (tertiary education, second phase)
 - PhD

- What is your profession?
 - Specialised Medical Doctor
 - General Medical Practitioner (GP)
 - Nurse / Other Medical Professional
 - (Medical / PhD) Student
 - Policy Maker
 - Researcher
 - Monitoring and Evaluation specialist
 - Other... (please specify)

- At what type of organisation do you work (or study)?
 - University / Research Institute
 - Public Hospital / Clinic
 - Private Hospital / Clinic
 - Non-governmental Organisation
 - Government Administration
 - Other... (please specify)

- What is your nationality?

- In which country do you work?

- Which type of EDCTP scheme have you been involved in since the creation of EDCTP? (multiple responses are allowed)
 - Integrated Projects (clinical trials)
 - Senior Fellowships
 - Career Development Fellowships
 - PhD Studentships
 - Master's studentships
 - Master's training schemes
 - Ethics and National Regulatory Authorities
 - Clinical Trial Registry
 - WHO regulatory systems
 - Member States Initiated Projects
 - Joint Programme Activities
 - Joint Call by Member States
 - Networks of Excellence
 - Networking grants
 - Strategic Primer grants

Characterisation of the project

Please complete the following information regarding the project your involved in.

- Year of project initiation?
- Duration of the project (in months)?
- Please indicate the status of your project:
 - On-going
 - Nearly completed
 - Completed
- What percentage of your time has been spent on the project?
 - less than 10%
 - 10 to 25%
 - 25 to 50%
 - 50 to 75%
 - over 75%

- Which disease area/topic is addressed by your project?
 - HIV/AIDS
 - HIV/tuberculosis co-infection
 - Tuberculosis
 - Malaria
 - Ethics and regulatory
 - Other... (please specify)

- Which intervention is the focus of your project?
 - Treatment
 - Diagnostics
 - Vaccines
 - Microbicides
 - Other... (please specify)

Motivation for the project

- How did you first hear about the EDCTP programme?
 - Through another researcher/colleague
 - Through direct communication by EDCTP
 - Through direct communication by the national authorities
 - Through a conference that I attended
 - Through an on-line search for research funding opportunities
 - Other... (please specify)

- Who took the initiative to become involved in the project (to apply for research funding)?
 - Me personally, as the intended project coordinator
 - Another researcher from my institution
 - A researcher from another African institution
 - A researcher from another European institution

- To what extent have the following motivations to participate in this particular EDCTP project been applicable to you?

	Not at all	To a very small extent	To a small extent	To a moderate extent	To a large extent	To a very large extent
Develop a new medical product/treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to funds for clinical trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to physical research resources (laboratories, equipment, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to human resources	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Development of your own network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Collaborate with internationally renown researchers/institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increase your own research capabilities (training on clinical research)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training other researchers (senior and junior fellows)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training of students (MSc and PhDs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improve compliance with internationally accepted standards (through establishing ethical committees)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Get in contact with private partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Learn about latest technological developments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other... (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Results and impacts from the project

- Please indicate to what extent the following objectives apply to your project:

	Not at all	To a very small extent	To a small extent	To a moderate extent	To a large extent	To a very large extent
To perform clinical trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To strengthen the capacity in design of health policies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To strengthen the capacity in clinical research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To develop a network and increase research collaboration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To promote career development of researchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To build capacity in ethics and/or regulatory framework	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other... (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- What recommendations can be made to EDCTP in its second programme with regards to activities (focused at clinical trials, capacity building, networking, etc.)?
- To what extent did (or will) the project achieve its objective?
 - The project yielded results beyond expectation
 - The project met its objectives
 - The project largely achieved its objectives
 - The project only partly achieved its objectives
 - The project failed in reaching its objectives
 - N/A, please explain...
 -
- How relevant was the project undertaken to the public health needs in your country?

Very relevant	Relevant	Somewhat relevant	Not relevant
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If not relevant please briefly explain:

- To what extent did your project (or related findings) result in one of the following concrete results? (please tick box where relevant for each possible result)

Impact on clinical trial development

	N/A (this was not a project objective)	This result was not achieved	This result was partly achieved	This result was largely achieved	This result was achieved	This result was achieved beyond expectation
Development of a new medical product such as a drug or vaccine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improvement of existing medical intervention or product (more effective, safer, easier to use...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adaptation of existing medical intervention or product to the needs of specific vulnerable groups such as malnourished children or pregnant women	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Development of a more affordable medical product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Progress of a candidate product in clinical development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Impact on capacity development

	N/A (this was not a project objective)	This result was not achieved	This result was partly achieved	This result was largely achieved	This result was achieved	This result was achieved beyond expectation
Development of formalised training/education courses (diploma/certificate)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved training as a component of the project	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved and updated infrastructure and facilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Enhanced international competitiveness of African scientists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Led to knowledge sharing between all project participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Impact on health policies

	N/A (this was not a project objective)	This result was not achieved	This result was partly achieved	This result was largely achieved	This result was achieved	This result was achieved beyond expectation
Improved prevention of the disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Enabled better population surveillance and epidemiological monitoring/screening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved national/regional/local guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved national/regional/local policy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Impact on leadership, engagement and co-ownership

	N/A (this was not a project objective)	This result was not achieved	This result was partly achieved	This result was largely achieved	This result was achieved	This result was achieved beyond expectation
Generated a sense of ownership and partnership amongst stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Contributed to attract and retain scientific leadership in Africa	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stimulated a long term commitment of local authorities in capacity strengthening of clinical research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Impact on networking (coordination and integration)

	N/A (this was not a project objective)	This result was not achieved	This result was partly achieved	This result was largely achieved	This result was achieved	This result was achieved beyond expectation
Strengthened north-south cooperation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strengthened north-north cooperation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strengthened south-south cooperation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strengthened public-private cooperation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Involved strong partners from across Europe and Africa	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- How satisfied are you with the collaboration with the other partner researchers and institutions?

Very satisfied	Satisfied	Somewhat satisfied	Not satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If not satisfied please briefly explain:

- What will be the effect of your project on the longer term?

	Very limited effect	Limited effect	Large effect	Very large effect
Increased availability of the treatment/diagnostic/vaccine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased effectiveness of the treatment/diagnostic/vaccine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased efficiency of the treatment/diagnostic/vaccine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased safety of the treatment/diagnostic/vaccine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved competencies of the medical staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved health situation for the individual patient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved quality of life for the individual patient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased life expectancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reduction of the number of patients in hospitals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reduction of health care costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Earlier diagnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other... (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Did the project have any unintended outcomes (positive and/or negative)? Could you please briefly elaborate on these outcomes?

The EDCTP programme

- Overall, how satisfied are you with the communication and execution of the EDCTP programme?

Very satisfied	Satisfied	Somewhat satisfied	Not satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If not satisfied please briefly explain:

- Please indicate your level of agreement with the following statements about the funding process:

	Totally agree	Agree	Somewhat agree	Do not agree
The proposal review was transparent (clear definition of evaluation criteria, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The communication about the results of the review process (motivation for award or non-award)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The timing for the proposal review was appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project budget is sufficient to achieve the desired results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The budget allocation and negotiation led to a cost-effective allocation of funds per planned activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- What can be improved regarding the governance and management of the EDCTP programme?
- How satisfied are you with the systems in place for monitoring and evaluation of EDCTP projects?

	Very satisfied	Satisfied	Somewhat satisfied	Not satisfied
Clarity of indicators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Template for progress reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Timing of reporting (frequency)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Access to monitoring and evaluation outputs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- How can the monitoring and evaluation of projects be improved?

- How satisfied are you with EDCTP risk management processes:

	Very satisfied	Satisfied	Somewhat satisfied	Not satisfied
Identification of potential risks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analysis of risks during project progress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Response to reduce risk of project failure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Communication and advocacy

- How satisfied are you with EDCTP's communication efforts?

	Very satisfied	Satisfied	Somewhat satisfied	Not satisfied
Annual reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Newsletters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meeting reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Website	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Key documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Evaluation reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Please indicate your level of agreement with the following statements regarding EDTPC advocacy and external communication efforts (website, newsletter, press releases and announcements, publications, videos, media contact):

	Totally agree	Agree	Somewhat agree	Do not agree
EDCTP communication tools are relevant and of good quality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advocacy efforts contributed to expand and strengthen relationships with EU member states	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advocacy efforts contributed to expand and strengthen relationships African political and scientific leadership	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EDCPT is an attractive and visible player to the scientific community worldwide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EDCPT is an attractive and visible player to African health scientists, health officials and regional organisations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- What can be improved regarding EDCTP communication and advocacy activities?

Strengths and weaknesses of the programme

- Please assess the EDCTP programme in terms of key strengths:
- Please assess the EDCTP programme in terms of weaknesses (i.e. opportunities for improvement):

Final remarks

Thank you very much for participating in this survey. We would welcome any comments that you may have relating to this survey, our study or any other general comments.

- Please leave your comments here:

After submission, redirection to the website of EDCTP: www.edctp.org

Appendix I Case study South Africa

From Monday 28 April till Friday 2 May 2014 the evaluation team visited South Africa to meet EDCTP stakeholders and researchers to compile a country case study as part of the evaluation of the first programme of EDCTP.

I.1 South African participation in EDCTP projects

The figure below shows that South African institutions are involved in 65 out of the 246 projects (26%). A total of 40% of the projects are clinical trials and integrated projects, followed by fellowships and training grants (28%). In total 29 projects are coordinated by South African researchers, the majority are fellowships and integrated projects.

Figure 64 Participation of South African institutions in EDCTP projects

Grant scheme category	# of projects	# of coordinators	Total grant value	Total contribution to EDCTP
Clinical Trials and Integrated Projects	26	8	€36,599,034	€6,011,921
Strategic Primer Grants	5	4		
Fellowships and training grants	18	12		
Ethics and regulatory framework	9	3		
Coordination and integration	2	1		
Networking	5	1		
TOTAL	65	29		

Source: Information provided by EDCTP (2014).

I.2 Overview of the institutions visited

During the field mission, the following institutions have been visited, including the numbers of projects the institutions are involved in and people interviewed at the institutions. The three institutions are involved in 48 out of the 65 projects in which South Africa participates.

Figure 65 Overview of institutions visited and number of people interviewed

Date	Place	Name of institution	# of projects involved in	# of people interviewed
Tuesday 29 April	Cape Town	University of Cape Town	33	4
		South African Medical Research Council	13	3
Wednesday 30 April		University of Stellenbosch	19	8
Friday 1 May		University of Cape Town	33	3

Source: Technopolis Group (2014).

I.3 Background on the disease burden

This section presents some information on the health situation in South Africa, based on data provided by the World Health Organization. This information include figures on the general health profile of the country, the public spending on health and an overview

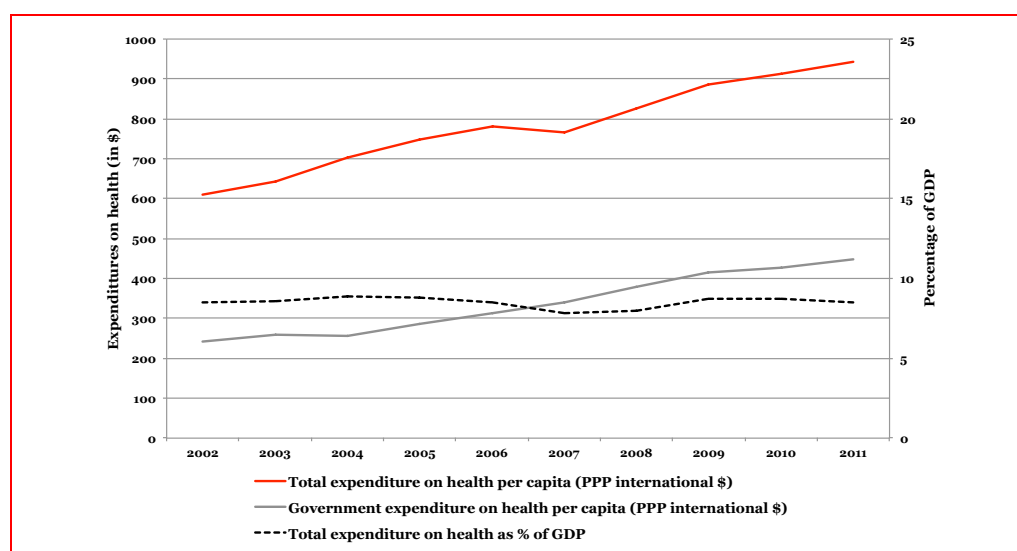
of the latest available figures on the disease burden on HIV/AIDS, tuberculosis and malaria.

Figure 66 General health profile of South Africa

	1990	1995	2000	2005	2010	2011	2012
Life expectancy at birth (M)	59	59	55	55	55	57	57
Life expectancy at birth (F)	67	67	59	59	59	60	60
Probability of dying under 5 years per 1,000 live births M/F	61	60	74	79	53	53	45
Probability of dying between 15 and 60 years per 1,000 populations M	334	334	457	457	457	474	474
Probability of dying between 15 and 60 years per 1,000 populations F	190	190	365	365	365	407	407

Source: Figures made available by WHO (2014).

Figure 67 Public spending on health in South Africa



Source: Figures made available by WHO (2014).

Figure 68 Disease burden of HIV/AIDS, tuberculosis and malaria in South Africa

	2010	2012
HIV/AIDS		
Number of people living with HIV/AIDS	-	5,700,000
Number of people newly infected with HIV/AIDS	-	370,000
Number of deaths due to HIV/AIDS (estimated)	-	240,000
Prevalence among adults aged 15 to 49 (%) (estimated)	-	17.9
Tuberculosis		
Incidence estimated	500,000	530,000
Mortality estimated	1,800	1,800
Prevalence estimated	410,000	450,000

	2010	2012
Malaria		
Cases reported	3,875	5,629
Deaths reported	83	72

Source: Figures made available by WHO (2014).

For the period 2012-2016 the South African government has fixed objectives in terms of fighting infectious diseases in The National Strategic Plan for HIV and AIDS, STIs and Tuberculosis⁴⁷. According to the researchers interviewed and health statistics, HIV/AIDS is the leading public health problem in South Africa, notably in the Western Cape, and is increasingly associated with tuberculosis co-infection.

According WHO's 2011 report on HIV/AIDS in Sub-Saharan Africa, HIV epidemic in South Africa is the most important in the world: the number of South African who were living with HIV in 2009 (estimated between 5.4 and 5.8 million) was equivalent to the whole HIV infected persons living in Asia⁴⁸. In 2010, half of the 1.2 million of Africans who died because of HIV were living in South Africa.

According to the *South African Health Review 2012-13*, in 2013, 9.3% of the total population was infected and according to WHO data in 2012, 17.9% of adults aged 15-49 were infected; some provinces are particularly concerned by HIV Prevalence: KwaZulu Natal (12.9%), North West (11.1%), Free State of Orange (10.4%), Gauteng (9.8%) and Mpumalanga (9.6%)⁴⁹

Nevertheless, healthcare has made some progress: the number of persons infected who have started a treatment increased by 43% between 2009 and 2010⁵⁰ and about 80% of infected people are covered by anti-retroviral therapy⁵¹ according to WHO in 2012.

South Africa is one of the countries the most affected by tuberculosis, with significant numbers of drug-resistant cases. An integrated approach to the management of HIV and TB is promoted in South Africa, but the health system remains fragmented.

Although treatment success rates in South Africa's public sector tuberculosis programme remain below target, the country has been recognised for the progress being made in relation to expanding access to isoniazid preventive therapy in HIV-positive patients. However, the diagnosis and management of children with tuberculosis remains challenging⁵².

There were 140 deaths due to tuberculosis per 100,000 people in 2009. The East of the country is more concerned than the West. KwaZulu Natal is the most concerned province, with a death rate of 197 per 100,000⁵³.

Although malaria is only endemic in three provinces (KwaZulu-Natal, Mpumalanga, Limpopo), cases are increasingly being reported in other provinces. Many of these patients appear to have contracted malaria in neighbouring countries, but sought care in South Africa (notably in Gauteng).

⁴⁷ http://www.sahivsoc.org/upload/documents/National_Strategic_Plan_2012.pdf

⁴⁸ http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.5_fre.pdf

⁴⁹ http://www.hst.org.za/sites/default/files/Chapter17_Indicators.pdf

⁵⁰ http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.5_fre.pdf

⁵¹ <http://apps.who.int/gho/data/node.country.country-ZAF>

⁵² http://www.hst.org.za/sites/default/files/Chapter17_Indicators.pdf

⁵³ http://www.hst.org.za/sites/default/files/Chapter17_Indicators.pdf

In 2012, there were 10.4 cases reported per 100,000 people. Some North-eastern territories are particularly concerned, like Mpumlanga (56.2 per 100,000), Limpopo (31.3) or Gauteng (10.2)⁵⁴.

I.4 Organisations visited

This section briefly introduces the organisations that have been visited in terms of their background, main (research) focus and current activities.

Traditionally the Western Cape is the region for health research, and the University of Cape Town (UCT) is ranked among the top-20 universities concerning medical research, and many interactions occur among researchers from the Western Cape, Pretoria and KwaZulu Natal.

University of Cape Town

The Department of Medicine of the University of Cape Town plays a role in medical education and research and provides clinical services. The department consists of 18 clinical divisions amongst which the Division of Infectious Diseases and HIV Medicine. Also ten major research units are part of the division, amongst which the Desmond Tutu HIV Research Centre, the Lung Infection and Immunity Unit. Overall the department has three activities:

- Education: with 33 doctoral, 77 Master and 936 undergraduate students in 2009;
- Clinical care: services provided in Groote Schuur Hospital (teaching hospital), in George Hospital (satellite training unit) and in other associated regional hospitals (GF Jooste Hospital, Somerset Hospital, Victoria Hospital and the UCT Private Academic Hospital);
- Research⁵⁵.

The Division of Infectious Diseases and HIV Medicine⁵⁶ offers inpatient and outpatient services at Groote Schuur Hospital, and outreach services to UCT's affiliated secondary level hospitals and primary health care clinics. The division is actively involved in clinical research, particularly in the fields of HIV, tuberculosis and travel medicine. The work of the division is heavily supported by funding from the President's Emergency Plan For AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID) and the ANOVA Healthcare Trust. The division is involved in a number of policy development initiatives as a consultative body for the Provincial Government of the Western Cape.

Undergraduate lectures are given to medical students in their clinical years and to students in professions allied to medicine.

The division is actively involved in research projects within HIV and tuberculosis fields, including a number of international collaborative projects. The division has collaborated with the Department of Transplant Surgery at Groote Schuur Hospital in pioneering the use of HIV-infected donor kidneys for transplantation into HIV-infected recipients, resulting in the first such transplant in the world.

The day-to-day work of the division is intimately integrated with that of the National Health Laboratory Service (NHLS) Departments of Microbiology and Virology, to provide a seamless infection service to the hospital. The division runs a same-day

⁵⁴ http://www.hst.org.za/sites/default/files/Chapter17_Indicators.pdf

⁵⁵ <http://www.medicine.uct.ac.za/med/about>

⁵⁶ <http://www.medicine.uct.ac.za/med/divisions/infectious>

inpatient consult service for Groote Schuur Hospital resulting in approximately 500 specialist consults per year. 80% of the work of the division is HIV-related, and occult tuberculosis infection is the commonest final diagnosis.

South African Medical Research Council

The South African Medical Research Council (SAMRC) was established in 1969 with the aim to deliver on a mandate to promote the improvement of health and quality of life of the population through research, development and technology transfer. The scope of the SAMRC's research includes basic laboratory investigations, clinical research and public health studies. Research at the SAMRC focuses on the top ten causes of death in South Africa including tuberculosis and HIV⁵⁷.

The SAMRC's HIV Prevention Research Unit is based in Durban – the largest city of the highest infected population rate province. Its mandate is to address women's vulnerability to HIV through a comprehensive research program consisting of epidemiological, behavioural, basic science and clinical studies⁵⁸.

The SAMRC's Centre for Tuberculosis Research is housed in the Faculty of Health Sciences at the University of Stellenbosch (see below). The centre provides a teaching and research environment to approximately 50 scientists, technicians and postgraduate students. Visitors from Europe, the United States and other African countries also pursue specific research and training projects at the Centre⁵⁹. The recently appointed president of the SAMRC, Prof. Glenda Gray, is the winner of EDCTP Outstanding Scientist Award in 2013.

University of Stellenbosch

The Faculty of Medicine and Health Sciences of Stellenbosch University has ten academic departments⁶⁰. The Department of Medicine has a Division devoted to infectious diseases⁶¹. The University of Stellenbosch is actively involved in teaching infectious diseases. Outpatient services of the division are based at the Infectious Diseases Clinic in Tygerberg Hospital. The division realises outpatients' initiation and monitoring of anti-retroviral therapy in advanced HIV disease, HIV and pregnancy, HIV and renal disease, and HIV and liver disease. Inpatient services include antibiotic control and clinical infection diseases consults to all departments of Tygerberg Hospital. The Division of Infectious Diseases has a standard HIV antiretroviral rollout clinic including Prevention-of-Mother-To-Child-Transmission (PMTCT), a clinic for complicated infectious diseases problems (including HIV and tuberculosis), and a dedicated clinic for primary immunodeficiencies. There is also an active infectious diseases outreach service to the towns of Paarl, Stellenbosch, Worcester, Malmesbury and Khayelitsha. Staff is involved in research projects on:

- TB/HIV co-infection and TB-IRIS (Immune Reconstruction Inflammatory Syndrome);
- HIV renal disease;
- TB infection prevention and control;
- HIV and pregnancy;

⁵⁷ <http://www.mrc.ac.za/>

⁵⁸ <http://www.mrc.ac.za/hiv/hiv.htm>

⁵⁹ <http://www.mrc.ac.za/molecular/molecular.htm>

⁶⁰ <http://www.sun.ac.za/english/faculty/healthsciences/academic-departments>

⁶¹ <http://www.sun.ac.za/english/faculty/healthsciences/medicine/divisions/infectious-diseases>

- Viral Hepatitis in HIV;
- HIV clinical trials;
- HIV epidemiology;
- Primary immunodeficiency;
- Transplant infectious diseases;
- HIV rapid assessment.

I.5 Results and impact achieved by the projects

This section presents the results and impact achieved by the projects collected during the visit, clustered around research activities, especially clinical trials, capacity development and sustainability and networking and research coordination.

In general terms, EDCTP got support from African countries, notably thanks to the support of Dr. Pascoal Mocumbi, former President of Mozambique and High Representative for EDCTP during its first phase (he took his leave from the position at the end of 2013). Dr. Mocumbi did much in the ground breaking work of destigmatising clinical trials and bringing confidence to scientists across Africa, bridging language and culture barriers.

Among these African countries, South Africa has the highest rate of participation in EDCTP funded projects, before Tanzania, mostly linked to the excellence of its research and the quality of its research infrastructure. The University of Cape Town is the biggest recipient of EDCTP funds. The focus on the Western Cape universities is quite strong. Many researchers have been distinguished, for instance by the EDCTP awards for outstanding scientists.

Impact on research activities, especially clinical trials

While the US Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) largely fund biomedical research, clinical trials were not easily funded before EDCTP started its interventions in South Africa and Africa in general. EDCTP has funded a wide range of clinical trials and research activities in South Africa, in the field of HIV, tuberculosis and co-infection and delivered a number of patents and publications.

No new tuberculosis vaccine was found, but one clinical trial allowed adjustment to the treatment course of tuberculosis (dosage of drugs and length of treatment) and this was adopted by WHO and modified WHO guidelines and several government guidelines for treatment of tuberculosis.

Concerning HIV, one of the major breakthroughs so far is on adolescent health. Adolescent health was not well defined and described in Africa, while it is a key population affected by HIV and tuberculosis. Thanks to research conducted under EDCTP, the South African Minister of Health has put adolescent sexual and reproductive health higher on the agenda. HIV vaccine is now being rolled out at the right time with the right focus. Very few funders take the risk to fund such type of research. All aspects of clinical research have been taken on board (behavioural, legal aspects, et cetera) and the principal investigator is now consulted internationally for clinical research in this area.

EDCTP has set credibility of many South African researchers whom could subsequently apply to NIH grants and continue their work. Additionally, EDCTP indirectly did much for the legitimisation of the Medical Research Council of South Africa.

Nevertheless, some interviewees stated that in EDCTP mechanisms of selection of trials, there shall be a global understanding of the whole field, and an additional step of careful

analysis of which product shall be funded. This implies funding of clinical trials that fit into a global agenda with a likelihood to have an impact on population's health on the longer term, but are not be especially aligned with the Bill & Melinda Gates Foundation.

Impact on capacity development and sustainability

Impact on capacity development is considered as tremendous as a high number of researchers (Masters, PhDs, Postdocs) and health professionals have been trained on EDCTP projects. Not only medical officers, but also nurses have developed clinical trial knowledge and deal with the requirements. Even though the level of expertise and funding for researchers in South Africa is much higher than in other African countries, EDCTP still made a difference to the clinical trial field and trainees acknowledge that.

Personal career of trainees is developing quite well, but the challenge is sustainability and also to give the next generation some space. Clinical trial sites are being set up, but there is a threat that they might not have future work once a project ends, and that trained staff would leave the site.

Ethical legal framework implementation is part of the whole capacity building as each site which has carried out clinical trials had gone through a specific training programme, unpacking the ethical legal component which has later become a best practice, later shared with other African countries such as Kenya for example.

Another field that benefited much from EDCTP funding is research ethics. A book on the history of research ethics in Africa was produced under EDCTP funding. 27 chapters into 4 sections tackling the history of research ethics in Africa and basic principles, how research committees work, all issues applicable to research and education priorities for Africa and Africans. The book is free of charge, will be available for downloading from the internet is expected to be translated in French and Portuguese. This book presents for the first time what is the African perspective on research ethics and breaks from the American and European streams.

Impact on networking and research cooperation

The Trials of Excellence in Southern Africa (TESA), one of the four Networks of Excellence funded by EDCTP was initially set up and funded under a call from EDCTP with the goal to respond to several identified gaps in the sub-region, i.e. capacity building in laboratory and in clinical trials, notably in tuberculosis (while HIV was quite established), networking the trials, bridging gaps between several research projects and infrastructure support. The network was initially lead by the Medical Research Council but was later on transferred to the University of Stellenbosch.

The network has had tremendous difficulties in implementing activities, due to weaknesses in communication and actual engagement of project leaders in several of the partnering countries.

The added value of the TESA network for South African researchers could have been mainly of two quite different nature:

1. The first one being that it feeds the passion of researchers for health issues they tackle, as they transfer their knowledge to other researchers whom they train thanks to TESA; and
2. The second one lying in the need of funds collection, less acute in South Africa than in other African countries, but similar in any research laboratory across the world.

Nevertheless many interviewees concur that TESA did not achieve much. It is perceived as a forced collaboration between partners who are exclusive of others.

The Pan African Clinical Trial Registry (PACTR) is on the opposite considered as a brilliant idea with much success to date and quite some potential for the future. It was

set up and implemented by the Medical Research Council. It has an agreement by the WHO as one of the world's primary registries and provides a view of on-going African clinical trials. There was no visibility of what happens in the area of clinical trials at the level of the African continent at all before its implementation. A proof of its utility is that the Ministry of Health of South Africa recently decided to merge and replace its National Registry with PACTR.

Researchers mention being quite interested in following clinical trials being registered on PACTR. Another registry is ClinicalTrials.gov from the National Institutes of Health, but PACTR starts to have much importance for African researchers.

I.6 The process of implementation of EDCTP's activities

There is wide acknowledgment from all interviewees that after a difficult start, EDCTP became very well tuned and that support provided to researchers, grantees and administrator is almost optimal.

Dissemination of information concerning EDCTP is well appreciated, notably the electronic newsletter. The Ministry of Science and Technology of South African will soon hold a conference in participating to Horizon 2020, which prove the visibility that EDCTP has acquires, even though budgets available for research from EDCTP are quite smaller than these of other type of funders (i.e. NIH, Bill & Melinda Gates Foundation).

EDCTP's focus on what other funders do not support is a very good thing: clinical trials and ethics capacity building.

EDCTP stimulates cooperation and partnership and in such a way it is quite different from other funders. This is considered so beneficial, as well as the fact that EDCTP does not require a European principal investigator. For many African researchers, this is a good and non-colonial way of working, and considered as the only right way to do. EDCTP is relatively hands off in terms of implementation, which is quite appreciated by researchers.

Some interviewees nevertheless mention that it would have been good if there were room for extra funding application as their research were often constrained by tight budgets.

I.7 General opinion on EDCTP's performance by interviewees

Even though the Bill & Melinda Gates Foundation funds 65% of the product development in HIV/AIDS, tuberculosis and malaria, and not all interviewees reckoned the impact of EDCTP in Africa, as some did not know much about EDCTP at all, the research funded by EDCTP is perceived as big promise of impact on health policy.

EDCTP has funded ideas that have emerged from African researchers. These are local questions, local needs. EDCTP is an added value to the medical research, as it funds different projects than BMGF and NIH, and while PEPFAR stopped recently. Keeping a focus on clinical trials is a differentiation mark, and key to achieve global impact.

EDCTP has come a long way and has still long to go. Translating EDCTP in terms of health impacts is still quite difficult today, as it would need 20 years looking back to do so.

It would be good for EDCTP to fund research in Africa to better define the public health problems, the needs, develop diagnostics for tuberculosis (which could make a big difference in the future). The clinical trials shall inform policy. Today HIV research is more funded than tuberculosis research, which does not match the burden of disease in South Africa, as the biggest cause of death is tuberculosis. Project selection is key to success for a programme such as EDCTP and some interviewees call for better attention to this.

Strengths

- The funding mechanism of EDCTP, which is broader than just research ideas, also covering capacity development and networking.
- The fact that EDCTP also funds African principal investigators is different from other funders, which is a good thing.
- EDCTP funds research that emerged from African researchers, not defined in Europe.
- Created the opportunity to develop new research areas, that is still evolving (e.g. on tuberculosis).
- The combination of both fellowships and large-scale projects is very much appreciated, however the mid-level fellowship is an important gap that is missing (the career development fellowships).
- The Strategic Primer Grants are awarded positively, however the duration of three years to conduct the study is sometimes too short.
- The PACTR is considered to be real good idea (compliance with WHO requirements), but can be exploited more.
- EDCTP has brought a model that is easily transportable to the rest of the world.
- EDCTP is a good exposure.

Weaknesses

- The co-funding arrangements are sometimes difficult for grantees to deal with, especially for those institutions that lack the financial resources. Other financial aspects like exchange rate issues are sometimes causing challenges.
- Not everyone is aware of the existence and added value of PACTR.
- TESA is facing some challenges (not all institutions are aware of the network, not all institutions are part of the network, not easy to organise meetings with all countries due to travel problems and the added value is unclear).
- Not enough time or funding devoted for paper writing.

Recommendations

- EDCTP should pay attention to continuity (a horizon of grants) as essential in maintaining the research and capacity that has been built.
- Having not two European principal investigators, but giving African the chance to become a principal investigator himself (with mentoring) is a good way to sustain the capacity that has been built.
- EDCTP, as a precondition to renew funding the TESA Network of Excellence, shall require engagement from all partner organisations.
- EDCTP could strengthen the communication towards all potential stakeholders in informing them about the existence of PACTR and its benefits.
- As real impact is not expected right after the end of a project, the follow up of progress after project has been finished (i.e. 3 years) is something for EDCTP to think of when further developing a monitoring and evaluation strategy. A suggestion to follow up on longer-term impacts could be to request an impact report 3 years after the end of the project.

- In addition to the current electronic newsletter on EDCTP in general, EDCTP could provide specific information through electronic communication to dedicated target groups (e.g. Senior Fellows)
- EDCTP could better align to national projects, to Medical Research Council portfolios in order to support a critical mass of research in priorities in the national health policies agendas.
- Quality assurance of clinical trials is an issue and has to be strengthened in the future. Data management systems in clinical trial, strengthening the regulatory capacity, improving biostatistics are additional opportunities for EDCTP funding.
- EDCTP could fund research on research ethics, as the first steps that have been undergone so far have raised interest in research ethics. It is an opportunity to go further.
- EDCTP could link up the senior fellows that have been funded during its first programme and create a network of them in order to keep them linked to the programme.

I.8 Programme and overview of interviewees

Tuesday 29 April

University of Cape Town, Faculty of Health Sciences

Cape Town

Time	Name of interviewee	Role at institution/involvement in project
09.00 – 10.00	Prof Linda-Gail Bekker	Coordinator Integrated Project (SASHA)
10.00 – 11.00	Prof Keertan Dheda	Senior Fellow, Coordinator Integrated Project (TB NEAT), Collaborator Integrated Project (PanACEA-SQ109) and Collaborator Trials of Excellence for Southern Africa (TESA)
11.00 – 12.00	Dr Catherine Orrell	Senior Fellow and Collaborator Career Development Fellow (Molebogang Rangaka)
12.00 – 13.00	Dr Graeme Meintjes	Coordinator Strategic Primer Grant (PredArt) and winner of the EDCTP Rising Star Scientist award 2013

Medical Research Council South Africa

Cape Town

Time	Name of interviewee	Role at institution/involvement in project
14.00 – 15.00	Dr Glenda Gray	Current President of Medical Research Council South Africa (host institution of EDCTP), Collaborator Integrated Project (SASHA) and winner of the EDCTP Outstanding Scientist Award 2013
15.00 – 16.00	Dr Nireesh Bhagwandin	Head of Strategic Research Initiatives and focal person for EDCTP
16.00 – 17.00	Dr Roxana Rustomjee	Collaborator Networking Grant (Amina Jindani)

Wednesday 30 April

University of Stellenbosch, Faculty of Medicine & Health Science

Cape Town

Time	Name of interviewee	Role at institution/involvement in project
10.00 – 11.00	Prof Paul Van Helden	Head of Department of Tuberculosis and Coordinator Integrated Project (TB SurMark)
11.00 – 12.00	Prof Gerhard Walzl	Coordinator Integrated Project (AE TBC), Coordinator Trials of Excellence for Southern Africa (TESA), Collaborator Integrated Project (TB SurMark), Collaborator Member States Initiated Project (TBTEA), Collaborator Senior Fellow (Wendy Burgers)
12.00 – 13.00	Prof Jimmy Volmink	Dean of the Faculty of Medicine & Health Science, Co-director MRC South Africa Cochrane Centre, Coordinator Pan African Clinical Trial Registry (PACTR) and Collaborator Ethics Project (Moodley-ERECCA-Ethics)
	Dr Tamara Kredo	Co-director MRC South Africa Cochrane Centre and Collaborator Pan African Clinical Trial Registry (PACTR)
14.00 – 15.00	Prof Andreas Henri Diacon	Senior Fellow and Collaborator Integrated Projects (PanACEA-SQ109, PanACEA-HIGHRIF and REMox I and II)
15.00 – 16.00	Prof Jean Nachega	Senior Fellow
16.00 – 17.00	Prof Mariana Kruger	Coordinator Ethics Project (Kruger-SAREN-Ethics) and Collaborator Ethics Projects (Wassenaar-SARECCER-Ethics and Atashili-Buea-Ethics)
	Dr Lyn Horn	Collaborator Ethics Projects (Kruger-SAREN-Ethics and Moodley-ERECCA-Ethics)

Friday 2 May

University of Cape Town, Faculty of Health Sciences

Cape Town

Time	Name of interviewee	Role at institution/involvement in project
09.00 – 10.00	Dr Mark Hatherill	Senior Fellow, Coordinator Integrated Project (AERAS 402/Crucell Ad35), Collaborator Integrated Project (Rifaquin)
10.00 – 11.00	Prof Gary Maartens	Collaborator Integrated Projects (CHAPAS-3, PPK.DDK - HIV and TB medications, Rifaquin), Collaborator Strategic Primer Grants (Li in HAND & PredART), Collaborator Senior Fellow (Catherine Orrell) and Collaborator Career Development Fellow (Molebogang Rangaka)
11.00 – 12.00	Dr Wendy Burgers	Senior Fellow

EDCTP, Executive Secretariat (Africa Office)

Cape Town

Time	Name of interviewee	Role at institution/involvement in project
13.30 – 14.30	Ms Nuraan Fakier	Project Officer
14.30 – 15.30	Dr Thomas Nyirenda	South-South Networking & Capacity Development Manager
15.30 – 16.30	Dr Michael Makanga	Director South-South Cooperation and Head of Africa Office

Appendix J Case study Republic of the Congo

From Monday 26 till Wednesday 28 May 2014 the evaluation team visited Brazzaville (Republic of the Congo) for a case study as part of the evaluation of the first programme of EDCTP.

J.1 Congolese participation in EDCTP projects

The figure below shows that Congolese institutions are involved in 3 out of the 246 projects: one senior fellow, one ethics grant and the participation in the Central African Network of Excellence (CANTAM). The first two projects are coordinated by a Congolese researcher.

Figure 69 Participation of Congolese institutions in EDCTP projects

Grant scheme category	# of projects	# of coordinators	Total grant value	Total contribution to EDCTP
Clinical Trials and Integrated Projects	0	-	€1,899,607	€150,000
Strategic Primer Grants	0	-		
Fellowships and training grants	1	1		
Ethics and regulatory framework	1	1		
Coordination and integration	0	-		
Networking	1	0		
TOTAL	3	2		

Source: Information provided by EDCTP (2014).

J.2 Overview of institutions visited

During the visit the following institutions have been visited, including the numbers of projects the institutions are involved in and people interviewed at the institutions. The five institutions visited are involved in all three projects in which the Republic of the Congo participates.

Figure 70 Overview of institutions visited and number of people interviewed

Date	Place	Name of institution	# of projects involved in	# of people interviewed
Tuesday 26 May	Brazzaville	Université Marien Ngouabi	0	1
		Centre d'Etudes sur les Ressources Végétales (CERVE)	3	1
		Fondation Congolaise pour la Recherche Médicale (FCRM)	0	2
Wednesday 27 May		Fondation Congolaise pour la Recherche Médicale (FCRM)	0	2
		Laboratoire National de Santé Public	3	2
		Centre Anti Tuberculeux	0	1
		Ministry of Research and Innovation	0	5
		Fondation Congolaise pour la Recherche	0	1

Date	Place	Name of institution	# of projects involved in	# of people interviewed
Thursday 28 May		Médicale (FCRM)		
		World Health Organization, Regional Office for Africa	0	1
		Comité d'Ethique de la Recherche en Sciences de la Santé	1	1
		Fondation Congolaise pour la Recherche Médicale (FCRM)	0	3

Source: Technopolis Group (2014).

J.3 Background on the disease burden

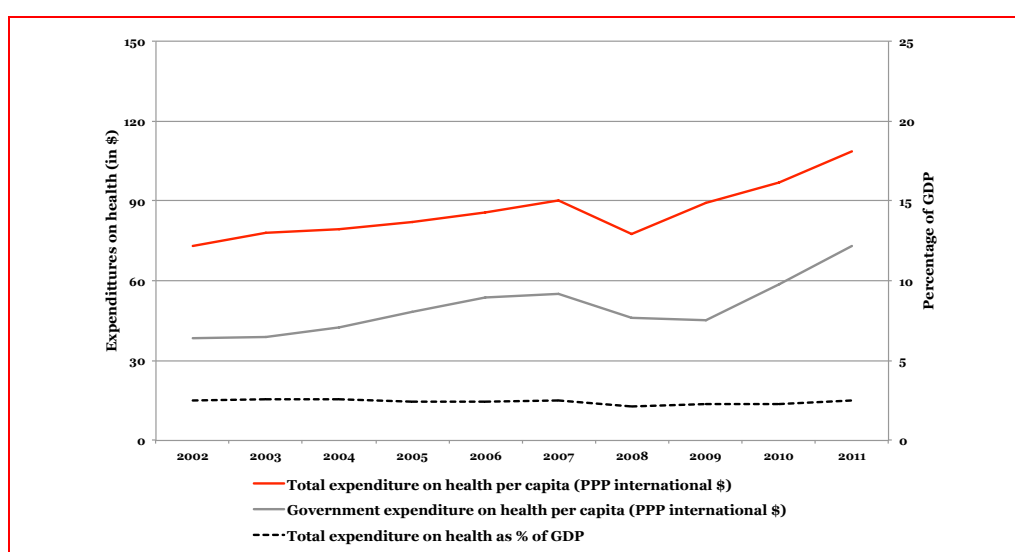
This section presents some information on the health situation in the Republic of the Congo, based on data provided by the World Health Organization. This information include figures on the general health profile of the country, the public spending on health and an overview of the latest available figures on the disease burden on HIV/AIDS, tuberculosis and malaria.

Figure 71 General health profile of Republic of the Congo

	1990	1995	2000	2005	2010	2011	2012
Life expectancy at birth (M)	55	55	53	53	53	57	57
Life expectancy at birth (F)	58	58	55	55	55	59	59
Probability of dying under 5 years per 1,000 live births M/F	100	110	118	113	102	102	96
Probability of dying between 15 and 60 years per 1,000 populations M	364	364	409	409	409	332	332
Probability of dying between 15 and 60 years per 1,000 populations F	291	291	369	369	369	287	287

Source: Figures made available by WHO (2014).

Figure 72 Public spending on health in Republic of the Congo



Source: Figures made available by WHO (2014).

Figure 73 Disease burden of HIV/AIDS, tuberculosis and malaria in Republic of the Congo

	2010	2012
HIV/AIDS		
Number of people living with HIV/AIDS	-	61,000
Number of people newly infected with HIV/AIDS	-	4,700
Number of deaths due to HIV/AIDS (estimated)	-	5,200
Prevalence among adults aged 15 to 49 (%) (estimated)	-	2.8
Tuberculosis		
Incidence estimated	16,000	17,000
Mortality estimated	1,800	1,800
Prevalence estimated	23,000	23,000
Malaria		
Cases reported	-	3,717
Deaths reported	-	623

Source: Figures made available by WHO (2014).

In 2012, the life expectancy at birth in the Republic of the Congo was about 57-60 years. The mortality rate of children under 5 of age was in 2012 at 96‰, which is very high⁶².

WHO's data shows a strong link between HIV/AIDS and tuberculosis: 33% of tuberculosis patients are also HIV-positive. In 2012, the mortality rate due to HIV and tuberculosis was of 24 per 100,000 people. Moreover, 3,600 new cases of HIV/TB were detected in Congo in 2012, which represent a rate of 83 persons per 100,000 people⁶³.

AIDS appeared in Congo in 1984. In 2003, the Republic of Congo founded the Centre National de Lutte contre le SIDA, a national agency specialised on AIDS issues⁶⁴. A HIV prevalence survey was published in 2009 by the national health authorities. According to this survey, 3.2% of population aged between 15-49 years were HIV positive (women were twice more concerned than men)⁶⁵. In 2012, this rate was down to 2.8%⁶⁶. Nevertheless, 74,000 people are still living with HIV in Congo (2012) and AIDS caused about 5,200 deaths⁶⁷.

In 2006, 18,035 cases of tuberculosis were detected in the Republic of the Congo. This represents a rate of 464 cases per 100,000 people. The number of detected cases increased to 1,179 in 1992, then to 9,959 cases in 2005. The periodic wars waged in Congo contributed to a degradation (abandonment of treatment, malnutrition, health infrastructure destructions...)⁶⁸. A National TB Programme, started in 1980, contributed to create a tuberculosis centre in each department of the country⁶⁹. In 2013, 1.8 million \$

⁶² <http://www.who.int/countries/cog/en/>

⁶³ https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=CG&outtype=html

⁶⁴ <http://www.unaids.org/en/regionscountries/countries/congo/>

⁶⁵ <http://www.cnsee.org/pdf/RapSyntESISC.pdf>

⁶⁶ <http://www.unaids.org/en/regionscountries/countries/congo/>

⁶⁷ <http://www.unaids.org/en/regionscountries/countries/congo/>

⁶⁸ <http://www.afro.who.int/fr/congo/programmes-pays/3260-tuberculose.html>

⁶⁹ <http://www.afro.who.int/fr/congo/programmes-pays/3260-tuberculose.html>

was allocated to the National TB Programme (59% were funded domestically, and 41% internationally)⁷⁰.

Concerning malaria, according the French government, the Republic of the Congo is ranked 3 on a 4-step scale⁷¹.

J.4 Organisations visited

This section briefly introduces the organisations that have been visited in terms of their background, main (research) focus and current activities.

The Fondation Congolaise pour la Recherche Médicale (FCRM), Université Marien Ngouabi

The Fondation Congolaise pour la Recherche Médicale (FCRM) is a not-for-profit organisation created in 2008 with the aim to support medical research in the Republic of the Congo. The organisation was created in cooperation with the Université Marien Ngouabi with the aim to develop research activities in the university and reduce local risks related to this goal. Local risks include lack of financial support and infrastructure for research, lack of competencies, and inefficiency of administrative institutions that are not used to manage funds and projects.

The FCRM was launched after the submission of the project to EDCTP. The organisation manages projects supported by EDCTP and other donors. Its current director Prof. Francine Ntoumi is the coordinator of the Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM), one of the Networks of Excellence funded by EDCTP. She holds a PhD in molecular biology from Paris VI (Pasteur) and has contributed to the creation of EDCTP.

The FCRM is located at the Université Marien Ngouabi together with the laboratory of molecular biology it has set up with EDCTP's support.

Comité d’Ethique de la Recherche en Sciences de la Santé (CERSSA)

The Comité d’Ethique de la Recherche en Sciences de la Santé (CERSSA) is the ethics committee set up at institutional level. It is attached to the Ministry of Research and has 15 members. The committee is operational since 2009. Its members gather once a month to review research protocols submitted to the committee. In 2012 a proposal was submitted to EDCTP to support the committee's development: to have a working space, office equipment, internet access and ethics training for its members, Congolese researchers and students. In the past 2 years CERSSA has received 25 to 30 protocols. The committee evaluates scientific and ethics aspects. For international projects it also ensures that the projects include a national co-investigator. CERSSA also communicates information and guidelines on ethics and how to set up a scientific project to higher education and research organisations.

Laboratoire Nationale de Sante Publique (LNSP)

The Laboratoire Nationale de Sante Publique (LNSP) is a public body in charge of medical biology analyses. The laboratory's mission is to carry out studies, research and analysis to deal with public health issues, to define national standards in biology and to

⁷⁰ https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=CG&outtype=html

⁷¹ <http://www.diplomatie.gouv.fr/fr/conseils-aux-voyageurs/conseils-par-pays/congo-12306/>

ensure quality control of public and private laboratories located in Congo the Republic of the Congo.

LNSP also advises the Ministry of Health and is responsible for quality control of environment (water, air, soil, food and medications).

The laboratory is not a direct beneficiary of EDCTP funds, but some of the staff member have been involved in projects funded by EDCTP. Its director of research is a member of CERSSA. He benefited from trainings in the field of ethics and facilitated training sessions on ethics himself. In addition the laboratory's technician took part in Dr. Ndounga's project through analysis of biology samples but did not benefit from EDCTP trainings.

Centre d'Etudes sur les Ressources Végétales (CERVE)

The Centre d'Etudes sur les Ressources Végétales (CERVE) is a public body created in 1985 to conduct scientific studies and research on vegetal resources. The centre's missions include:

- Floristic and plant inventory in Congo;
- Studies on medicinal properties of plants;
- Characterisation and study of ecosystems;
- Exchange of plant material with foreign laboratories.

CERVE benefits from EDCTP funds through CANTAM (220K€).

WHO Regional Office for Africa

The World Health Organization's Regional Office for Africa is located in Brazzaville. It aims to support African countries to develop research capacities through support in the setting up of governance, strategies, policies and ethic committees. The organisation produces guidelines, trainings and conferences. It has organised a training seminar in ethics in cooperation with CANTAM. In addition WHO has offices in each country in relation with the local Government and in capacity to deal with specific needs. It's newly appointed director Dr. Martin Ota is a former grantee of EDCTP.

J.5 Results and impact achieved by the projects

This section presents the results and impact achieved by the projects collected during the visit, clustered around research activities, especially impacts on clinical trials, capacity development and sustainability and networking and research coordination.

Impact on research activities, especially clinical trials

Even though no laboratory in the Republic of the Congo is yet able to conduct clinical trials, tremendous achievements were reached since the first EDCTP funds were granted in 2008.

Notably, a full laboratory at the Faculty of Medicine (Universite Marien Ngouabi) was rehabilitated, equipped and staffed and now is operational thanks to EDCTP grants through CANTAM. The laboratory performs research activities in molecular biology for the first time in Congo. Two researchers are currently trained for clinical trials and FCRM aims to conduct the first clinical trials in 2015.

EDCTP's investments for the development of ethics in Congo also have a great impact on research activities in the country. The Faculty of Medicine and the Faculty of Sciences have both integrated ethics lessons in their curriculum. A few years ago this would have

been impossible. CERSSA was able to fund communication actions to raise awareness on ethics through media and these were useful. As a consequence the committee started receiving an increasing number of projects to evaluate. Initially the quality of the projects was rather poor; therefore CERSSA produced and disseminated guidelines on ethics and on how to set up a scientific research project. The projects received for review today are generally up to standards.

Interviewees also highlighted communicating on EDCTP's support to CERSSA has given greater credibility to the committee and contributed to convince doctors and mathematicians to work with the committee.

The country is now planning to set up a national multidisciplinary ethics committee.

Impact on capacity development and sustainability

Needs in terms of research capacities were critical in Congo and achievements are important. EDCTP has contributed to train laboratory technicians, biostatisticians, and quality managers. The country still needs to strengthen its research competencies; there are for instance no epidemiologists in Congo. Data is very limited in the country and EDCTP has helped to establish baseline data. Besides the sustainability of the competencies developed is a challenge.

Public authorities do not fund research. There is a promise from the Minister of Research to mobilise a fund for medical research but this is still to be implemented. FCRM has made great efforts to communicate on its activities and results with the aim to raise additional funds. It was successful in raising additional funds from private actors such as the oil company Total⁷² and other organisations such as CNSL or ONU SIDA⁷³ seeking sustainability of its activities despite the lack of public funding. Funds raised are counted in some 544K€ representing about 20% of the funds managed by FCRM (80% are EDCTP's funds for CANTAM, senior fellowships and the CERSSA grant).

EDCTP has greatly contributed to awareness raising and capacity building in ethics for research. Training in ethics targeted researchers and students as well as members of the ethics committee. These were short-term trainings on 2-3 days and interviewees pointed out that this is insufficient to cover the learning needs. However awareness-raising activities have contributed to the creation of ethics lessons in the Science and Medicine Faculties that is a great achievement.

EDCTP has a great impact on the career of grantees. This is the case for the newly appointed Director of Vaccine for the WHO Regional Office for Africa who received EDCTP funds to carry out a research project that gave him scientific visibility and new skills.

Retaining trained resources is a challenge. Qualified resources usually leave the country for Germany or France. The best way to prevent trained researchers from leaving the country is to offer them the possibility to pursue their research activities in Congo. For FCRM the objective is to keep them at least 4-5 years so that they can transfer their knowledge to others. Prof. Ntoumi explains to all beneficiaries how important this is because they were given the opportunity to benefit from this training they have to make sure they transfer their knowledge to others who did not have the same possibility. For the moment all beneficiaries are still based in Congo and still engaged in research activities, however their career paths should be tracked on the medium and long term.

⁷² Total funds two projects in Congo one for the introduction of new vaccines against rotavirus (255K€) and a second on Malaria (217K €)

⁷³ CNLS (62 K€) and ONU SIDA (8K€) have both funded projects relating to early diagnosis of HIV/AIDS during pregnancy aiming to eliminate the mother-child transmission of the disease.

Impact on networking and research cooperation

The CANTAM Network of Excellence was set up following an EDCTP call for proposals in 2007 answered by OCEAC a regional organisation fighting against endemics in central Africa (based in Cameroon).

CANTAM was created with the aim to build research capacities of institutions in central Africa to support safety and efficacy studies in Phase II and III trials on HIV/AIDS and malaria (drugs and/or vaccines) and to initiate/develop clinical research activities on tuberculosis.

Professor Ntoumi took the leadership of the network, many institutions were present at the launch of the project but many have not been active and today only three African countries are part of CANTAM (Congo, Cameroun and Gabon) and one European (Germany). However CANTAM is said to be very active in terms of number of collaborative projects but also for knowledge and information sharing between its members.

Some interviewees identified a few weaknesses with regards to networking pointing that regional Networks of Excellence (NoEs) are very individual focused and that the mentor/mentee component needs to be closely assessed.

Regarding north-south cooperation, interviewees highlighted the fact that traditional bilateral cooperation networks tend to be reproduced through EDCTP.

Some researchers have expressed the need to access to a contact database of CANTAM and/or EDTCP partners. At the moment they need to go through their senior colleagues in Congo to contact a technician or a biostatistician in another country.

J.6 The process of implementation of EDCTP's activities

Interviewees confirmed that support and communication with EDCTP is very effective.

Several have stressed difficulties with reporting during the first programme; templates for reporting on activities and contracts have followed a trial-and-error process that actors had to deal with. Nevertheless they have acknowledged EDCTP's efforts to ease the learning process through organisation of training sessions in finance and project management.

Some actors have noted that English can be a barrier to work with EDCTP. On the other hand senior researchers consider that language should not be a difficulty, as researchers need to publish in English to be visible. Still this can be a difficulty for staff in charge of financial and performance reporting.

The calls for proposals published by EDCTP require a considerable amount of administrative work and interviewees expressed the need for further simplification.

The need for co-funding is an important barrier for African researchers as most of the time national funding is not possible.

Finally some interviewees stated that communication and advocacy needs to progress. EDCTP needs to better disseminate its results to governments.

EDCTP is not visible to actors beyond the programme stakeholders and beneficiaries. However FCRM is very visible and we have been told the Minister for Research and Innovation will talk about EDCTP and its achievements in Congo during the Africa science day in Brazzaville on 30 June 2014.

J.7 General opinion on EDCTP's performance by interviewees

EDCTP achievements in Congo are substantial, interviewees were all very thankful for what EDCTP has enabled to achieve in terms of capacity building, access to infrastructure, access to funds for research and access to networks.

Given that Congo was far behind most African countries in terms of research, EDCTP's achievements can be considered as very positive.

Actors are all concerned about the sustainability of these achievements. Despite the FCRM advocacy efforts, the Congolese government has still not demonstrated its support to research activities. As a consequence EDCTP's achievements in the country are not sustainable and if EDCTP withdraws its funds this would have a very serious impact on health research in Congo.

Strengths

- EDCTP invests important amount of funding in tackling all local barriers and weaknesses: lack of public funding, lack of competencies, lack of infrastructure, internet access, etc. This has enabled to set up a laboratory of molecular biology that has all the necessary inputs to be operational.
- Senior researchers are grateful that EDCTP has 'trusted' them to handle large amounts of money. This opportunity was not given to them by public authorities or other donors; they know it is a unique chance for them to implement a comprehensive project.
- The links with the university of Tübingen in Germany is deep rooted and today go beyond projects financed via CANTAM.

Weaknesses

- Activities of FCRM are limited because of a lack of working space, the government promised a new building two years ago but this was not fulfilled and cannot be funded through EDCTP. Activities are also limited because of a lack of equipment. The medical biology lab has some, but still needs to send samples to Tübingen for example.
- The CANTAM Network of Excellence is very much relying on the dynamism and capacities of a few individuals in Congo. Striving for and achieving a critical mass is a must for sustainability.
- EDCTP was not able to involve local authorities in the development of research capacities. The Minister of Research has committed to finance medical research but this has yet to become real. Without public investment in research some of EDCTP investments are not sustainable and might collapse.
- The need for co-funding is an issue for African researchers. Because of the lack of national funding they have to raise money from European countries. This is very challenging and leads to partnerships with traditional bilateral cooperation actors.
- Links between researchers and doctors are weak. Clinical trials will need further cooperation with the University Hospital Centre (CHU).

Recommendations

- EDCTP should further involve African stakeholders in the EDCTP governance.
- EDCTP could strengthen its communication and advocacy towards governments in order to further involve them in the programme's activities, demonstrating direct benefits for the people.
- EDCTP should open up to fund research on other tropical diseases. Diarrhoea is an important cause of mortality as well as hepatitis (co-infection between HIV/AIDS and Hepatitis).
- EDCTP could consider re-entry grants to attract qualified researchers.

- EDCTP should continue strengthening south-south partnerships.
- EDCTP should pursue capacity development activities based on specific needs of the country (e.g. in epidemiology, biostatistics, data management and ethics).
- EDCTP should encourage new partnerships avoiding reproduction of traditional bilateral cooperation. EDCTP could contribute to the establishment of new networks creating the conditions for researchers from French speaking regions to meet researchers from English speaking countries for instance.
- Other key actors should be further involved in EDCTP's activities in order to develop a critical mass, this include researchers from the LNSP and the University's mathematics' department.

J.8 Programme and overview of interviewees

Tuesday 26 May

Université Marien Ngouabi, Faculté des Sciences de la Santé

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
10.00 – 12.00	Prof Ange Antoine Abena	Former Minister of Higher education and former dean of the Faculty for Health Sciences and Collaborator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Centre d'Etudes sur les Ressources Végétales (CERVE)

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
14.00 – 15.00	Dr Ndouga Mathieu	Former director of the CERVE, Senior Fellow and Collaborator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Fondation Congolaise pour la Recherche Médicale (FCRM)

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
15.00 – 17.00	Dr Felix Koukouikila	Research coordinator project CANTAM Malaria
17.00 – 18.00	Mr Gotrand Mayindou	

Wednesday 27 May

Fondation Congolaise pour la Recherche Médicale (FCRM)

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
08.00 – 09.00	Mr Jean Eric Massamba	Beneficiary training activities Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)
09.00 – 10.00	Mr Chris Vouvogui	Beneficiary training activities Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Laboratoire National de Santé Public

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
13.00 – 14.00	Ms. Amona Mbani Rachelle	Collaborator Senior Fellow (Ndounga)
14.00 – 15.00	Dr Jean Vivien Mombouli	Collaborator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Centre Anti Tuberculeux

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
15.00 – 16.00	Dr Madzou Laboum	Director of the Centre Anti Tuberculeux and Collaborator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Ministry of Research and Innovation

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
16.00 – 17.00	Mr Bruno Jean Richard Itoua	Minister of Research and Innovation
	Prof Francine Ntouni	Coordinator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)
	Ms Karine Cades	Office Manager FCRM
	Mathieu Ndounga	Former director of the CERVE, Senior Fellow and Collaborator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)
	Ms. Marie-Yvonne Nkodia	

Fondation Congolaise pour la Recherche Médicale (FCRM)

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
17.00 – 18.00	Mr Makita Clem	Financial Manager Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)

Thursday 28 May

World Health Organization, Regional Office for Africa

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
08.00 – 10.00	Dr Martin Ota	Newly nominated WHO AFRO Observer to EDCTP SAC and former EDCTP grantee

Comité d'Ethique de la Recherche en Sciences de la Santé

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
10.00 – 12.00	Prof Honoré Ntsiba	Président du Comité d'Ethique de la Recherche en Sciences de la Santé

Fondation Congolaise pour la Recherche Médicale (FCRM)

Brazzaville

Time	Name of interviewee	Role at institution/involvement in project
14.00 – 15.00	Mr Mayetela	Member of the FCRM ethics committee
15.00 – 16.00	Prof Francine Ntoumi	Coordinator Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM)
16.00 – 17.00	Ms Karine Cades	Office Manager FCRM

Appendix K Case study Tanzania

From Tuesday 20 till Friday 23 May 2014 the evaluation team visited Tanzania for a case study as part of the evaluation of the first programme of EDCTP.

K.1 Tanzanian participation in EDCTP projects

The figure below shows that Tanzanian institutions are involved in 51 out of the 246 projects. Half of the projects are clinical trials and integrated projects. Remarkable is the absence of Tanzanian senior fellows in the programme (the reason for this will be explained later in the case study). In total 15 projects are coordinated by Tanzanian researchers, the majority are projects concerning ethics and regulatory framework.

Figure 74 Participation of Tanzanian institutions in EDCTP projects

Grant scheme category	# of projects	# of coordinators	Total grant value	Total contribution to EDCTP
Clinical Trials and Integrated Projects	25	5	€23,846,271	€2,037,982
Strategic Primer Grants	5	1		
Fellowships and training grants	0	-		
Ethics and regulatory framework	12	8		
Coordination and integration	6	1		
Networking	3	-		
TOTAL	51	15		

Source: Information provided by EDCTP (2014).

K.2 Overview of institutions visited

During the visit the following institutions have been visited, including the numbers of projects the institutions are involved in and people interviewed at the institutions. The five institutions are involved in 45 out of the 51 projects in which Tanzania participates.

Figure 75 Overview of institutions visited and number of people interviewed

Date	Place	Name of institution	# of projects involved in	# of people interviewed
Tuesday 20 May	Dar es Salaam	National Institute for Medical Research (NIMR)	22	1
Wednesday 21 May	Dar es Salaam	Ifakara Health Institute (IHI)	13	6
		Muhimbili University of Health and Allied Sciences (MUHAS)	5	4
Thursday 22 May	Mbeya	Mbeya Medical Research Center (MMRC)	13	5
Friday 23 May	Moshi	Kilimanjaro Clinical Research Centre (KCRI)	9	3

Source: Technopolis Group (2014).

K.3 Background on the disease burden

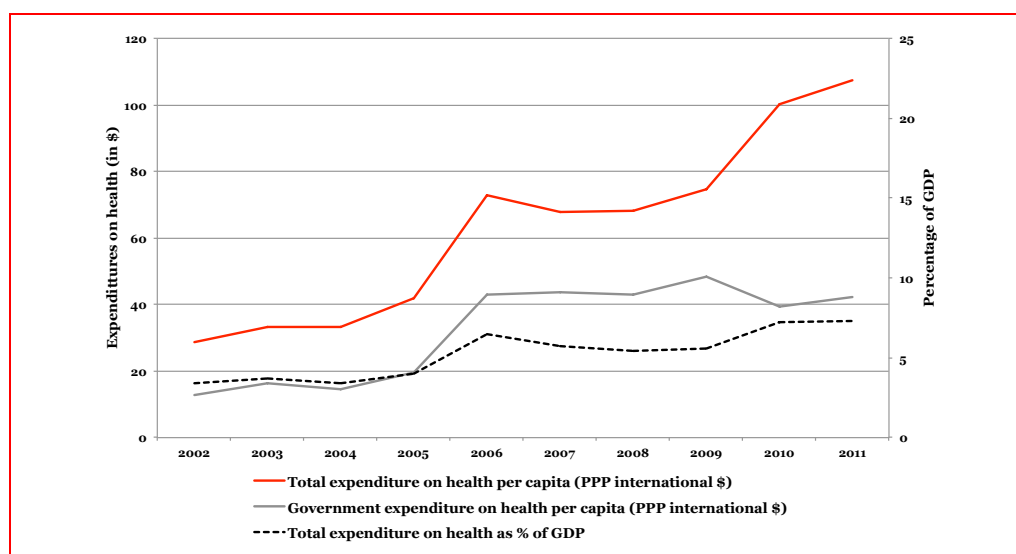
This section presents some information on the health situation in Tanzania, based on data provided by the World Health Organization. This information include figures on the general health profile of the country, the public spending on health and an overview of the latest available figures on the disease burden on HIV/AIDS, tuberculosis and malaria.

Figure 76 General health profile of Tanzania

	1990	1995	2000	2005	2010	2011	2012
Life expectancy at birth (M)	50	50	49	49	49	58	58
Life expectancy at birth (F)	30	30	51	51	51	61	61
Probability of dying under 5 years per 1,000 live births M/F	166	160	132	90	62	62	54
Probability of dying between 15 and 60 years per 1,000 populations M	405	405	500	500	500	363	363
Probability of dying between 15 and 60 years per 1,000 populations F	338	338	461	461	461	322	322

Source: Figures made available by WHO (2014).

Figure 77 Public spending on health in Tanzania



Source: Figures made available by WHO (2014).

Figure 78 Disease burden of HIV/AIDS, tuberculosis and malaria in Tanzania

	2010	2012
HIV/AIDS		
Number of people living with HIV/AIDS	-	1,200,000
Number of people newly infected with HIV/AIDS	-	83,000
Number of deaths due to HIV/AIDS (estimated)	-	80,000
Prevalence among adults aged 15 to 49 (%) (estimated)	-	5.1

	2010	2012
Tuberculosis		
Incidence estimated	80,000	79,000
Mortality estimated	1,800	1,800
Prevalence estimated	86,000	84,000
Malaria		
Cases reported	1,278,998	1,986,955
Deaths reported	15,867	7,820

Source: Figures made available by WHO (2014).

According to the people interviewed, malaria is considered the leading public health problem in Tanzania, although it is going down because of the use of prevention methods (i.e. bed nets). The Kilimanjaro Clinical Research Centre (KCRI) is the leading institution in Tanzania addressing malaria.

In addition to malaria there is also a considerable problem related to tuberculosis in Tanzania. As a result a National TB and Leprosy Programme has been set up. Because of special campaigns from the North leprosy went down while tuberculosis went up. In 1983 there have been 11,000 cases, which increased to around 65,000 cases in 2013. Tanzania belongs to the 22 countries with the highest burden in the world (295 out of 1,000 individuals are infected by TB). People come late when they are infected, so they transmit the disease to others. The issue is how to inform people to go a hospital as soon as possible. The epidemiology has changed a lot (from a poor peoples disease to also a disease of the richer); 50% of the people in sub-Saharan Africa are already infected with the tuberculosis bacteria, however for those with a strong immune system there is no immediate risk. Due to other diseases the immune system is weakened which leads to active tuberculosis.

Therefore co-infection with HIV is also prominent in Tanzania; HIV and tuberculosis are fuelling each other (50% of the people infected with tuberculosis are also infected with HIV). HIV as the third disease is still a problem too. Its prevalence has increased due to antiviral treatment (currently 7% is the national average).

K.4 Organisations visited

This section briefly introduces the organisations that have been visited in terms of their background, main (research) focus and current activities.

National Institute for Medical Research (NIMR)

The National Institute for Medical Research (NIMR)⁷⁴ is the largest public health research institution in Tanzania. It was established as a parastatal organisation under the Tanzanian Ministry of Health. NIMR was established as a response to the needs to generate scientific information required in developing better methods and techniques to enhance disease management, prevention and control in the country. NIMR was established amongst others to carry out and promote medical research designed to alleviate disease among the people of Tanzania and to cooperate with the government in promoting or providing facilities for the training of local personnel in carrying out scientific research. The institute runs a number of projects in the country at different locations. It receives money from different research organisations and funding donors.

⁷⁴ <http://www.nimr.or.tz/>.

Ifakara Health Institute (IHI)

The Ifakara Health Institute (IHI)⁷⁵, previously the Ifakara Research and Development Centre, is a not-for-profit entity established 50 years ago as part of the Swiss Tropical Institute. In 1966 the Swiss considered this not to be sustainable anymore and discussed alternatives with the Tanzanian government. This resulted in the creation of a foundation, governed by both the Tanzanian and the Swiss government. IHI supports the Tanzanian Ministry of Health and performs translational research (“from bench to bedside”), which includes basic biology, environmental science and clinical interventions to develop vaccines, diagnostics and treatments. It also conducts health systems and health policy research and impact assessments. Like NIMR, IHI is equally spread over the country in terms of clinical sites. Most of the current staff is from Tanzanian origin, but IHI also works with staff outside the country and collaborates with many international partners. The institute depends on competitive research grants for more than 80% of its income, supplemented by core funding from the governments of Tanzania, Switzerland, the United Kingdom, Ireland and Norway.

Muhimbili University of Health and Allied Sciences (MUHAS)

The Muhimbili University of Health and Allied Sciences (MUHAS)⁷⁶ is a successor to the Muhimbili University College of Health Sciences (MUCHS), a constituent college of the University of Dar es Salaam. The Faculty of Medicine originated from the Dar es Salaam School of Medicine, which was established in 1963 by the Ministry of Health with the primary aim of training clinical health staff. The current objectives of the university are the advancement of knowledge, diffusion and extension of technology and learning, the provision of higher education and research and nurturing of the intellectual, aesthetic, social and moral growth of the students. MUHAS has a range of programmes in basic, clinical and allied health sciences. In 1976 the Faculty of Medicine was incorporated into Muhimbili Hospital to establish the Muhimbili Medical Centre (MMC).

Mbeya Medical Research Center (MMRC)

The Mbeya Medical Research Center (MMRC)⁷⁷ is a partnership between the Mbeya Referral Hospital, the Mbeya regional medical office, the National Institute for Medical Research (NIMR), the University of Munich and the U.S. Military HIV Research Program. MMRC has been a pioneer in research in Tanzania, studying epidemiology of HIV through cohorts. MMRC is also involved in social science studies trying to describe the risk behavior for HIV and STI in different study populations. Also MMRC carries out innovative diagnostics tool research in fields of malaria and tuberculosis. From 2008 MMRC, as a real health center, has become part of a legal structure created by the NIMR. The organisation is led by Tanzanians and supported by international partners. Some of its staff is currently employed by the Tanzanian government.

Kilimanjaro Clinical Research Centre (KCRI)

The need to establish a medical research institute as one of the three pillars of Kilimanjaro Christian Medical Center (KCMC) was identified in the early 1970s. However, the lack of infrastructure and the need for capacity development for research personnel led to the delay in establishing the institute. To address these two areas whilst still undertaking research activity, KCMC developed important collaborations with various partners in the North including the Netherlands, the United Kingdom, the

⁷⁵ <http://www.ihl.or.tz/>.

⁷⁶ <http://www.muchs.ac.tz/>.

⁷⁷ <http://www.mmrc.org/>.

United States and Norway. The collaboration between KCMC and the Radboud University in the Netherlands through the APRIORI Program was significant in establishing a facility to support the coordination of medical research at KCMC. In 2006 the Kilimanjaro Clinical Research Center (KCRC) was established, with support from the Dutch government and EDCTP, which led to a physical infrastructure and support capacity development for staff. In 2009 the Kilimanjaro Clinical Research Institute (KCRI)⁷⁸ was established. KCRI coordinates all research activities at KCMC. The research environment at KCMC has enabled KCRI to serve as an academic center for evidence based health interventions.

K.5 Results and impact achieved by the projects

This section presents the results and impact achieved by the projects collected during the visit, clustered around research activities, especially clinical trials, capacity development and sustainability and networking and research coordination.

Impact on research activities, especially clinical trials

The institutions that have been visited participated in a broad variety of clinical studies around each of the three targeted diseases. In addition they have conducted some epidemiological studies around the trials topics.

Based on the progress made in the clinical trials, like the one undertaken by NIMR, there is an impact in reducing the malaria burden. There are some findings, which are immediately taken up by the Tanzanian Ministry of Health. Some of the bigger clinical trials take a considerable amount of time to develop and produce results. However, with each clinical trial there are complementary projects that can show results on an earlier basis. For NIMR it has become more easy to inform policy makers since they are directly involved in the project because of a better dissemination process. The people at the ministry know about the support from EDCTP. The PREGACT project (although not conducted at Tanzanian clinical trial sites, aimed to determine the safety and efficacy of four artemisinin-based combination treatments⁷⁹ when administered to pregnant women with *P. falciparum* infection, is about to produce results; it is expected to lead to the adoption by African policy makers and influence the role out of malaria tests and diagnostics in the near future. Currently there has already been a significant decline of malaria in the Tanga and Kilimanjaro regions also because of a clear focus on prevention (see before).

For Ifakara EDCTP opened up new opportunities for clinical trials in areas where there is a need and where there were no funding opportunities before. Those that existed before were driven by pharmaceutical companies or by a broader programme that set the priorities. EDCTP is different in the way that is open for out-of-the-box thinking and developing the institutions' own priorities. The projects opened the eyes of the researchers in the region to think about future research directions.

In the past there were just a few locations to perform GCP trials, now there are many not only in Tanzania, but also in other countries. Most of the EDCTP grants are based in another part of the country. The sites have a good laboratory structure and good communication facilities (the internet is working). There are not so many comparable clinical trial facilities in Africa. One of the good things of EDCTP, compared to other funders (e.g. the Bill & Melinda Gates Foundation), is that they do not expect specific infrastructure to be in place before becoming eligible for funding. EDCTP creates opportunities for institutions to establish the infrastructure.

⁷⁸ <http://www.kcri.ac.tz/>.

⁷⁹ Dihydroartemisinin-piperaquine, mefloquine-artesunate, amodiaquine-artesunate and artemether-lumefantrine.

Another change in the way clinical trials are conducted is the fact more and more steps in the research process can be done in-house by the African institutions. In the past (five to 10 years ago), after the clinical trials are finished, the collected samples were shipped to other countries for further analysis. Now the institutions are able to perform preparatory work, immunology and molecular biology.

Some of the interviewees from the institutional review board of IHI mention that there is some impact in the way clinical trials take on board feedback and recommendations from oversight visits. The on-site training opened up some compliance issues that have not been addressed yet. Oversight visits are considered to be very helpful in further improving the clinical trial process.

Some of the projects in which interviewees participated also produced considerable scientific outputs. For instance, the innovative TAM-TB assay that has been developed as part of the TB CHILD project was subject of some scientific publications as it has become more promising for diagnosis of TB than other diagnostic methods. The assay can be used more widely, however finding sufficient funding is a challenge.

For MUHAS the experiences in the HIV trials have their spillovers to other parts of the world as well since it is an idea that is widely acceptable. The institute stressed that it has done something that has not been done before. Specifically for HIV there has been a significant impact on incidence and prevalence.

MMRC participated in the second vaccine trial in Tanzania, which led to a lot of misconception about the studies in the local community. During the establishment of the TaMaVac-01 project a specific board was set up in order to better connect the site and community to explain the aim of the project and to collect the rumours. The project helped in trying to reduce the number of rumours. During the follow-up project, TaMoVac II, there are frequent meetings and much more attention about the trial. This resulted in less rumours and made people more eager to get screened (the people have less questions and do not feel so worried anymore).

Another impact that MMRC achieved through participation in the EDCTP funded TB NEAT project is that they managed to include a local hospital in being part of the research. This basically relates to the question how to follow up on protocols within the hospital in recruiting and treating patients. This can be beneficial in future studies as there used to be almost no research activity in the hospitals although there are hospitals involved in many of the EDCTP funded projects.

Impact on capacity development and sustainability

For all of the institutions visited, the capacity building activities through EDCTP projects considerably helped in establishing a suitable research infrastructure and training people in performing clinical research. This specifically includes training of human resources: PhD, technical staff on how to operate the equipment, ethical issues and GCP. Furthermore the procurement of certain laboratory equipment, computers, deep freezers and archive facilities have been made possible through the grants. This capacity still can be used in future research, which helps in attracting additional funding. This also comprises sustainability on the personal level as people have been able to stay at the institutions because of the EDCTP grant.

The interviewees state that the way EDCTP supports independent fellowships (senior scientists) is the way to go. You need to create independent scientists to develop new insights. Other funders now also follow this approach as some sort of seed funding for scientists. The situation in Tanzania is different from some of the other countries as there are only a few researchers in the top segment and some less experienced, however those that can apply for senior fellowships are lacking. There has been a period where there was no funding and interest in doing research. For that reasons there are no senior fellows participating in EDCTP (see Figure 64). As a result there is a strong need for career development fellowships in Tanzania to bridge the gap.

The interviewees also mention that capacity for lower cadres (e.g. for nurse who needs training as well as data entry) is lacking. There are almost no capacity building opportunities (money) to train these people, but they are essential in performing the research.

Maintaining the infrastructure that has been built and the staff that has been trained is a challenge for almost all of the institutions visited. The Tanzanian government or the institutions themselves do not have sufficient resources to take care of the sustainability, which ideally should be their responsibility. When more resources are provided to research it sends the correct signal to the community. This is currently somewhat changing in the country. The current president is a strong believer of research and is willing to put in money into the research system, however this has not been made into reality yet. Another point that is important for institutions that perform clinical trials is to have an adequate clinical trial unit space. It is very challenging to perform a phase III study in a small room, because it implies hundreds of people. If institutions cannot attract substantial research funding they cannot maintain or strengthen the infrastructure or keep the people at the institution. The capacity development then becomes very fragile. For the institutions EDCTP2 is very important in terms of sustainability, in addition to other funding organisations. Additional funded projects build on the infrastructure and capacity that has been developed; continuation of funding is essential to compete on international level. KCRI is considered as a good example of this evolution of grants building on the achievements of previous projects.

The projects should furthermore pay attention to ethics as an integral part. EDCTP could help in more formally include requirements on ethics in the project set up (e.g. include a budget for oversight visits (see below)). Another aspect is that seniors often do not attend training courses, but as they are responsible for large projects, this should be made mandatory as the field of ethics is changing all the time and you should update people.

Not all the people interviewed were familiar with the Pan African Clinical Trial Registry (PACTR). Those that know about its existence see a clear added value in informing researchers about similar registered clinical trials. Before this initiative there was nothing that shows what the different African countries are doing in the area of clinical trials and that can serve as a learning platform. The registry is also instrumental in identifying potential collaboration partners.

The main objective of the EDCTP grant for NIMR was related to capacity building of human resources and infrastructure to facilitate research on malaria through the Joint Malaria Programme (JMP)⁸⁰. The programme started in 2001 and was funded by the Medical Research Council in the UK and established by four institutions: NIMR in Tanzania (mainly in Tanga and Moshi), the Kilimanjaro Christian Medical Centre (KCMC), the Centre of Medical Parasitology (CMP) in Denmark and the London School of Hygiene and Tropical Medicine (LSHTM). Later on the programme also got support from the Global Fund to Fight AIDS, Tuberculosis and Malaria by the Bill & Melinda Gates Foundation. The programme coordinates all malaria research and has specific building that has been established in Dar es Salaam. In 2010 there were some problems related to human resources of the programme. The EDCTP grant supported the establishment of a secretariat for the programme and other activities (e.g. creating infrastructure capacity in terms of laboratory, human capacity and networking). The grant was instrumental in maintaining the infrastructure and the JMP as a whole.

At the coordination office of NIMR in Dar es Salaam there was no internet connection at all, but the EDCTP grant has made it possible to create a fiber network connection. Through the participation in EDCTP NIMR have been able to organise four scientific workshops that have been attended by a total of 260 people from the Ministry of Health, Commission for Science and Technology, the WHO, IHI and the media. During these

⁸⁰ <http://www.jmp.or.tz/>.

workshops, the results from the research projects have been disseminated and the workshops also created a platform to learn from each other. Because EDCTP covered the four years, NIMR was able to get a surplus from other donors to organise the workshop. This funding will help to sustain the workshops for the next years. In addition to the workshop, NIMR have been able to train a considerable number of staff members (127) on short courses. This includes courses on GCP, quality assurance of laboratories, statistics, financial management with a focus on donor-funded projects, project and performance (time) management (as people do not know how to set targets, use of time sheets, how to set up a work plan) and grant writing. All of the trained staff members are still working at NIMR.

For IHI the EDCTP grant customised the office and equipment and supported the recruitment of a data manager and partially sponsor her training (as so much information is coming in that needs to be organised effectively and efficiently). Through the project the approach was improved step by step. Also an intranet system has been set up, which can be used by the investigators directly instead of entering the project data manually. This makes it easier to see the number of submissions, the types of submissions and to remind the investigators when to submit progress reports. If an investigator applies with the IRB, he/she automatically enters the information in the database. The EDCTP grant also created the opportunity to perform oversight visits done by the IRB, as an important though expensive part of research ethics. During the visits several projects with a mixture of trials (clinical trials and epidemiological field site studies) are monitored. After the visit the investigators are briefed and asked for comments. Through oversight visits the IRB is able to see what the project has done, to have up-to-date information and to speak with participants. A manuscript with the lessons learned from oversight visits is currently under development. Another component of the project was that there have been 5 types of training (for field workers who speak Swahili up to the investigators and IRB members). Out of these trainings IHI developed a training guide (in English and in Swahili) for fieldworkers that can be shared with others. Training for investigators and IRB members was open for people outside Tanzania, but due to travel costs that have not been able to take care of this has not happened. Finally, the communities have been trained as well to inform about informed consent, which is still a big challenge to get. Preferably these training sessions need to be continued.

At MUHAS, there are currently two people with a PhD degree, which are teachers at the university who think of initiating their own projects. The funding of EDCTP and the training of those people had increased their capacity in performing clinical research.

An example of capacity building at MMRC concerns the scientists in the lab who have learned new procedures, laboratory upgrade and trained clinicians and nurses how to treat patients. The MAMS project has brought the use of a tablet computer in capturing the information and data electronically and real-time. This has improved a lot.

The laboratory facilities that have been developed by KCRI to perform the clinical research projects are impressive. Almost all stages of the research process are taken care of by the institute; from the preparatory phases, the recruitment and screening of patients, the actual clinical trials and the analytical phases. People have been trained specifically on biostatistics, financial management and administration, immunology, etc.

Impact on networking and research cooperation

All of the institutions are very positive about the networking achievements. Through the partners they have established a great network of close relationships with information sharing and spillover effects. Working with other local sites enhanced standardisation of practice (south-south) and enabled the lab staff to go to Europe and participate in the analysis phase that is done over there (north-south).

The East Africa Consortium for Clinical Research (EACCR), one of the four Networks of Excellence created by EDCTP, is perceived as good by the institutions visited. There is an

overlap between the participating organisations in the different projects, which is instrumental in networking and sharing of information. EACCR is a platform for exchanging research findings, building up further research capacity and stimulating institutions finding the right partners. The focus on south-south cooperation (one of the main objectives of the Network of Excellence) ensures that the countries in the South think of each other. EDCTP was very instrumental in supporting the south-south networking.

The EDCTP project helped NIMR to get easier access to national governments and international donors. This is mainly achieved through the workshops that have been organised, which has been considered to be a forum to disseminate information about the projects performed by the institution and results obtained. It is now possible to show them the way the institute operates. They have additional capacity from the North. Transfer of knowledge and technology from the north and south is essential. The network NIMR established will be there for the future.

K.6 The process of implementation of EDCTP's activities

The implementation of the activities by EDCTP has been very well coordinated according to most of the interviewees. Overall, they are very positive about EDCTP, especially the support received from the executive secretariat from day one of the project until the final stages. The officers are dedicated, always responsive and communicate that they are willing to provide support. Depending on the type of projects, people are more involved with the office in The Hague or in Cape Town.

For the project activities there are opportunities to meet physically, during which the researchers update each other and share experiences. EDCTP has been very instrumental in facilitating this.

Some of the interviewees mention that it is important for EDCTP to look at the bottlenecks and be flexible with them. EDCTP supported the establishment of ethics committees and institutional review boards, but still the approval of clinical trials takes up to 9 months (e.g. related to some of the Strategic Primer Grants). This is something that EDCTP could address and improve during its second phase in making the African institutions real competitive on a global level, otherwise pharmaceutical companies will prefer Asia and Australia where approval times of clinical research are shorter.

The calls for proposals published by EDCTP (like those of the EC) are sometimes difficult to understand and use complicated language (the wording is not quite easy). Some of the researchers prefer to structure a proposal like a scientific manuscript, as they are more used to this.

The change of the reporting structure initially brought some challenges related to the timing of submission. The structure itself seemed now to be more user-friendly by limiting the amount of information required. The financial reporting template is still considered to be a bit complicated. In addition, sometimes the review of the reports takes a bit long and when that is the case the reimbursements come a bit late as well. Aspects that have not initially included in the budget are not so easy to get integrated in the project. At the beginning of the project EDCTP expects to have the budget as complete as possible, however there might always be things that become necessary in the project implementation (*"in this part of the world it is extremely difficult to predict things 3 years in advance and budget accordingly"*). For instance in one situation the fee for regulatory authority has increased significantly compared to the budget, which caused problems in the overall project budget.

Another issue related to finance is that only after the submission of the final report the final payment is made. For some of the institutions, that are largely publicly funded, this causes a lot of constraints. Getting money from the university or government to fund the final stages of a project is very challenging and sometimes impossible.

Some of the interviewees find a bit disappointing that the capacity building activities are restricted to African staff and not open for European researchers that are working in Africa. It is very difficult for a European researcher to participate in conferences and workshops.

The way the information on the results of the projects is shared is not always that clear to all of the interviewees; they are not always aware of the content of the website and the newsletters that are distributed. It is unknown whether EDCTP sends out the newsletter to all its grantees or whether they should subscribe to them. For those that are familiar these communication channels are of added value.

The workshops that have been organised by EDCTP are perceived as very helpful to the institutions.

According to one interviewee that is familiar with the governance structure of EDCTP, the Strategic Advisory Committee (SAC) is an important platform for the executive secretariat to advise on the ideas from the field and to decide on the outcomes from the stakeholder consultations.

K.7 General opinion on EDCTP's performance by interviewees

Generally speaking when looking at the experiences of the previous and current trials that are on-going in Tanzania, the interviewees agree that EDCTP has performed very well. The objectives of EDCTP have been realised in most of the activities supported (i.e. a very strong emphasis on clinical trials, which have produced useful information that help researchers to further develop their research and built the necessary capacity). EDCTP has been a major source for African institutions. The capacity building part was important, which is not taken into account by other funders.

As mentioned before, the issue of sustainability has been raised frequently during the country visit, as there was so much time between EDCTP1 and EDCTP2. Especially for centers where EDCTP played an important role in terms of capacity strengthening additional funding is essential to maintain the people and to perform future studies. Currently, there is no government money that could take care of this. Strictly there needs to be a phase where you establish the capacity, then a phase where you strengthen the capacity and finally a phase where you sustain the capacity. Only when institutions reach this last phase the institutions are able to stay on their own. Prior to that a continued support from international funding organisations will be essential.

Strengths

- The funding mechanism of EDCTP, which is broader than just research ideas, also covering capacity development and networking.
- EDCTP is one of the most important partners for clinical research and capacity building in Tanzania tackling the diseases of public importance (HIV/AIDS, tuberculosis and malaria); there are not so many funders that focus on research on tuberculosis.
- The fact that EDCTP did not define the focus of the project, but that it is up to the institution themselves to identify their challenges and priorities. EDCTP accommodated these priorities.
- The ethics component is important in creating reliable and ethical institutes in Tanzania. It also influences other funders to include a budget for issues on ethics.
- The north-south collaboration between has been very useful (*"it gives a chance to work with the experienced institutions"*) and stimulated the south-south collaboration, which was not very easy before.

Weaknesses

- Much attention is paid to tropical and communicable diseases, there is no focus on non-communicable diseases (hypertension, diabetes, etc.), which are becoming more important in Africa compared to the past.
- Sometimes the amount of money is limiting the project expectations. This needs to be taken into account when defining realistic goals.
- The need for co-funding is very challenging, as in most cases there is no national funding. This frequently leads to partnering with the usual suspects in the North.
- The dependence from the institutions in the North, there should be also a role for African scientists to be the overall project coordinator.
- The requirements for the partnerships are very difficult (some partners from the European Union, some middle-income countries, some low-income countries).
- The complexity of the financial report templates.
- The lack of opportunities to fund the physical laboratories in addition to equipment and people.
- If institutions are left without funding there is fair chance that the sites will collapse.

Recommendations

- In its second phase, the national priorities of the participating African countries should be leading in selecting the priorities of EDCTP. The projects funded by donors do not always reflect the national priorities (e.g. dengue fever is currently a major priority for Tanzania, which is not yet incorporated by the donors).
- EDCTP could try to bring studies that have shown some results one step further, not leaving them at the current stage (e.g. the PanaCEA consortium). EDCTP should not forget the studies that have been done. Capacity has been built, people are willing to participate and looking forward to phase 3 trials. There could be a difference in funding for those institutions that already have a track in EDCTP projects versus those that are new to EDCTP.
- EDCTP could further simplify the proposal template; a suggestion is to follow the structure of a scientific manuscript that is known to most of the researchers (i.e. describe the action – what are the methods – what is the background).
- EDCTP could be more flexible on financial matters (i.e. not so strict budget requirements and late final payments) and could strengthen the financial management of the institutions through workshops training courses and refresher courses.
- The current funding does not include building facilities, which is a major challenge in Tanzania. Some of the clinical trial sites that are in use are very small buildings that serve the activities, but not proportional to what is needed. The trials also produced lots of information and samples for testing which all have to be archived for a long period of time. To have a dedicated storage space for valuable material is another huge challenge. These aspects could be taken into account by EDCTP.
- EDCTP could also revise and simplify the financial templates.
- EDCTP could increase the overhead percentage of projects to around 20%. The overhead is essential (i.e. electricity to maintain the equipment, back-up systems to secure power supplies, etc.).
- EDCTP could consider training of senior researchers on ethics as the field of ethics is constantly evolving and knowledge needs to be updated.

- EDCTP could pay attention to training the European researchers that are mentoring local researchers in African institutions.
- EDCTP could increase the training of the lower cadres in addition to researchers.
- EDCTP could develop online training courses on GCP and ethics. This will be helpful to educate African researchers on these aspects.
- EDCTP could increase the dissemination of information dedicated to specific target groups (e.g. junior researchers, as this group might have a different requirement and is not interested in the same level of detail of the projects as more established researchers are).
- EDCTP could improve the onsite monitoring and evaluation (*“every site that has received funding should be visited once”*).

K.8 Programme and overview of interviewees

Tuesday 20 May

National Institute for Medical Research (NIMR)

Dar Es Salaam

Time	Name of interviewee	Role at institution/involvement in project
12.00 – 13.30	Mr Obed Ole-Kaondo	Director of Finance and Administration and Collaborator Member States Initiated Project (Magesa MSI-Malaria Capacity Building)

Wednesday 21 May morning

Ifakara Health Research and Development Centre

Dar Es Salaam

Time	Name of interviewee	Role at institution/involvement in project
10.15 – 11.15	Dr Salim Abdulla	Director and Coordinator Strategic Primer Grant (P27ACTB)
11.15 – 12.15	Ms Beverly Msambichaka	Coordinator Ethics Project (Msambichaka-Tanzania-Ethics)
	Mr Ahmed Saumu	Collaborator Ethics Project (Msambichaka-Tanzania-Ethics)
	Mr Abdallah Mkopi	Collaborator Ethics Project (Msambichaka-Tanzania-Ethics)
12.15 – 13.00	Mr Fred Lwillla	Coordinator Integrated Project (TB CHILD)
13.45 – 14.15	Dr Abdunoor Mulokozi	Collaborator Integrated Project (MiPPAD)

Wednesday 21 May afternoon

Muhimbili University College of Health Sciences (MUHAS)

Dar Es Salaam

Time	Name of interviewee	Role at institution/involvement in project
15.30 – 16.15	Prof Muhammad Bakari	Coordinator Integrated Project (TaMoVac-01)
	Prof Eligius Lyamuya	Coordinator Integrated Project (TaMoVac II)
	Dr Said Aboud	Collaborator Integrated Project (TaMoVac II)
16.15 – 17.00	Prof Ferdinand Mugusi	Collaborator Integrated Project (HIV-TB Pharmagene)

Thursday 22 May

Mbeya Medical Research Programme (MMRP)

Mbeya

Time	Name of interviewee	Role at institution/involvement in project
08.30 – 09.30	Dr Leonard Maboko	Director NIMR-MMRC, Collaborator Integrated Projects (FATI, 2LADY, TaMoVac-01, TaMoVac II, AfrEVacc and PanACEA-SQ109) and Collaborator East Africa Consortium for Clinical Research (EACCR)
09.30 – 10.30	Dr. Tessa Lennemann	Collaborator Integrated Projects (FATI, 2LADY)
10.30 – 11.30	Dr. Marco Missanga	Collaborator Integrated Projects (TaMoVac-01 and TaMoVac II)
11.30 – 12.30	Dr. Nyanda Elias	Collaborator Integrated Project (TB CHILD)
14.00 – 16.00	Dr. Petra Clowes including tour of facilities	Collaborator Integrated Projects (TB CHILD and TB NEAT)

Friday 2 May afternoon

Kilimanjaro Christian Medical Centre (KCMC)

Moshi

Time	Name of interviewee	Role at institution/involvement in project
12.00 – 14.30	Prof Gibson Kibiki, including tour of facilities	Collaborator Integrated Projects (REMox I and II, PanACEA-HIGHRIF and TB Vac prep Ethiopia/THYB-03) and Collaborator East Africa Consortium for Clinical Research (EACCR)
14.30 – 15.15	Dr Hugh Reyburn	Collaborator Member States Initiated Project (Magesa MSI-Malaria Capacity Building)
15.15 – 16.00	Dr Balthazar Nyombi	Collaborator Integrated Project (HIVTAB)
16.00 – 16.30	Prof Gibson Kibiki wrap up	Collaborator Integrated Projects (REMox I and II, PanACEA-HIGHRIF and TB Vac prep Ethiopia/THYB-03) and Collaborator East Africa Consortium for Clinical Research (EACCR)

Appendix L Case study Mali

In June 2014, the evaluation team performed phone interviews with key actors in Mali for a case study as part of the evaluation of the first programme of EDCTP.

L.1 Malian participation in EDCTP projects

The figure below shows that Malian institutions are involved in 12 out of the 246 projects. Almost half of the projects are fellowships and training grants. In total 4 projects are coordinated by Malian researchers, three of them are senior fellows.

Figure 79 Participation of Malian institutions in EDCTP projects

Grant scheme category	# of projects	# of coordinators	Total grant value	Total contribution to EDCTP
Clinical Trials and Integrated Projects	2	1	€3,344,803	€180,738
Strategic Primer Grants	1	0		
Fellowships and training grants	5	3		
Ethics and regulatory framework	2	0		
Coordination and integration	1	0		
Networking	1	0		
TOTAL	12	4		

Source: Information provided by EDCTP (2014).

L.2 Overview of institutions interviewed

The following institutions have been interviewed, including the numbers of projects the institutions are involved in and people interviewed at the institutions. The two institutions are involved in all 12 projects in which Mali participates.

Figure 80 Overview of institutions and number of people interviewed

Place	Name of institution	# of projects involved in	# of people interviewed
Bamako	University of Bamako	8	2
	Malaria Research & Training Center (MRTC)	6	3

Source: Technopolis Group (2014).

L.3 Background on the disease burden

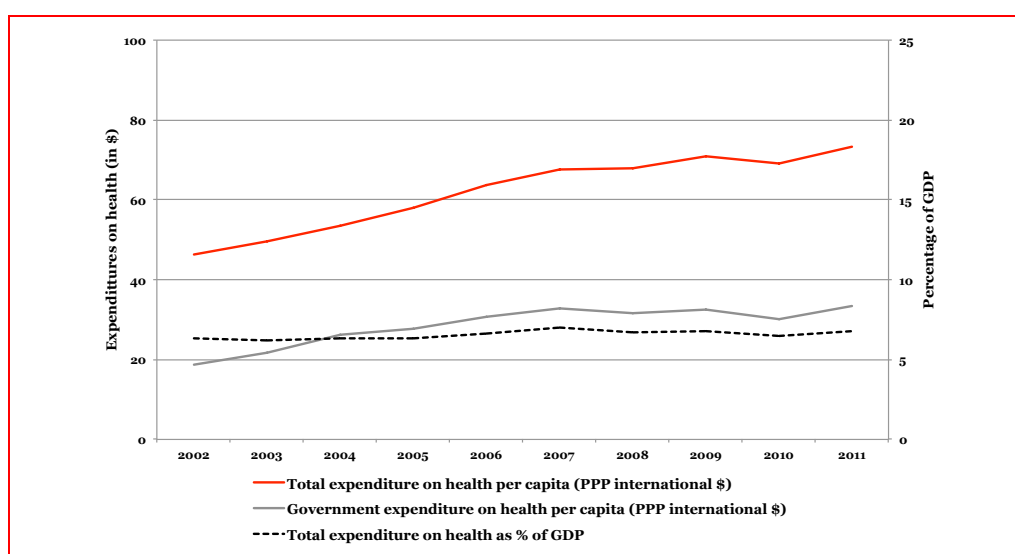
This section presents some information on the health situation in Mali, based on data provided by the World Health Organization. This information include figures on the general health profile of the country, the public spending on health and an overview of the latest available figures on the disease burden on HIV/AIDS, tuberculosis and malaria.

Figure 81 General health profile of Mali

	1990	1995	2000	2005	2010	2011	2012
Life expectancy at birth (M)	41	41	45	45	45	50	50
Life expectancy at birth (F)	44	44	48	48	48	53	53
Probability of dying under 5 years per 1,000 live births M/F	253	240	220	173	138	138	128
Probability of dying between 15 and 60 years per 1,000 populations M	476	476	440	440	440	369	369
Probability of dying between 15 and 60 years per 1,000 populations F	395	395	372	372	372	304	304

Source: Figures made available by WHO (2014).

Figure 82 Public spending on health in Mali



Source: Figures made available by WHO (2014).

Figure 83 Disease burden of HIV/AIDS, tuberculosis and malaria in Mali

	2010	2012
HIV/AIDS		
Number of people living with HIV/AIDS	-	84,000
Number of people newly infected with HIV/AIDS	-	4,200
Number of deaths due to HIV/AIDS (estimated)	-	4,900
Prevalence among adults aged 15 to 49 (%) (estimated)	-	0.9
Tuberculosis		
Incidence estimated	8,800	9,000
Mortality estimated	1,300	1,300
Prevalence estimated	13,000	14,000
Malaria		
Cases reported	227,482	886,482
Deaths reported	3,006	1,894

Source: Figures made available by WHO (2014).

L.4 Organisations interviewed

This section briefly introduces the organisations that have been interviewed in terms of their background, main (research) focus and current activities.

University of Bamako

Created in 1996 the University of Bamako counts over 80,000 students⁸¹ and offers higher education in the fields of general medical practice, pharmacy and odontostomatology. The university aims to train doctoral candidates and to promote biomedical and pharmaceutical research. It highly encourages international networking.

The university has 4 research centres:

- The Malaria Research and Training Center (MRTC, see below);
- The SEREFO Center for HIV and Tuberculosis Training and Research;
- Santé Publique conducting research on public health; and
- The Labo de Langue in charge of English teaching.

Malaria Research & Training Center (MRTC)

The Malaria Research and Training Centre (MRTC)⁸² was created in 1992 within the Department of Epidemiology of Parasitical Diseases at the University of Bamako. The center has developed through cooperation with universities and research institutions worldwide such as the Wenner-Gren Institute, University of Sweden, University of Rome or the University of Maryland.

The MRTC is involved in all aspects of research on malaria, directed at the development and testing of appropriate strategies for the eventual control of malaria and the reduction of the burden of disease in the people of Mali, the region and all of Africa.

The MRTC has developed an integrated approach to the study of malaria using molecular biology as a basis for addressing field epidemiological and entomological problems at the community level. The MRTC has conducted numerous large, longitudinal cohort studies, case-control studies, drug efficacy trials and malaria vaccine trials. The center maintains ten separate research units located in Bamako with different malaria epidemiology and transmission characteristics. In addition the MRTC has research stations in Tieneguebougou (Kolokani), Doneguebougou and Bancoumana (Kati).

The centre is the main recipient of EDCTP grants in Mali through individual applications of researchers working at the institution.

L.5 Results and impact achieved by the projects

This section presents the results and impacts achieved by the projects collected during the interviews, clustered around research activities, especially clinical trials, capacity development and sustainability and networking and research coordination.

⁸¹ Data for 2010-2011, Council of Ministers 28th September 2011, <http://www.journaldumali.com/article.php?aid=3674>.

⁸² Source : <http://www.malariagen.net/node/197>

Impact on research activities, especially clinical trials

Results in terms of clinical trials are considered to be on a good path. Dr. Abdoulaye Djimdé, senior fellow of EDCTP, conducted a phase IV randomised trial on 780 subjects⁸³. The project's objectives were:

1. To test hypothesis that repeated administration of artesunate/amodiquine (AS/AQ), artesunate pyrimethamine (AS/SP) and coartem (AR-L) for treatment of consecutive episodes of uncomplicated malaria reduces the incidence of uncomplicated malaria and attributable malaria; and
2. To measure the impact of repeated administration of the drugs on malarial immunity and malaria transmission.

The project experienced 2,463 cases of malaria and concluded that combined therapy of Arsumax or Arsumax reduced malaria incidence more than Coartem. Outputs include several international publications. These two artemisinin-combination therapies are now used concomitantly or simultaneously to treat malaria in Mali.

Another senior fellowship coordinated by Prof. Kouriba at the Université de Bamako was supported by EDCTP in 2011-2013. The project carried out immunological cohort studies on the role of monocytes in protection against malaria. The objective was to assess the role of monocytes activation by infected red blood cell in the protection against clinical falciparum malaria in endemic area and determine the frequency of monocytes subpopulations according to the clinical outcome (asymptomatic, mild and severe) of malaria infection. A cohort of 210 children aged 1-15 years was established, the project is not finished yet.

The West African Network for Clinical Trials of antimalarial drugs (WANECAM) is a regional network coordinated by Mali following an EDCTP call for proposal in 2007⁸⁴. The network has conducted clinical trial for new malaria treatments and vaccines.

Through WANECAM a partnership has been set up with Medicines for Malaria Venture (MMV), *Shin Poong* (South Korea) and *Sigma Tau* (Italy) for the implementation of clinical trials (phase III and IV) in which 14,000 cases of Malaria were experienced over a period of 2 years. The study aimed to test new artemisinin based combination therapies (artesunate+pyronaridine and dihydro artemisinin+piperaquine) to add to and bypass resistance to current anti malaria treatments in Africa. The results are very encouraging; they are currently being submitted to the European Medicines Agency.

WANECAM's project in Guinea has set up a functional team and facility from scratch. Guinea had a research centre that was not operational. EDCTP funds have enabled re-entry of a PhD based in France (Lyon) to support the project. The laboratory was fully renovated and equipped for clinical and bio molecular research. Investments also included short-term trainings and two Masters. The laboratory is now operational and has contributed to a clinical trial through recruitment of 800 patients; it has obtained a senior fellowship from EDCTP and funds for the development of its ethic committee.

WANECAM has also contributed to the development of infrastructure in Burkina Faso (Sakabe and Niangoloko sites), and in Mali (Bougoula-Hameau and Sotuba sites).

In addition some interviewees stated that WANECAM has helped to improve surveillance and detection of diseases in participating countries.

⁸³Assessment of the Public Health Benefit of artemisinin based combination therapies for uncomplicated malaria treatment in Mali.

⁸⁴ It should not be confused with the West African NoE for TB, AIDS and Malaria (WANETAM).

Impact on capacity development and sustainability

The MRTC counts about 70 beneficiaries of trainings through EDCTP funded projects which have contributed to develop their capacities in ethics, drafting of scientific articles, good clinical practices, data management, cellular biology, immunology and to raise the general quality of research at the MRTC. EDCTP has also supported the development of Mali's ethics committee considered as more dynamic thanks to the training received.

Dr. Djimé helped to develop capacities for 3 students that have obtained their PhDs and to carry out several training sessions on good clinical practices and good ethical practice. All trained staff are still conducting research activities in his unit, 12 were offered permanent positions.

WANECAM is training three PhDs and three Master's students in Burkina Faso, Mali and Austria. All will submit their thesis or dissertations by the end of year. Interviewees indicated that fifteen per cent of trained staff are women. Besides, the network offers short-term training to dozens of young scientists and staff in areas from good clinical and laboratory practice to ethics, data management, finance and even driving.

WANECAM is considered as successful in terms of capacity development in Africa, it has enhanced the quality of research in participating countries.

Some interviewees highlighted that without EDCTP funds they would not have been able to conduct independent research and would have probably have left the country.

Not all the people interviewed were familiar with the Pan African Clinical Trial Registry (PACTR). Those that know about its existence see a clear added value in informing researchers about similar registered clinical trials and identifying potential collaboration partners.

Impact on networking and research cooperation

All of the interviewees were very positive about the achievements of the regional networks involving Mali, both the WANECAM and WANETAM networks.

The West African Network for Clinical Trials of antimalarial drugs (WANECAM) aims to develop a sub-region consisting of Burkina Faso, Guinea and Mali that is equipped with clinical trial sites and laboratories, qualified research teams and a study population prepared to undertake Phases I-IV trials for the development of new drugs against malaria. The network is coordinated by Mali and involves five African institutions from Burkina Faso, Guinea, Gambia and Mali and research units from France, Sweden, the United Kingdom and Germany. The network's main activities are the following:

- Developing antimalarial drugs;
- Training of staff;
- Networking through partnerships;
- Developing research labs and field sites (Guinea, Burkina Faso and Mali).

WANECAM has raised a total of €4,8 million. It is mainly funded by EDCTP but has also raised funds from MMV, Shin Poong, Sigma Tau, Sanofi, and Quintiles.

Interviewees claimed that the network functions well, all parties play their role. The network has strengthened and created new links between African scientists. It has also developed north-north and north-south collaborations.

Nevertheless some interviewees consider that north-south relationships should have research partnerships where African scientists take leadership roles and where African countries benefit from technology transfer.

EDCTP has also supported the creation of the West African network against aids, tuberculosis and malaria (WANETAM). WANETAM aims the creation of a multi-

disciplinary network for regional scientific collaborations (on the three diseases) with multi-site clinical trials.

Interviewees consider that WANETAM's development is very positive. It has succeeded in developing capacities to perform clinical trials in participating countries and to create synergies between lusophone, English and French speaking African countries.

L.6 The process of implementation of EDCTP's activities

Interviewees were generally satisfied with the support they received from the Executive Secretariat. The officers are dedicated, always responsive and have a good understanding of projects and local context. Only one interviewee reported difficulties because the project officer had changed during the project.

Several actors were unsatisfied with delays for validation of reporting documents and final payment. Receiving payments only after the reporting documents are validated can put the institutions under pressure as it can take 6 to 9 months before the first payment is received.

Reporting documents (technical and financial) are considered as complex and difficult to complete. However actors have learned to meet EDCTP's requirements and although the templates are still considered to be complicated changes in the reporting structure would not be welcomed unless there is a significant simplification.

The way the information on the results of the projects is shared is not always clear to all of the interviewees. Interviewees generally have access to EDCTP press releases and/or newsletter per email, some take part to the EDCTP Forum organised every two years. They are not always aware of the content of the website and the newsletters that are distributed. The forum is very appreciated as it is a good opportunity for networking.

L.7 General opinion on EDCTP's performance by interviewees

Interviewees are very positive about EDCTP's contributions to the development of medical biology at the University of Bamako. EDCTP has funded many projects on the three diseases and provides significant funding to carry out ambitious projects.

Interviewees consider that EDCTP's capacity development activities were very relevant, in particular the development of ethics and good clinical practices but also the training of several PhDs that is very expensive for African institutions and has a real impact on their research activities.

Actors agreed on the fact that capacity development activities have contributed changing the landscape in Mali. Today the country has human resources with the necessary competencies to address health issues and supported institutions are more competitive.

Additionally EDCTP has changed the nature of the south-south relationships. Interviewees stated that thanks to networking activities funded through EDCTP, African countries have learned to work as partners rather than competitors.

Nevertheless some interviewees have highlighted that 10 years of investments are not enough to develop a critical mass, African countries need more time. Efforts and investments have to be continuous on the long term. The lack of public funding in research slows the progress and reduces sustainability of investments.

Strengths

- The funding mechanism of EDCTP, which supports integrated approaches, i.e. scientific research and needs in terms of capacity development, networking and infrastructure development.

- The amounts invested by EDCTP are important and enable funding of ambitious projects. EDCTP is one of the most important funders for capacity building and clinical research in Mali.
- Regular contact and communication with the Executive Secretariat. EDCTP project officers have a very good understanding of projects and problems encountered on the field.
- EDCTP offers African scientists the possibility to identify their challenges and priorities without defining the focus of the projects in its call for proposals.
- South-south collaborations have been very useful and countries are now aware that working together makes them stronger.
- North-south relationships can be mutually beneficial, in the WANECAM project students from Europe come to Africa in the framework of their Master's degree.
- Capacity development activities were very relevant and have helped to develop key competencies in health research.

Weaknesses

- The need for co-funding is considered as a major issue. Scientists have to raise money from European governments, this is very challenging for scientists as they are not fully qualified for this.
- The administrative work is considered as too important (in quantity) and complex in particular when scientists do not have a project manager to deal with these requirements and need to carry out all reporting activities themselves.
- Communication between the African institutions part of the Networks of Excellence could be more efficient: progress can be made in terms of information sharing and dissemination.
- Brain drain is an important issue for the sustainability of EDCTP's investments. African institutions need to be able to offer permanent positions with clear career paths for EDCTP trained staff. These positions should enable scientists continue to carry out independent research activities.
- EDCTP's delays for payments are too long.
- A funding period of two years is too short to obtain results. The programme loses in efficiency because of the energy spent to apply for additional funding.
- Lack of public funds reduces sustainability of EDCTP investments.
- Needs in terms of capacity building are still very important in biomedical research but also for training of the lower cadres such as laboratory technicians.

Recommendations

- Projects would benefit from funding on 3 to 5 years periods. This will allow more time for the project to produce first outcomes and it could offer the possibility to organise more advanced level trainings (longer trainings).
- EDCTP's portfolio of projects should enlarge to other neglected diseases, which can constitute major concern in Africa such as the Ebola fever.
- EDCTP should support local institutions to develop permanent research positions with clear career paths for the 5 to 10 upcoming years. Offering stable positions with the possibility to conduct independent research and to progress over the years should help to retain qualified scientist that were trained through EDCTP funds.

- EDCTP's call for proposals should have re-entry grants for young PhDs that cannot apply for Senior Fellowships but that need to find funds to pursue their research activities in Africa as independents scientists.
- African leadership in international partnerships should be strengthened; African scientists should take overall project coordination roles more frequently to reduce dependence from institutions in the North.
- EDCTP should further simplify reporting requirements, online reporting systems could be considered.
- Networks of Excellence should continue to be supported and developed as they have played an important role in developing south-south, north-south and north-north collaborations.
- EDCTP could be more flexible on financial matters (i.e. not so strict budget requirements and late final payments).

L.8 Overview of interviewees

Malaria Research & Training Center (MRTC)

Bamako

Name of interviewee	Role at institution/involvement in project
Prof Abdoulaye Djimde	Coordinator Integrated Project (WANECA) & Senior Fellow
Dr Bourema Kouriba	Senior Fellow
Mr Charles Arama	PhD Student

University of Bamako

Bamako

Name of interviewee	Role at institution/involvement in project
Prof Mahamadou Thera	Collaborator Integrated Project (WANECA) and Collaborator Strategic Primer Grant (PfSPZ Challenge Study)
Dr Kassoum Kayentao	Collaborator Integrated Project (IPTp-SP)

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