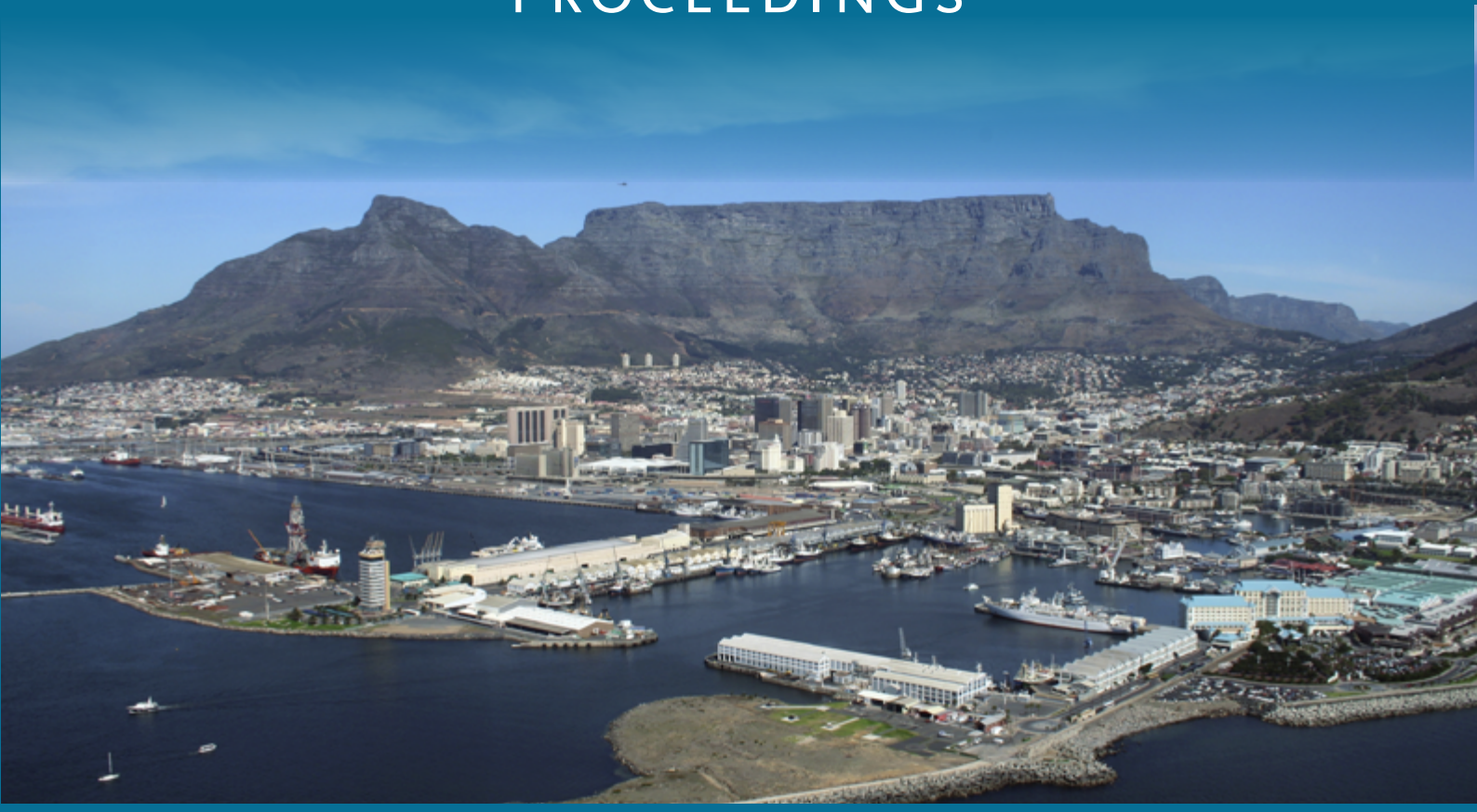
HIGH-LEVEL CONFERENCE ON THE

SECOND EDCTP PROGRAMME

PROCEEDINGS



CAPE TOWN, SOUTH AFRICA

5 NOVEMBER 2012

Towards the second EDCTP programme

The High-Level Conference was held as part of preparations for the second EDCTP programme (EDCTP2, 2014-2024). It aimed to provide a forum to discuss stakeholders' needs, opportunities and expectations, as well as an occasion to endorse the programme and to announce commitments and pledges.

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EDCTP was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria. Currently EDCTP is a partnership between 16 European countries, the European Union and sub-Saharan African countries. The aim of the programme is to accelerate the development of new and improved drugs, vaccines and microbicides against HIV/AIDS, tuberculosis and malaria through a balanced partnership of European national research programmes on PRDs with their African counterparts in collaboration with the pharmaceutical industry and like-minded organisations.

The second EDCTP programme is expected to start in 2014 as part of the European research framework programme Horizon 2020. Its scope is based on the current objectives and achievements and will be expanded to include: all clinical trial phases I-IV including health services optimisation research; other neglected infectious diseases; closer collaboration with industry, like-minded product development partners and development agencies; and collaborative research with other developing countries outside sub-Saharan Africa when possible and desirable.

Contents

Acronyms and abbreviations

ACP	African Caribbean Pacific Group of States
ANDI	African Network for Drugs and Diagnostics Innovation
ARROW	Antiretroviral Research for Watoto (children)
ARV	antiretrovirals
CANTAM	Central African Network for TB, AIDS and Malaria
DART	Development of Antiretroviral Therapy in Africa
DFID	(UK) Department for International Development
EC	European Commission
EDCTP	European & Developing Countries Clinical Trials Partnership
EDCTP2	Second phase of the EDCTP programme
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FP7	EU Seventh Framework Programme
Gates Foundation	Bill & Melinda Gates Foundation
GSK	GlaxoSmithKline
KEMRI	Kenya Medical Research Institute
MEP	Member of the European Parliament
MRC	Medical Research Council
NEPAD	New Partnership for Africa's Development
PanACEA	Pan-African Consortium for Evaluation of Anti-tuberculosis Antibiotics
PDP	product development partnership
PRD	poverty-related disease
SATVI	South African Tuberculosis Vaccine Initiative
TASO	The AIDS Support Organisation
TB	tuberculosis
UK	United Kingdom
UNAIDS	United Nations AIDS programme
WHO	World Health Organization

1. Executive summary

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a partnership between Europe and sub-Saharan Africa. EDCTP aims to accelerate the research and development of new or improved drugs, vaccines, microbicides and diagnostics in the fight against poverty-related diseases (PRDs). During the Partnership's first phase, which began in 2003, funding has been provided to over 200 projects in 30 sub-Saharan Africa countries to support research on HIV/AIDS, tuberculosis and malaria. Currently EDCTP is funded by 16 European partner countries and the European Union under Article 185 (ex Article 169) of the EU Treaty. The anticipated second phase of the programme (EDCTP2) is scheduled to begin in 2014 and will see a broadening of the remit of EDCTP as under EDCTP2 neglected infectious diseases will also receive attention. All phases of clinical trials (I-IV) will also be included.

As part of preparations for EDCTP2 a high-level conference was held in Cape Town, South Africa on 5 November 2012, in order to provide a forum to discuss stakeholders' needs, opportunities and expectations, as well as an occasion to endorse the programme and to announce commitments and pledges. A further aim was to raise the level of public and private engagement in the programme. Invited participants included mainly African and European high-level representatives from government, industry, patient organisations and the research community. The 244 participants in the meeting heard presentations from 15 senior speakers and also two panel discussions, each of which was followed by contributions from the floor.

The speakers were unanimous in praising the achievements so far made by EDCTP and in welcoming the broadening of the Partnership's remit. Máire Geoghegan-Quinn – European Commissioner responsible for Research, Innovation and Science – described EDCTP as *"a beacon of hope"* and *"a brilliant success story for EU–Africa research cooperation"*. She said the fight against PRDs was a global challenge in which Europe could and must make a major contribution. Appreciation and continued support for the work of EDCTP was also expressed by representatives from African and European countries, research institutions, the Bill & Melinda Gates Foundation, and GlaxoSmithKline.

Ms Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science at the opening session

Many speakers highlighted the importance of equality within the Partnership. For example, Maria da Graça Carvalho Member of the European Parliament (MEP), described EDCTP as, *"a genuine partnership with Africa, in which African partners have retained a high degree of ownership and leadership"*. Nevertheless, the need for African governments to participate more actively was stressed by several speakers. Also much referred to was the need to increase the involvement of other partners – including industry, product development partnerships (PDPs), charities and foundations, and communities themselves. It was regarded as essential that research supported by EDCTP should be translated into effective new products that reach those most in need.

All of those who addressed the meeting emphasised that there is much that still needs to be done and that lessons should be learned

from what has been achieved so far. These lessons must be put to use in the preparation of EDCTP2. This was also clear from the panel discussions and the contributions from the floor. Seven themes emerged from the meeting that will be central in the planning of the second phase of the programme.

1. Partnership and co-ownership – EDCTP's focus on these principles as a means of achieving progress against the PRDs must be maintained, but more effort should be made to expand the range of partners and to ensure that all partners participate actively. Co-ownership requires co-investment.

2. Africa's contribution – Africa itself has many resources to contribute to PRD research. Its governments should engage more fully as partners in EDCTP, and this includes contributing financially. Every effort must be made to enable Africa's people – particularly those with the greatest needs, including women and children – to be given attention in the programme. Their voices must be heard.

3. Capacity building – This has always been central to the goals of EDCTP and should remain so. Through enhancing its resources, Africa can be made stronger.

4. Expanded remit – EDCTP's plan to broaden its focus to include all phases of clinical trials and to address the burden caused by neglected infections has been endorsed by the meeting. (While some participants suggested further expansion, notably to include non-communicable diseases, others considered this would result in resources being spread too thinly.)

5. Translation – EDCTP must ensure that the findings of research are translated into policy and practice, and that new products reach communities and individuals in most need. This will require that support is given to implementation trials and health systems research.

6. Ethics review and regulatory oversight – These are essential aspects of clinical trials, but they are often associated with unnecessary delays. EDCTP must continue its activities as a broker to find ways of reducing these delays, particularly through training, infrastructure development and harmonisation of procedures as appropriate.

7. Communication – Researchers, governments and other partners are often poor communicators. Essential feedback is often lacking. Again acting as a broker, EDCTP should continue to build bridges between partners by facilitating effective communication. It must also continue its efforts to streamline its own procedures.

Commissioner Máire Geoghegan-Quinn and Prof. Hannah Akuffo, Chair of the EDCTP General Assembly, **at the welcome reception**

Participants of the High-Level Conference on EDCTP2

2. Key achievements of EDCTP1

Increased public and private investment in clinical trials

Funding clinical trials constitute the co-activity of EDCTP. Under EDCTP1, a total of 88 clinical trials have been funded, promoting African-European and notably trans-African partnerships in clinical trials involving more than 80,000 African patients: 31 trials on HIV/AIDS (including one early termination), 25 trials on TB, 32 trials on malaria.

Many of the clinical trials supported by EDCTP1 address the improvement and adaptation of existing medical interventions and drug treatments to specific, vulnerable target groups such as malnourished children or pregnant women. These trials were launched in accordance with International Conference on Harmonisation (ICH) standards on good clinical practice.

Most clinical trials are still on-going (64 out of the 88). However, some first positive results have been achieved:

- Kesho Bora study of highly active antiretroviral therapy during pregnancy and breastfeeding: demonstrated a 43% reduction in HIV infections in infants and more than 50% reduction of mother-to-child transmission during breastfeeding. Findings were influential for the new 2010 WHO guidelines on prevention of mother-to-child transmission of HIV
- HIV-TB Pharmagene: evaluated drug regimens for optimisation of tuberculosis and HIV co-treatment in Africa. The pharmacokinetic and pharmacogenetic data collected on drug-drug interactions will guide treatment policy on optimum dosage
- 4ABC study: conducted at twelve trial centres in seven sub-Saharan African countries (Burkina Faso, Gabon, Mozambique, Nigeria, Rwanda, Uganda, and Zambia). More than 10,000 children between 6 and 59 months old were screened and a total of 4,116 children were included in the study and treated. Three novel artemisinin-based combination drugs were found to be safe and efficacious in treating children with uncomplicated malaria. The study informed African Ministries of Health on relative safety and efficacy of available artemisinin-based combination therapies, and its results supported the WHO recommendation of dihydroartemisinin-piperaquine (DHAPQ) as a treatment option for uncomplicated malaria
- Severe Malaria in Children (SMAC) network: demonstrated that 3 doses of iv artesunate over 2 days is as effective as the 5 doses over 3 days regimen) thereby contributing to the development of a lower cost regimen with the potential to reduce the risk of incomplete treatment. A phase III follow-up clinical study completed enrolment of a total of 1046 children with severe malaria, and aims to further optimise the drug administration in the treatment of patients
- CHAPAS trial: contributed to the FDA approval and WHO prequalification of Triomune Baby/Junior, a fixed-drug combination formulation for the treatment of HIV in children.

Building of clinical research capacity in sub-Saharan Africa

- EDCTP1 has provided 400 career and training awards to African scientists, including 50 senior fellowships that almost without exception have remained in their own countries after the training
- More than 800 research collaborators in Africa and almost 450 in Europe were cooperating in EDCTP-funded activities

and benefitting directly or indirectly from EDCTP support
- Establishment of four regional networks of excellence, one in each sub-Saharan African region, i.e. in Western, Eastern, Southern and Central Africa. These networks facilitate the interaction between individual African research teams, help exchange knowledge and pool resources for the conduct and management of clinical trials, including mentoring of less experienced research institutions with experienced ones.
- A milestone has been the support to the establishment of the Pan-African Clinical Trials Registry (PACTR, www.pactr.org), which since 2010 has been officially recognised as WHO Primary Registry
- EDCTP has also funded 74 projects for ethics and regulatory capacity building. This includes support to the establishment of the African Vaccine Regulators Forum (AVAREF), National Ethics Committees (NECs) in Benin, Gabon, Mozambique and Rwanda, and the MARC (Mapping African Research Ethics and Drug Regulatory Capacity) project, which created an interactive, online map of African countries' capacity to conduct ethics review of health research (www.researchethicsweb.org).

Aligning the European research landscape for PRDs

Clinical trials are of such scale and complexity that no single country alone can provide the necessary financial/personnel resources or number of patients, as regards multicentre and/or late stage clinical trials. The EU-level approach on which EDCTP is built allows achieving the required critical mass of resources, with EU-funding complementing MS investments.

EDCTP provides a single common European platform for research cooperation with sub-Saharan Africa in the fight against PRD. It is instrumental in:

- Bringing together and aligning European public funders and authorities towards common objectives
- Brokering new partnerships between European and African researchers, research institutes and clinical centres
- Designing common funding strategies
- Responding to African needs and cooperating with national authorities in Africa
- Attracting and leveraging additional investments from other public and private funders.

Competitive funding provided by EDCTP through open calls for proposals raises the level of competition from national levels to European level, which in turn results in spill-over effects on the quality of research partnerships and projects funded (from bilateral to multi-lateral teams and projects), on the development of European capacities and competences, and on the outcome and impact of public investments.

EDCTP is instrumental in raising EU's visibility on the international agenda for global health. It has been mentioned in high-level international meetings, i.e. G8 Declaration on the Fight against Infectious Diseases (2006) at the G8 Summit in St Petersburg (2006) and referred to as success story and role model for international partnerships between developed and developing countries.

This reputation reflects the growing attractiveness of EDCTP to private funders, such as the Bill & Melinda Gates Foundation. Such developments could lead other major private funders in the field to join, thus leveraging on private investments.

3. The High-Level Conference on EDCTP2

EDCTP is approaching the launch of the second phase of the programme (EDCTP2) which will run from 2014 to 2024. It is planned that the scope of the programme will be broadened. All phases of clinical trials (I, II, III and IV) will now be included. So far the disease focus has been on HIV/AIDS, tuberculosis and malaria but, under EDCTP2, neglected infectious diseases[1] (NIDs)will also receive attention.

As part of preparations for the second phase, the High-Level Conference on EDCTP2 was held in Cape Town, South Africa on 5 November 2012. The intention was to provide a forum to discuss stakeholders' needs, opportunities and expectations of EDCTP2, as well as an opportunity to endorse the programme and to announce commitments and pledges. A further aim was to raise the level of public and private engagement in the programme. Invited participants included mainly high-level African and European representatives from government, industry, patient organisations and the research community. A total of 244 participants attended the event, which was jointly organised by the South African Department of Science and Technology, the European Commission (EC) and EDCTP. The four strategic issues the meeting was intended to address were:

- Lessons learned from EDCTP1
- The scope of EDCTP2
- The role and commitment of the participating European and African countries
- Third-party participation and engagement in EDCTP2, in particular of industry, foundations and charities.

1 The list of NIDs in EDCTP2 has not yet been defined; for the purpose of this report reference is made to the WHO-TDR list. (source: http://whqlibdoc.who.int/hq/2012/WHO_HTM_NTD_2012.1_eng.pdf)

Opening presentations

The meeting was opened by the **Honourable Derek Hanekom**, South Africa's Minister of Science and Technology, who said that South Africa has benefited from its collaboration with EDCTP; its support in areas such as TB has been particularly valued. The high-level meeting marked a broader strengthening of EU–African collaboration in research and offered an opportunity that should be seized. However, it is important to be critical, to strive to do more and to do it better. He highlighted some important recent research findings from South Africa and pledged the country's active participation in EDCTP2.

Hon. Derek Hanekom, South Africa's Minister of Science and Technology, at the opening session

Stressing the importance of co-ownership in EDCTP2, he made clear that this will require co-investment; African governments must continue to expand their commitment to medical research. He went on to tell the meeting that:

> *"South Africa is already investing significantly from our national budget to support the participation of South African researchers in EDCTP projects. We will continue to do so and stand ready to enter into discussions with our partners for even more ambitious*

cooperation during the next phase of the EDCTP. It is my hope that we will be joined by many of our African partners in this endeavour".

Máire Geoghegan-Quinn, European Commissioner responsible for Research, Innovation and Science, described EDCTP as *"a beacon of hope"*, providing *"a brilliant success story for EU–Africa research cooperation"*. It was also:

"a fine example of a principle that we advocate in Europe: to open our research and innovation to worldwide collaboration".

She gave examples of successful EDCTP-supported studies conducted in South Africa. EDCTP has also been successful in supporting the setting up of new initiatives (e.g. the Pan African Clinical Trials Registry and ethics review bodies) and in capacity building, including the training of health professionals. But much more remains to be done to make possible access to innovative health care products in Africa.

Europe conducts two-thirds of global vaccine research and has a duty to extend health benefits achieved by such research to other parts of the world, though it must not do so alone; the EU contribution to EDCTP2 will require similar contributions from other partners. At this time of economic crisis, many would ask, *"Why should Europe pay?"* The answer, the Commissioner said, lies in the scale of the disease burden and the many tragic individual stories that underlie the statistics; Africa bears the greatest PRD burden but eliminating these infections is a global challenge. It is also worth noting that efforts to defeat the PRDs where they are most common will help safeguard European health. Knowledge must flow both ways, she said.

EU funding for EDCTP2, which will be provided under the Horizon 2020 programme (the next EU Framework Programme for Research and Innovation) is intended to *"act as a magnet"* to attract more funding. Trials are expensive undertakings and few organisations can run them alone. The Commissioner called on European countries, African governments, industry, charities and foundations to match the EU contribution of €1 billion. The successes of EDCTP represent *"many saved lives"* and must now be built upon.

EDCTP's High Representative and former Prime Minister of Mozambique, **Honourable Pascoal Mocumbi**, outlined the scale of the PRD burden and said that:

"To address global health challenges, we urgently need to scale up the existing initiatives of clinical research and integrate them with capacity building. In collaboration with other partners we have to accelerate the development of public goods for the effective control and eventual eradication of the main poverty-related diseases".

He summed up the partnership's achievements to date and went on to discuss EDCTP's structure, governance and decision making processes, to which adjustments will be made in the course of EDCTP2. Improvements in the process of collaboration will be of particular importance.

He was confident that, through partnerships, the objectives of EDCTP can be realised, but two *"burning practical issues"* are how to better integrate sub-Saharan African countries into the EDCTP decision making process, and to find ways to encourage African ownership and thus create a stronger African voice:

"African ownership, stewardship and leadership will ensure that the clinical trials and the research funded by EDCTP will address the needs and priorities of African countries".

Honourable Maria da Graça Carvalho MEP, described EDCTP as:

> *"a genuine partnership with Africa, in which African partners have retained a high degree of ownership and leadership".*

The Partnership had:

> *"proven itself to be remarkably effective in improving medical intervention and the quality of the research designed to combat poverty-related diseases" [and would serve as] "a model that will guide us in the future".*

She said she hoped to hear from the meeting how the EU might improve its contribution to EDCTP, and spoke of how the Horizon 2020 funding programme due to begin in 2014 would facilitate the work of EDCTP2. Ms Carvalho is member of the European Parliament's Committee on Industry, Research and Energy (ITRE) and the Delegation to the ACP-EU Joint Parliamentary Assembly.

Horizon 2020, like EDCTP itself, will be a partnership that includes member states, industry and others. It will cover the whole cycle of product development and will feature many improvements over its forerunner, Framework Programme 7 (FP7). The first challenge it will address will be health and wellbeing; the need for new vaccines will be an area of emphasis. Horizon 2020 is more than just a funding programme and will seek to enable collaboration in research. It will avoid duplication of efforts and ensure end-users benefit from research findings as rapidly as possible. Access to finance will be simplified, and funds from public and private sectors will be brought to together. She said every effort will be made to ensure that the new programme's processes are flexible and simple, so that EDCTP2 can make good use of it.

The meeting then heard two keynote addresses, the first from **Sheila Tlou**, UNAIDS Regional Support Team for East and Southern Africa. She focused on the role of civil society, noting that while there is often said to be a need to *"empower Africa"*, in her view Africa is already empowered – all that is needed is to enhance Africa's capacity. In particular, she looked forward to the day when Africa makes its own drugs. There were many challenges to be overcome, including the human rights of key populations, stigma against people living with HIV and other infections, keeping mothers alive and avoiding the orphaning of children, and the current over-reliance on external funding.

Much of her presentation centred on the control of HIV/AIDS; Africa's response to this major health challenge will determine other achievements in the future. There are many success stories, but Africa's HIV transmission rates are still far too high, and women remain at particular risk. Better drugs are needed, ideally with treatment regimens of one dose taken orally. The African region's roadmap on AIDS, TB and malaria has three action pillars: a more diversified approach; improved access to medicines; and better leadership, governance and oversight – with zero tolerance of corruption. EDCTP is *"a vital component of the response"* to AIDS and can be regarded as *"a model partnership"*; EDCTP2 will increase Africa's ability to conduct trials. Research efforts must, however, be coupled with advocacy for global health justice.

The second keynote address was from **Trevor Mundel**, President of the Bill & Melinda Gates Foundation's (Gates Foundation) Global Health Program. He described the Gates Foundation's activities in Africa, focusing mainly on HIV/AIDS, TB, malaria and polio. He used, however, the example of the meningococcal A conjugate vaccine (MenAfriVac™) project as an illustration of the major impact that should be aimed for in the fight against PRDs. Previously, there was no cost-effective meningococcal vaccine; now Neisseria meningococcal disease caused by serogroup A has been dramatically reduced in

areas where vaccination has been done. He gave details of the Gates Foundation's current research & development programme matrix, noting that quality manufacturing and regulatory pathways are new priority areas. The Gates Foundation will shortly be establishing two other regional offices in Africa, in Ethiopia and Nigeria in addition to South Africa.

Dr Mundel described the cost of late-stage clinical trials as *"the Everest we need to climb"*. The risk of these costly trials could be reduced through more thorough and effective research at the proof-of-concept stage. He is looking forward to seeing the development of next-generation malaria vaccines; translational approaches to HIV and TB vaccine research; and novel treatments and vaccines for neglected diseases. Regulatory delays are also a huge concern; new initiatives are needed here with harmonization as one of the aims. He also pointed out that disease prevalence monitoring is another area where improvements are needed.

He ended by outlining the advantages of partnership between the Gates Foundation, the EU and EDCTP: joint investments, sustaining EU leadership in global health innovation, and the acceleration of the development and delivery of life-saving tools.

Dr Trevor Mundel, President of the Bill & Melinda Gates Foundation's Global Health Program **at the opening session**

In his summary of the first part of the meeting, the session Chair **Phil Mjwara** (Director-General of the South African Department of Science & Technology) said some of the challenges faced by EDCTP together with the lessons learned had received attention, and that the meeting had got a sense of the needs of the various stakeholders.

4. Lessons learned from EDCTP1

After brief introductory comments from the Chair, **Ruxandra Draghia-Akli** (EC Director for Health Research & Innovation), the first presentation was made by **Honourable Margaret Jepkoech Kamar**, Kenya's Minister of Higher Education, Science and Technology. She said that health is seen by the African Union as a flagship programme. Many important initiatives in health are now in operation, including those of the African Network for Drugs and Diagnostics Innovation (ANDI), the New Partnership for Africa's Development (NEPAD), Research for Health Africa and EDCTP. The activities of EDCTP to date have had several impacts on health research in Africa. She focussed on capacity building (particularly as regards the availability of research fellowships), improved collaboration (greatly assisted by the creation of the EDCTP regional networks of excellence) and other funding opportunities or activities. Examples included the work of the Pan-African Consortium for Evaluation of Anti-tuberculosis Antibiotics (PanACEA) and of TB vaccine trials. Research funded by EDCTP had been used in the formulation of policy and guidelines by governments and international agencies.

Dr Ruxandra Draghia-Akli and Prof. Elly Katabira at the session 'Lessons learned from EDCTP1'

Honourable Margaret Kamar described the current meeting as a *"stock-taking exercise"*. She hoped that it would help in the development of effective strategies for coordination, and improve synergies for research and development. Other challenges are how to stimulate African governments to support research and more effective targeting of populations most at risk. Redefining what centres of excellence can do best was also on the agenda. Kenya is committed to supporting EDCTP2 and appreciates the support and commitment provided so far by both European and African countries.

Honourable Mauro Dell'Ambrogio, the Swiss State Secretary for Education and Research, said that recent visits he had made to research institutions in Africa had reinforced his view that African centres are important partners in the global fight against the PRDs. We must tackle these global challenges together because of their broad effect on humanity. EDCTP has evolved into an instrument capable of achieving scientific goals and training young scientists. It has made it possible to fund large clinical trials that one organisation could not support alone. Switzerland will maintain its strong support for EDCTP and will be committing new funding to the partnership.

Linda-Gail Bekker, Research Professor of the Desmond Tutu HIV Centre, acknowledged the importance of capacity building, and of both South-North and South-South collaboration. However, while trial capacity has been increased, it should be noted that *"once primed the cogs of a pump can become rusty"*. It is important to keep research activities flowing, in order to make the most of investments made in capacity. Other important issues included ensuring community engagement and good participatory practice. Voices from the South must help determine research priorities. As examples of priority needs, she referred to the search for anti-TB drugs that were compatible with antiretroviral drugs (ARVs), and for

methods to prevent HIV transmission intended for use by women. She had been encouraged by the diversity shown in the work of EDCTP and its support for research focusing on the needs of marginalised people, for example fishing communities.

Marja Esveld, Vice-Chair of the EDCTP General Assembly, spoke of the need for correct use of terminology – collaboration is not the same as integration. She pointed out that her country, the Netherlands, did not have a national programme for the support of clinical trials until one was established to collaborate with EDCTP. This has additional benefits for the Netherlands. She is encouraged by EDCTP's plans to increase collaboration with industry. Even at this time of economic crisis, it remains important to continue support for PRD research. Crises can even be helpful, because they force us to do things more efficiently.

James Connolly, President and CEO of Aeras, described EDCTP as an *"incredible partner"*. It has, for example, made possible the creation by Aeras of a dynamic pipeline of TB vaccine candidates. Without European investment this would not have been achieved. The training of local investigators and expansion of Africa's research capacity are other EDCTP achievements. Other partners are now interested in matching support; Aeras has just signed a collaborative agreement with GlaxoSmithKline (GSK) for a project that will include research conducted at African trial sites. But while progress against TB is being made the situation is still challenging, especially with regard to drug resistance. He described EDCTP as 'a model for the past and for the future'.

Linda Sibeko, Community Representative of The South African Tuberculosis Vaccine Initiative (SATVI), addressed the question of how the patient community has benefited from EDCTP-funded research. She said it gave the community hope to know that something is being done about diseases such as HIV/AIDS and TB. *"We are now starting to see the results"*. Referring to her own experiences in schools and elsewhere in the community, she said that many people are still being left out. As examples she referred to Xhosa-speaking

From left to right: Prof. Elly Katabira, Hon. Margaret Kamar, Hon. Mauro Dell'Ambrogio, Prof. Linda-Gail Bekker, Ms Marja Esveld, Mrs Linda Sibeko and Dr James Connolly at the session 'Lessons learned from EDCTP1'

people, women and the elderly. Older people still have an important part to play in the community; grandmothers help by telling stories and one story they could tell is of the search for vaccines.

Contributors from the floor raised a diverse range of issues.

- National ethics committees should collaborate with global initiatives. (For EDCTP, Charles Mgone responded that ethics groups and regulatory authorities do work together; EDCTP, WHO and NEPAD Agency are all active in this area)
- Research conducted at African universities has produced data that have not yet been put to use in the process of product development. Collaboration, brokered by EDCTP, could rectify this
- More research is needed on fighting disease transmission through behavioural change; TB control was achieved in the North before the advent of drugs and vaccines, as a result of community mobilisation and changes in behaviour. Some fear that if a vaccine is developed against HIV it will give a false sense of security and lead to reverses in behaviour change
- Ethics review boards continue to cause unnecessary delays, holding back the launch of clinical trials. Contributors called on EDCTP to continue to strengthen board capacities and to find out where the bottlenecks really are. In the case of National Regulatory Authorities, joint review of clinical trial applications might help streamline the process. The training of regulators – in which EDCTP is already involved – will also assist
- Participants in trials need adequate protection. Ethical review is not enough to achieve this; some form of insurance is required
- Empowerment of those most at risk of PRD infection is a key issue – most notable is the gender imbalance in HIV infection risk. To help in empowerment, people should be asked what they would like to do to improve their own situation
- We need to move on from efficacy trials to research at implementation level
- Vector control deserves more attention from EDCTP
- African governments should step up their poverty eradication programmes. This would have a big impact on many infectious diseases
- Several contributors remarked that the name "EDCTP" is not memorable and is not accurate; for example, the functions of the partnership extend beyond clinical trials. There is a case for changing the name. The contrary position is that the name and "brand" of EDCTP have become well known; renaming could cause confusion and a loss of impetus.

In closing the session, the Chair, **Ruxandra Draghia-Akli,** noted that much of the discussion had focused on the need to improve collaboration – at all levels, from community upwards. Session Moderator **Elly Katabira** said that it is also clear that scientists need to become more effective communicators.

5. Towards EDCTP2

Opening the meeting as Chair of the session, **Honourable Georg Schütte** (State Secretary at the German Federal Ministry of Education and Research) said that ownership and partnership had emerged as key issues from the morning sessions. But people have different ideas of ownership. For some it is something that is shared within the scientific and political communities. For others it involves sharing between countries. Here there are issues concerning reliability, responsibility and sustainability; these can be affected by frequent changes of personnel within government bodies. A much wider concept of shared ownership is now emerging that includes the public and private sectors and communities themselves. Dr Schütte went on to say that Germany regards EDCTP as a cornerstone of its engagement with international research; it is committed to supporting EDCTP2 through both cash and in-kind contributions.

John Savill, Chief Executive of the Medical Research Council, United Kingdom (UK), reminded the audience that the first ever randomised, controlled clinical trial was conducted by the MRC. He went on to describe the MRC's current strategic plan and its approach to international engagement; the MRC commits 10% of its spending to research relevant to developing countries. Many of its research programmes are longstanding; for example, 65 years in The Gambia and 25 years in Uganda. MRC has noted the rise of non-communicable disease prevalence in developing nations and is a founder member of the Global Alliance for Chronic Disease.

MRC works with many partners, including the Wellcome Trust and the UK Department for International Development (DFID). Collaboration with EDCTP is regarded as particularly important because:

> *"EDCTP enables the UK funders, MRC and DFID, to deliver our strategy of supporting late-phase trials for the development of new interventions through partnership with funders across Europe, with the European Commission and through partnership with African scientists."*

Many MRC trials have also involved collaboration with industry, including Development of Antiretroviral Therapy in Africa (DART) and antiretroviral research for watoto (children) (ARROW). An "open innovation" programme with AstraZeneca has allowed MRC researchers access to 22 compounds in partnership with the company. The Stratified Medicine Initiative, which aims to boost understanding of why groups of patients with the same diagnosis differ in their response to treatment, will also involve industry collaboration. He believes that MRC can achieve more through partnership and that partnerships could and should involve industry. Building bridges is a priority.

From left to right: Hon. Georg Schütte, Dr Olive Shisana, Sir John Savill, Hon. Nkandu Luo and Dr Ripley Ballou at the session 'Towards EDCTP2'

Honourable Nkandu Luo, Zambia's Minister for Chiefs and Traditional Affairs, was another participant who praised EDCTP for its successes and for its focus on partnerships. Nevertheless, partnerships need to be improved and redefined. Power relationships within a partnership are often unbalanced – for

example, between the North and the South. If partnerships are weak and unbalanced they will not achieve their goals.

It is time for African governments to stop being passive partners; they should participate actively in EDCTP. This will require a redefining of budgets and putting money on the table, *"how ever little it may be"*. Contributions in kind will also be important. African governments should also ensure partnership between their own health and science and technology ministries. African countries were invited to participate in EDCTP's General Assembly, but the response has been poor. Governments should seize the opportunity now that EDCTP2 is in preparation. Africans should decide who will represent them in EDCTP2; perhaps there should be envoys who travel widely and consult before speaking on Africa's behalf.

Honourable Nkandu Luo said that many companies operating in Africa have no interest in the health of their workers; she used the example of high TB prevalence among mine workers. The private sector must be made to contribute towards the costs of medical research.

Researchers must become better at communication. To illustrate this point, she said that the development of effective microbicides against HIV is the only way to empower women to reduce their risk of HIV infection, but media misrepresentation of a microbicide study in Zambia had led to public unease, forcing the abandonment of the programme. Amongst the other issues she raised were the importance of developing the capacity of Africa's centres of excellence and the need to involve social scientists in research. She concluded by emphasising the need to monitor the translation of research findings into policy and benefits for populations.

Ripley Ballou, Vice-President of GSK Clinical Research and Translational Science, explained his company's open innovation strategy. Many advances have been made against disease and in his view 90% of them have been due to the efforts of the pharmaceutical industry. Infectious diseases in tropical countries do not present a commercial opportunity, but the industry has a duty to help address the burden they cause. In 2009 GSK became the first company to give access to compounds from its library; seven other companies have since followed. The entire library has now been screened for compounds with malaria or TB activity, with the intention that these compounds will be shared by a research consortium. GSK trial results will also become openly available. These measures are fundamental changes to the way in which the pharmaceutical industry operates.

Ripley Ballou described the development of the RTS,S malaria vaccine, using it as an example of the way in which GSK is already working in partnership with other organisations. Other vaccine candidates are now under investigation and partners will be found to help develop them further. Pharmacovigilance is another area in which the company is eager to collaborate with partners.

The London Declaration – in which pharmaceutical companies were amongst those endorsing a new WHO roadmap for reducing the burden of neglected tropical diseases by 2020 – is another instance of the support the industry is now willing to provide to such initiatives. Further announcements of expanded commitment from the industry, particularly with regard to drug donation, may be expected.

A second panel discussion then followed. Answering a question as to the main opportunities for research under EDCTP2, **Hannah Akuffo**, Chair of the EDCTP General Assembly, said there will be a wide scope with trial

phases I to IV now being covered, although the emphasis on phase II and III will still remain. Targeted implementation research will also now be part of the EDCTP remit. She is particularly excited by the broadening of the disease focus; this will provide an opportunity to study co-morbidities. The bringing of public and private sectors together will make it possible to achieve more in a shorter time. It will also become possible to collaborate with a wider range of African countries, particularly in Central Africa. However, there will also be challenges. Partnerships must become more equal and there needs to be ownership by African policy makers. Partnerships need to be nurtured; it can take time for partners to get to know each other. Professor Akuffo also cautioned that with so many needs to be met there was a danger of spreading resources too thinly and that EDCTP should maintain its existing focus.

Adeyinka Falusi, Professor of Haematology with a strong interest in Bioethics, University of Ibadan, Nigeria, addressed the challenges faced by Central Africa in undertaking medical research. She identified the language barrier (French versus English) as one factor, saying that this impinges on academic leadership. Transport is also more of a problem in Central Africa; communication with other African countries is difficult. While governments across Africa tend to be insufficiently proactive and fail to engage adequately with science, this did seem to be a particular problem in Central Africa. Her view – subsequently challenged by contributors from the floor – is that the position of women is generally worse in Central Africa; women tend not to become scientists so 50% of human potential is wasted.

- Contributors from the floor later referred to new laboratories and other research initiatives in Central Africa, specifically in the Republic of Congo (Brazzaville) and Cameroon, some with funding from the oil industry. While it is the least dynamic of the African regions and faces many challenges (including gender issues and the loss of talented young scientists to jobs overseas), progress is being made. EDCTP has assisted through the creation of its Central African Network (CANTAM).

Honourable Louis Augusto Pelembe, Mozambique's Minister of Science and Technology, said that his country strongly supports the EDCTP programme, considering it to be part of its own agenda. It was important that research efforts should consider the whole of the production chain, through to access for end users. The management aspects of medical research and health care delivery were also of paramount importance. He emphasised the need for African countries, in partnership with the private sector, to financially contribute to the EDCTP2 programme.

Salim Abdool Karim, President of the South African Medical Research Council, addressed the issue of how the MRC might enhance its support for EDCTP. The responsibility of EDCTP is to develop excellence in research that responds to priority issues, and MRC's scientists are well placed to participate in this process. Drugs, vaccines, diagnostics and preventive strategies are all part of MRC's portfolio. It works with many international partnerships, for example ANDI and MMV. MRC aims to ensure that African investigators *"are not just on the receiving end"*; it is able to allocate funds and thereby lever further support. MRC also helps develop South Africa's national research agenda and does so both through research and bringing people and organisations together for discussion.

François Bompart, Vice-President and Medical Director of the Access to Medicines Department at Sanofi, speaking in his capacity as the Chair of the European Federation of Pharmaceutical Industries and Associations

(EFPIA) Global Health Initiative, noted that although pharmaceutical companies have to balance their books, the industry believes in advancing global health. EFPIA wants to create a virtuous circle from which everyone will benefit. With this in mind the industry is now doing more to benefit developing countries. With regard to PRDs, however, market forces are not strong enough to justify major financial investments. Nevertheless, the industry can share its resources; the EDCTP–Industry fellowship scheme[2] is an example of the way in which companies can assist. He addressed the issue of industry providing support to enable Africa to build its own research capacity. One way would be for companies to invest in epidemiological research. Much still needs to be known about disease in Africa, including non-communicable diseases, and we *"need to know our foe"*. He sees capacity building as a two-way process; pharmaceutical companies stand to gain by working with African scientists, from whom there is much to be learned.

Clara Menéndez, Research Professor of the Barcelona Centre for International Health Research, Spain, said that involving more women is one way to develop Africa's research capacity. Translating the findings of research into practice is, nevertheless, the main challenge. For example, the effectiveness of intermittent preventive therapy in pregnancy (IPTp) against malaria is now well established, but only 25% of African women currently receive it. It is also important that more reliable information should be obtained on causes of death, despite the limitations imposed by Africa's poor vital registration systems. For example, half of child mortality is due to neonatal deaths (i.e. occurring within the first 28 days), but very little is known about what these neonates are dying from. More about the causes of death of women also needs to be known. In our efforts we must ensure that the weakest members of society do not get left out. Professor Menéndez also looked forward to further development of South-South collaboration, noting that this could involve such countries as Brazil and Thailand.

Noerine Kaleeba, the Patron and Founder of The AIDS Support Group (TASO) in Uganda, spoke on the theme was involving communities in the search for new tools to fight disease. She described EDCTP as an excellent partnership that could have an important impact on the lives of ordinary people. These people were not physically present in the meeting but they were with us in spirit – she asked participants to imagine them sitting in the empty chairs. Particularly for HIV/AIDS, we cannot ignore the role of communities in fighting disease. Partnerships with communities must be made more meaningful. We need to involve children and adolescents. The term "community" does not necessarily mean, for example, a village – it is about different sectors of the population. The role of traditional healers and healing systems in Africa must not be forgotten; we need a strategic partnership that involves healers. The gatekeepers to healthcare services play a crucial role. Capacity building and training are important – but what are we training people in? Expertise in the social sciences is also needed; she would like to see united research groups in which both science and social science are represented.

Jutta Reinhard-Rupp, Head of Scientific Innovation and Partnerships, MerckSerono, said that pharmaceutical companies have traditionally focused on wealthier markets and have searched for "blockbuster" drugs, but this model is changing. Since 1990s some companies have been donating drugs under social responsibility programmes. The London Declaration is another step forward. The research and development of new products where there is no financial investment cannot be conducted in the same way that research and

2 On 24 January 2013, EDCTP and EFPIA signed a memorandum of Understanding for this scheme, the Clinical Research Fellowship.

development is done for other products; it would take too long. Other incentives and push-pull mechanisms must be found. There is a need to be creative – for example, compounds with antimalarial activity should be tested against other diseases. Researchers from endemic countries need to be more involved; their knowledge is needed. In common with the representatives of other pharmaceutical companies, she is in favour of open innovation – there is no need to keep candidate compounds against PRDs a secret. She agreed with the decision to include neglected tropical diseases in EDCTP2 – they contribute to the disease burden, but there is as yet no research pipeline established for these diseases.

Olive Shisana, CEO of the Human Sciences Research Council and the session moderator, noted that despite agreement on the importance of capacity building some were uncomfortable with the term – perhaps we should in future refer to *"capacity enhancement"*.

Contributors from the floor then made known their own views.

- Health ministers in African governments generally may not be receiving regular feedback on the progress of EDCTP in the African region. Frequent changes of ministers make the problem worse. Those whose role it is to represent the position of Africa will not be able to do their job effectively until feedback structures are in place. While a system is in place for all countries to be represented on the EDCTP General Assembly, experiences are still not being adequately shared
- Despite pledges, African governments are still not making enough money available for medical research.
- Africa has much in the way of natural resources; EDCTP should ensure that these are used
- Natural products from Asia and from South America have been used in the development of effective antimalarials. So far few if any African natural products have been developed in this way. High quality trials are needed of traditional medicines
- If products developed do not reach those who need them, then the efforts of EDCTP will be wasted. This is an ethical issue and demands more attention
- Mozambique is one African country that is increasing its support for research. It will also try to convince companies involved in the exploitation of the country's mineral resources to provide funding for research and disease control.

Summing up the discussions as Chair, George Schütte said an important lesson for EDCTP was that, *"We have to be more inclusive in numerous ways"*. He referred in particular to the need to include more African governments, more research phases, more types of data and more societal groups. He returned to the theme of the people whose spirits were represented by the empty chairs in the conference hall:

> *"Their voices are often not heard but the purpose of all our activity is to provide them with the help and support that will enable them to achieve the dream of a long and healthy life."*

6. Closing session

South Africa's Minister of Health, **Honourable Aaron Motsoaledi**, said that Africa as a continent can be proud of the achievements it has made in development. EDCTP is playing an important part in this process. Through working together sub-Saharan Africa can achieve more. South Africa has established a national clinical trials register and drafted guidelines for good clinical practice. He reaffirmed South Africa's wish to be a part of the EDCTP2 programme.

From left to right: Dr Phil Mjwara, Hon. Aaron Motsoaledi, Hon. Nirj Deva, Hon. Tomáš Hruda, Mr Robert-Jan Smits and Dr Pauline Mwinzi at the closing session

Honourable Nirj Deva MEP and Second Vice-Chair of the European Parliament's Committee on Development, speaking on behalf of the President of the European Parliament, said that millions still live in poverty and suffer from poor health. He asked how this could be allowed to continue in the 21st century. Health inequalities occur when medical research is focused, *"not on the needs of people, but on the value of potential markets exclusively in the developed world"*. The lack of an adequate diagnostic test for TB is just one consequence. Changing the situation presents an enormous challenge, but it is not just a question of money. Europe's economies are broken and need to be mended, but the EU is rightly increasing its funding for EDCTP.

Partnership projects that have led to improvements in malaria control have saved 1.2 million lives in Africa; this shows what can be achieved. There are 31 PRDs – but AIDS, TB and malaria take three-quarters of research funding. The European Parliament therefore welcomes the extension of the EDCTP remit to cover neglected infectious diseases. Nevertheless, while EDCTP's work is important good health services must also be available. EDCTP is a good example of cooperation but further effort is needed to bring in new partners.

Transparency, ethics and investment are all issues that need to be discussed in the planning of EDCTP2. Building capacity in Africa will have many advantages. He noted that clinical trials not acceptable to EU ethics committees are being approved in Russia, India and China. He concluded that EDCTP could become, *"one of the EU's most effective mechanisms of innovation in healthcare"*. There are, however, lessons that should be learned from the experience of the programme so far.

Pauline Mwinzi, Principal Scientist at the Kenya Medical Research Institute (KEMRI) spoke on behalf of Honourable Beth Mugo, Minister of Public Health and Sanitation, Kenya. Kenya is pleased to be a part of EDCTP and hails the achievements that have been made to date. KEMRI also welcomes the expansion planned under EDCTP2, particularly the broader disease remit. KEMRI has a long record of collaboration with EDCTP and this is expected to continue.

Honourable Tomáš Hruda, Vice-Minister for Higher Education and Research of the Czech Republic spoke of medical research in his country that had been crucial to the development of ARVs. Such drugs are now available at very low price in developing countries. Nevertheless, he recognised that bringing the results of research to those who need them is

a challenging task. The Czech Republic has shown it can contribute and it now wishes to participate more actively. He encouraged EDCTP to approach Czech research institutions for assistance.

Robert-Jan Smits, EC Director-General for Research and Innovation, said there were four take-home messages from this high-level meeting.

- There is a need for the scope of the programme to be expanded in EDCTP2, with regard to both budget and content. Nevertheless, it is important not to spread resources too thinly. A more flexible approach will be needed so that phase I and phase IV trials can be supported, in addition to phases II and III
- Partnership and co-ownership have been recognised as crucial to success. African governments must, therefore, now contribute their fair share to the funding of PRD research
- There is a pressing need to involve new partners. The pharmaceutical industry is one such partner and the good representation of the industry at this conference has been very pleasing. Also important, of course, is continued collaboration with other key organisations, such as Gates Foundation and WHO
- A *"lean and mean system"* is required. Excessive bureaucracy must be avoided in order to ensure the timely delivery of research results to those who most need them.

Mr Robert-Jan Smits, Director-General for Research and Innovation, European Commission, at the closing session

In his closing remarks, session Chair **Phil Mjwara** thanked all those who had contributed to the discussions, saying that their candid comments would help shape the course that EDCTP2 would take.

Participants of the High-Level Conference on EDCTP2

7. Discussion, analysis and conclusions

Some clear key messages emerged from the High-Level Conference on the Second EDCTP Programme, the first being that the achievements of EDCTP since its launch have been very well received. The Partnership was variously referred to in discussion as: *'a beacon of hope'* and *'an instrument capable of achieving scientific goals and training young scientists'*. Some speakers went further to describe EDCTP as a model for future EU programmes, especially those involving collaboration with developing countries. The planned expansion of the scope of the EDCTP programme in terms of both scale and breadth was well received. As a result, pledges of continued support were made by representatives of both African and European nations and research centres, with some speakers also describing their own country or institution's activities in the fight against the PRDs. The point was well made that European support for EDCTP should continue, regardless of Europe's current economic crisis. It was seen as a duty both to address the needs of the most disadvantaged in society – particularly women and children – and to give them due consideration in the programme.

Despite this positive assessment of EDCTP, it was agreed that there are lessons that must be learned from the first phase of the programme and put to good use in the planning and operation of EDCTP2. The issues which arose in the presentations and in the discussions which followed fell into seven main areas.

1. Partnership and co-ownership
Europe and Africa both have strengths but more can be achieved when nations work together; knowledge, as several speakers noted, should flow both ways. Likewise, there are many gains to be had when the public and private sectors work together; such collaboration has the potential for progress to be achieved more rapidly. Nevertheless, it was agreed that it takes time to nurture and build any partnership. The power balance within a partnership is important; an unequal balance will hold back progress. All partners must have a sense of "ownership".

The planned increased participation of the pharmaceutical industry in EDCTP2 was warmly welcomed, included the EDCTP-Industry Fellowship scheme. It was also regarded as a positive development that pharmaceutical companies are now more likely to work together against PRDs. However, the need to maintain and expand collaboration with other types of partner, most notably charities and foundations, was also recognised. Ways should be found to partner with communities and civil society, particularly those who are marginalised and most at risk of PRDs. Their voice must be heard. Involving women was seen by the meeting as being of particular importance.

The specific issue of African governments as partners received particular attention.

2. Africa's contribution
In the view of many speakers at the meeting, African governments should participate more actively as co-owners of EDCTP. Co-ownership requires co-investment and African governments should contribute financially, even if they are only able to do so in a relatively minor way.

Good governance is necessary for progress to be made and clearly this must also be a responsibility of governments. Many governments have failed to engage in dialogue with EDCTP and to provide feedback. This results in too weak an African voice at policy making level. The situation is complicated by frequent changes in government personnel at a senior level; systems should be put in place to ensure sustainability. There were also calls for African governments to redouble their efforts towards poverty eradication; lifting people out of poverty makes them less vulnerable to disease.

The importance of traditional healing systems and the widespread use of traditional medicines in Africa must be recognised at policy level. Studies on natural products used in traditional medicine were called for, as this could result in the development of effective new treatments.

Africa's universities have conducted quality research over the years but much of the data generated has yet to be put to good use. Centres of research excellence in Africa have their own individual strengths and establishing what each does best would be helpful in the planning of future research.

Africa's people are its greatest strength yet their voice often goes unheard. Their health is the reason why EDCTP was created and ways must be found of involving them as active participants in the work of the programme. Their voice – and in particular the voice of African women requires attention in the priority setting for future research.

3. Capacity building
The building of Africa's research capacity has been one of the core aims of EDCTP, and conference participants expressed their support for maintaining this effort. Training is a key part of capacity development and EDCTP was urged to continue its efforts to develop the talents of young scientists, and particularly young women as some emphasised. It was noted that the war against PRDs requires the availability of specialist skills in a number of areas, including the social sciences. This should be reflected in the type of training that EDCTP supports.

The particular need to enhance capacity in Central Africa – the least well-developed of the African regions – was also discussed.

4. Scope
Aspects of the extended remit of EDCTP2 received the meeting's attention. While the broader disease remit (the addition of neglected infectious diseases) was universally welcomed, the view was expressed that non-communicable diseases should also be added to EDCTP's portfolio. Other participants believed this would be a mistake as it would result in the programme's resources being spread too thinly.

Participants also noted with approval that EDCTP intends to focus on the whole life cycle of product development. This will require research that goes beyond clinical trials themselves. Epidemiological data is crucial and its collection must also be supported. A suggestion was made that the control groups of trials make a good source of epidemiological data. Good research is also needed at proof-of-concept stage to reduce the likelihood of failure at the more expensive trial stage.

5. Translation: research into policy and practice
Speakers frequently returned to the need to ensure that the findings of research result in changes in policy and practice and that healthcare products reach those who need them. This will require EDCTP to support research that assesses the "real-world" impact of new interventions, and health systems research. In this, the expertise of social scientists will be of value.

In determining the level of access to new products, their accessibility to women, children and marginalised groups must receive particular attention.

6. Ethical approval and regulatory procedures
Frequent mention was made in the discussions of the problem that researchers still face in overcoming delays due to ethical approval. Similarly, regulatory processes often delayed effective treatments reaching those who need them. EDCTP is already active in these areas seeking to improve communications and informing those in positions of authority, with a view to streamlining and harmonising the procedures in question. Conference

participants supported EDCTP in continuing this work.

It was also stated that, while ethical approval helps to protect patients who take part in trials, insurance policies are also needed.

7. Communication
All partnerships require good communications between partners. It was noted that scientists have tended to lack effective communication skills, and this has created problems. EDCTP should seek to build bridges between disciplines, partners and communities.

EDCTP will continue to make every effort to ensure that its own processes are simplified and streamlined – in particular so that researchers receive decisions on funding and financial support itself with a minimum of delay.

Participants of the High-Level Conference on EDCTP2

Annex 1. Conference programme

	Sunday 4 November 2012
	The Cullinan Hotel
16:00-19:00	**Registration**
19:00-21:30	**Welcome dinner**

	Monday 5 November 2012
	Cape Town International Convention Centre (CTICC)
08:00-09:00	**Registration**
09:00-10:30	**Opening session**
	Chairperson **Phil Mjwara**, Director-General of the South African Department of Science and technology
09:00-09:10	**Derek Hanekom**, Minister for Science and Technology, Republic of South Africa: Welcome Address
09:10-09:50	**Opening Addresses**
	Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science **Pascoal Mocumbi**, EDCTP High Representative and former Prime Minister of Mozambique **Maria da Graça Carvalho**, Member of the European Parliament, Committee on Industry, Research and Energy and Delegation to the ACP-EU Joint Parliamentary Assembly
09:50-10:30	**Keynote addresses**
09:50-10:10	**Sheila Tlou, Director**, UNAIDS Regional Support Team for East and Southern Africa: *Empowering Africa for global health in the 21st century*
10:10-10:30	**Trevor Mundel**, President of the Bill & Melinda Gates Foundation's Global Health Program: *Conducting clinical research in Africa – building blocks for success*
10:30-11:00	Coffee break
11:00-12:30	**Lessons learned with EDCTP1**
	Chairperson **Ruxandra Draghia-Akli**, Director for Health Research & Innovation, European Commission Moderator **Elly Katabira**, AIDS Chair 2012 and President of the AIDS International Society
11:00-11:20	**Margaret Kamar**, Minister of Higher Education, Science and Technology, Kenya: *Health research and development in Africa – the impact of EDCTP*
11:20-11:25	**Mauro Dell'Ambrogio**, State Secretary for Education and Research, Switzerland
11:25-12:30	**Roundtable discussion** Lessons learned from the first EDCTP programme

	Panellists **Peter Mwaba**, Consultant Physician and Permanent Secretary, Ministry of Health, Zambia **Linda-Gail Bekker**, Desmond Tutu HIV Centre (DTHC), South Africa **Marja Esveld**, Vice-Chair of the EDCTP General Assembly, The Netherlands **James E. Connolly**, President and CEO of Aeras, USA **Linda Sibeko**, Community Representative, South African TB Vaccine Initiative
12:30-14:00	Lunch
14:00-16:30	**Towards EDCTP2**
	Chairperson **Georg Schütte**, State Secretary at the German Federal Ministry of Education and Research Moderator **Olive Shisana**, CEO Human Sciences Research Council, South Africa
14:00-14:15	**John Savill**, Chief Executive and Deputy Chair of the UK Medical Research Council: *Working together for global goals*
14:15-14:30	**Nkandu Luo**, Minister of Chiefs and Traditional Affairs of Zambia: *African expectations and participation in EDCTP2*
14:30-14:45	**Ripley Ballou**, Vice-President of GSK Clinical Research and Translational Science: *Improving health through openness*
14:45-16:30	**Roundtable discussion** From health research to health delivery: opportunities and challenges for EDCTP2
	Panellists **Hannah Akuffo**, Chair of the EDCTP General Assembly, Sweden **Adeyinka Falusi**, Professor of Haematology, University of Ibadan, and President of Sickle Cell Hope Alive Foundation (SCHAF), Nigeria **Louis Augusto Mutomene Pelembe**, Minister of Science and Technology of Mozambique **Salim Abdool Karim**, President of the South African Medical Research Council, South Africa **François Bompart**, Chairman EFPIA Global Health Initiative, Vice-President, Medical Director and Deputy Head, Access to Medicines, Sanofi, France **Clara Menendez**, Research Professor of the Barcelona Centre for International Health Research (CRESIB), Spain **Noerine Kaleeba**, Patron and founder of The AIDS Support Organisation (TASO), Uganda **Jutta Reinhard-Rupp**, Head of Scientific Innovation & Partnerships at Merck Serono, Switzerland
16:30-17:00	Coffee break
17:00-18:05	**Closing session**
	Chairperson **Phil Mjwara**, Director-General of the South African Department of Science and Technology
17:00-17:15	**Aaron Motsoaledi**, Minister of Health, Republic of South Africa
17:15-17:30	**Nirj Deva**, Member of the European Parliament, Second Vice-Chair of the Committee on Development
17:30-17:40	**Pauline Mwinzi**, Kenya Medical Research Institute (KEMRI)
17:40-17:50	**Tomáš Hruda**, Vice Minister for Higher Education and Research, Czech Republic

17:50-18:05	**Robert-Jan Smits**, Director-General for Research and Innovation, European Commission: *Conclusions and next steps*
18:05-18:10	**Phil Mjwara**, Director-General of the South African Department of Science and Technology: *Closing remarks*
19:00-21:30	Conference dinner

	Tuesday 6 November 2012
09:00-15:30	Site visits to clinical trial sites supported by EDCTP (the programme of the site visits is available on the EDCTP website)

Annex 2. List of participants

Name	Affiliation	Country
Salim Abdool Karim	South African Medical Research Council	South Africa
Salim Abdulla	Ifakara Health Institute	Tanzania
Daniel Abdun-Nabi	Emergent BioSolutions Inc.	United States
Phakamile Abram Jim	Department of Science and Technology	South Africa
Akin Akkoyun	DLR	Germany
Hannah Akuffo	Sida/Chair of the EDCTP General Assembly, Sweden	Sweden
David Allen	Bill & Melinda Gates Foundation	South Africa
Ripley Ballou	GlaxoSmithKline Vaccines	Belgium
Miyelani Grace Baloyi	Technology Innovation Agency	South Africa
Karen Barnes	Worldwide Antimalarial Resistance Network / University of Cape Town	South Africa
Abdoulie Barry	EDCTP	Netherlands
Pauline Beattie	EDCTP	Netherlands
Linda-Gail Bekker	University of Cape Town	South Africa
John Bell	European Commission	Belgium
Bryan Bench	Ministry of Health	South Africa
Isabella Beretta	State Secretariat for Education and Research	Switzerland
Niresh Bhagwandin	South African Medical Research Council	South Africa
Sophie Biernaux	GlaxoSmithKline Vaccines	Belgium
Detlef Boecking	DLR	Germany
François Bompart	Sanofi	France
Rodger Bosch	EU Media	South Africa
Carla Botting	PATH Malaria Vaccine Initiative	United States
Fadila Boughanemi	European Commission	Belgium
Esther Bouma	European Union Delegation to South Africa	South Africa
Gabrielle Breugelmans	EDCTP	Netherlands
Andrea Brooks	Bill & Melinda Gates Foundation	United States
Nienke Buisman	European Commission	Belgium
Ana Lúcia Cardoso	EDCTP	Netherlands
Maria da Graça Carvalho	European Parliament	Belgium
Patslon Chilemba	High Commission of Zambia	South Africa
Paul Chinnock	EDCTP	United Kingdom
James Connolly	Aeras	United States
Eric Coreman	European Union	South Africa
Mark Cotton	Stellenbosch University	South Africa
Rafael De Andres-Medina	National Institute of Health Carlos III (ISCIII)	Spain
Mauro Dell'Ambrogio	State Secretary for Education and Research	Switzerland
Martina Desole	APRE	Italy

Nirj Deva	European Parliament	Belgium
Ali Dhansay	Medical Research Council	South Africa
Keertan Dheda	UCT Lung Infection & Immunity Unit	South Africa
Diassina Di Maggio	APRE	Italy
Eichinger Dietmar	European Union	South Africa
Alioune Dieye	Institut Pasteur de Dakar	Senegal
Vít Dočkal	St. Anne's University Hospital Brno	Czech Republic
Alexander Dodoo	University of Ghana Medical School	Ghana
Ruxandra Draghia-Akli	European Commission	Belgium
Christiane Druml	Medical University of Vienna	Austria
Daan Du Toit	Department of Science and Technology	Belgium
Saleh A Elmarghani	Libyan Embassy	South Africa
Marja Esveld	Ministry of Health	Netherlands
Blanka Fajkusová	Embassy of the Czech Republic	South Africa
Nuraan Fakier	EDCTP	South Africa
Adeyinka Falusi	University of Ibadan/ Sickle Cell Hope Alive Foundation	Nigeria
Patricia Fast	International AIDS Vaccine Initiative	United States
Jim Floyd	Bill & Melinda Gates Foundation	United States
Irene Flueckiger	Consulate General of Switzerland	South Africa
Nedson Fosiko	Malawi Consulate General	South Africa
Jacquelene Friedenthal	Embassy of Switzerland	South Africa
Sebastian Gelderbloem	Aeras	South Africa
Jose General Apolinario	Consulate General of Angola	South Africa
Máire Geoghegan-Quinn	European Commission	Belgium
Jan Gheuens	Bill & Melinda Gates Foundation	United States
Claudia Giehl	Eurice GmbH	Germany
Albert Gjedde	Panum, University of Copenhagen	Denmark
Richard Gordon	Medicines for Malaria Venture and TIA	South Africa
Bruno Gryseels	Institute for Tropical Medicine	Belgium
John Gyapong	University of Ghana	Ghana
Veronica Hall	Emergent BioSolutions Inc	United States
Václav Hampl	Charles University in Prague	Czech Republic
Willem Hanekom	University of Cape Town, South African Tuberculosis Vaccine Initiative	South Africa
Derek Hanekom	South African Minister for Science and Technology	South Africa
Magomarele Hlakudi	Ministry of Health	South Africa
Stéphane Hogan	Delegation of the European Union to the African Union	Ethiopia
Cedric Hollmuller	Institute Euresearch	Switzerland
Nina Holzhauer	Drugs for Neglected Diseases initiative (DNDi)	Switzerland
Toni Hoover	Bill & Melinda Gates Foundation	United States

Zdenek Hostmosky	Institute of Organic Chemistry and Biochemistry AS CR, v.v.i.	Czech Republic
Tomáš Hruda	Ministry of Education, Youth and Sports of the Czech Republic	Czech Republic
Carel IJsselmuiden	COHRED	Switzerland
Michael J. Klein	Quintiles	South Africa
Shabbar Jaffar	London School of Hygiene and Tropical Medicine	United Kingdom
Allen Jefthas	Medical Research Council	South Africa
Michael Jennings	European Commission	Belgium
Søren Jepsen	Statens Serum Institut	Denmark
Frans Joubert	Ministry of Health	South Africa
Tamar Kahn	Business Day	South Africa
Noerine Kaleeba	TASO	Uganda
Margaret Jepkoech Kamar	Ministry of Higher Education Science and Technology	Kenya
Margaret Kapihya	Ministry of Chiefs and Traditional Affairs	Zambia
Eric Mwangi Karanja	Ministry of Higher Education Science and Technology	Kenya
David Kaslow	PATH	United States
Elly Katabira	College of Health Sciences, Makerere University	Uganda
Joe Kaunda	High Commission of Zambia	South Africa
Rasha Wasim Kelej	Merck Serono	South Africa
Johannes Kgatla	Ministry of Health	South Africa
Brendar Khoza	Department of Science and Technology	South Africa
Crispus Kiamba	Ministry of Higher Education Science and Technology	Kenya
Gibson Sammy Kibiki	Kilimanjaro Clinical Research Institute	Tanzania
Andrew Kitua	National Institute for Medical Research	Tanzania
Lizel Kleingbiel	Stellenbosch University	South Africa
J. Kloppers-Lourens	Portfolio Committee on Science & Technology	South Africa
Anne-Laure Knellwolf	National Institute of Health	Italy
Gilbert Onyango Kokwaro	Consortium for National Health Research (CNHR)	Kenya
Philipp Lambach	World Health Organization	Switzerland
Darryl Langford	Merck (Pty) Ltd	South Africa
Deidre Laubscher	Department of Science and Technology	South Africa
Odile Leroy	European Vaccine Initiative	Germany
Boitumelo Letsoalo	Ministry of Health	South Africa
Elizabeth Lipiatou	European Commission	Belgium
Glaudina Loots	Biotechnology and Health Innovation	South Africa
Nkandu Luo	Ministry of Local Government	Zambia
Matimba Mabasa	Department of Science and Technology	South Africa
Eusebio Victor Macete	Manhiça Health Research Centre	Mozambique

Nathabi Madela	Department of Science and Technology	South Africa
David Maenaut	Embassy of Belgium	South Africa
Andile Mahlakata	Travel with Flair	South Africa
Joe Maila	Ministry of Health	South Africa
Popo Maja	National Department of Health	South Africa
Michael Makanga	EDCTP	South Africa
Livhuwani Tommy Makhode	Department of Science and Technology	South Africa
Munyaradzi Makoni	SciDev.Net	South Africa
Tebogo Malefetse	Bill & Melinda Gates Foundation	United States
Nellie Malefetse	Department of health	South Africa
Tichaona Mangwende	NEPAD	South Africa
Isaac Maredi	Department of Science and Technology	South Africa
Venancio Massingue	Ministry of Science and Technology	Mozambique
Sophie Mathewson	EDCTP	Netherlands
Khanyisa Matiwane	Department of Science and Technology	South Africa
Stephen Matiwane	Department of Science and Technology	South Africa
Line Matthiessen	European Commission	Belgium
Thulani Mavuso	Department of Science and Technology	South Africa
Apuk Mayen	Embassy of South Sudan	South Africa
Nokwethemba Mbatha	Department of Science and Technology	South Africa
Ntombi Mchuba	Department of Science and Technology	South Africa
Sibusiso Mdlalose	Logic Trials Clinical Research	South Africa
Ushma Mehta	University of Cape Town	South Africa
Clara Menendez	Barcelona Centre for International Health Research (CRESIB)	Spain
Paula Elyseu Mesquita	Foundation for Science and Technology	Portugal
Tsehaynesh Messele	ASLM	Ethiopia
Christian Meuwly	Embassy of Switzerland	South Africa
Charles Mgone	EDCTP	Netherlands
Phil Mjwara	Department of Science and Technology	South Africa
Muofhe Mmboneni	Department of Science and Technology	South Africa
Pascoal Mocumbi	EDCTP	Mozambique
David Molai	Ministry of Health	South Africa
Thabo Molebatsi	National Department of Health	South Africa
Kimera Moodley	Technology Innovation Agency	South Africa
Nurunessa Moola	Department of Science and Technology	South Africa
Anneline Morgan	Department of Science and Technology	South Africa
Aaron Motsoaledi	Ministry of Health	South Africa
Patience Mthunzi	CSIR	South Africa

David Mukanga	African Field Epidemiology Network	South Africa
Martin Mulchay	Department of Science and Technology	South Africa
Modest Mulenga	Tropical Disease Research Centre	Zambia
Trevor Mundel	Bill & Melinda Gates Foundation	United States
Bernadette Murgue	INSERN	France
Emidio Muscelli	European Union	South Africa
Pauline Mwinzi	KEMRI, Ministry of Public Health	Kenya
Esther Nakkazi	SciDev.Net	Kenya
Z. Ndlazi	Portfolio Committee on Science & Technology	South Africa
Deborah-Fay Ndlovu	Research Africa	South Africa
Peter Ndumbe	WHO-AFRO	Congo
Mabatho Ndwandwa	Department of Science and Technology	South Africa
Annalene Nel	International Partnership for Microbicides	South Africa
Beatrice Nere	Bill & Melinda Gates Foundation	United Kingdom
Hendrick Nesengani	Ministry of Health	South Africa
Z. Ngcobo	Portfolio Committee on Science & Technology	South Africa
Doorthy Ngila	Academy of Science of South Africa	South Africa
Alasford Ngwengwe	National Health Research Advisory Committee	Zambia
Patrick Nkanza		Zambia
Francine Ntoumi	Congolese Foundation for Medical Research	Congo
Thomas Nyirenda	EDCTP	Netherlands
Frank Oberholzer	European Union	South Africa
Renee Olende	Drugs for Neglected Diseases Initiative (DNDi Africa)	Kenya
Renee Osborne-Mullins	Parliament Monitoring Group	South Africa
Mark Palmer	Medical Research Council	United Kingdom
M. Iqbal Parker	International Centre for Genetic Engineering and Biotechnology	South Africa
Louis Augusto Mutomene Pelembe	Ministry of Science and Technology	Mozambique
Veronique Penlap Nintchom	University of Yaounde	Cameroon
Daniela Pereira	EDCTP	Netherlands
Juan Carlos Perez Navas	European Parliament	Belgium
John Phiri	Ministry for Education, Science and Technology	Zambia
Thamizhanban (Anban) Pillay	National Department of Health	South Africa
Antoni Plasencia	CRESIB	Spain
Jeffrey Pullicino Orlando	Malta Council for Science and Technology	Malta
Alexander Pym	Nelson Mandela School of Medicine, UKZN	South Africa
I. C. Quingolo	Consulate General of Angola	South Africa
Takalani Rambau	ASSAF	South Africa

Gita Ramjee	Medical Research Council	South Africa
Gwendoline Malegwale Ramokgopa	Ministry of Health	South Africa
Steve Reed	IDRI	United States
Patricia Reilly	European Commission	Belgium
Jutta Reinhard-Rupp	Merck Serono	Switzerland
Mary-Ann Richardson	ACRO	South Africa
Tobias Rinke de Wit	Amsterdam Institute for Global Health and Development	South Africa
Zeda Rosenberg	International Partnership for Microbicides	United States
Edith Roset Bahmanyar	GlaxoSmithKline vaccines	Belgium
Bertha N Rotich	Government of Kenya	Kenya
Roxana Rustomjee	Emergent BioSolutions	South Africa
Deon Salomo	Medical Research Council	South Africa
Nicholas Sammut	Malta Council for Science and Technology	Malta
Francina Sathekge	Department of Science and Technology	South Africa
John Savill	Medical Research Council	United Kingdom
Georg Bernard Schütte	Federal Ministry of Education and Research	Germany
Christopher Seebregts	Medical Research Council	South Africa
Mamokolo Sethosa	Ministry of Health	South Africa
Olive Shisana	Human Sciences Research Council	South Africa
Allen Shofe	Emergent BioSolutions	United States
Linda Sibeko	SATVI Community Advisory Board	South Africa
Meagan Simpson	Medical Research Council	South Africa
Michelle Singh	EDCTP	South Africa
Sodiomon Bienevnu Sirima	Centre National de Recherche et de Formation sur le Paludisme	Burkina Faso
Gail Smith	EDCTP	South Africa
Robert-Jan Smits	European Commission	Belgium
Mandy Solomo	Medical Research Council	South Africa
Thozama Spotose	Public Organisation	South Africa
Kari Stoever	Aeras	United States
Adrian Streinu-Cercel	National Institute for Infectious Diseases Prof. Dr. Matei Bals	Romania
Nathalie Strüb Wourgaft	Drugs for Neglected Diseases initiative (DNDi)	Switzerland
Dereck Tait	Aeras	South Africa
Marcel Tanner	Swiss TPH	Switzerland
Simon Tanui		Kenya
Mamohloding Tlhagale	Department of Science and Technology	South Africa
Tlou Tlhako	National Department of Health	South Africa
Sheila Tlou	United Nations Joint Programme on HIV&AIDS (UNAIDS)	South Africa

François Trémège	Institut de Recherche pour le Développement (IRD)	France
Anne Tuiskunen Bäck	Sida	Sweden
Constantine Vaitsas	FORTH / PRAXI Network	Greece
Esthel Van Brackel	GlaxoSmithKline Vaccine	Belgium
Roeland Van de Geer	European Union Delegation	South Africa
Gianpietro Van De Goor	European Commission	Belgium
Gert Onne van de Klashorst	EDCTP	Netherlands
Bogdan Van Doninck	Belgian Science Policy Office	Belgium
Alfred Adriaan Van Kent	Ministry of Education	Namibia
Guy Vernet	Fondation Merieux	France
Jarmo Wahlfors	Academy of Finland	Finland
Gerhard Walzl	Stellenbosch University	South Africa
Anna Wang	Bill & Melinda Gates Foundation	France
Steven Ward	Liverpool School of Tropical Medicine and Hygiene	United Kingdom
Timothy Wells	Medicines for Malaria Ventures (MMV)	Switzerland
Robert Wilkinson	University of Cape Town, Imperial College London and MRC National Institute for Medical Research	South Africa
Anna Wrochna	European Union Delegation	South Africa
Richard Young	European Union Delegation	South Africa
Lynn Zijenah	University of Zimbabwe College of Health Sciences	Zimbabwe

Colophon

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Author: Paul Chinnock
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Europe Office

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

Visiting address
Laan van Nieuw Oost Indië 334
The Hague, The Netherlands

Phone +31 70 344 0880/0897
Fax +31 70 344 0899
E-mail info@edctp.org
Internet www.edctp.org

Africa Office

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

Visiting address
Francie van Zijl Drive, Parowvallei
Cape Town, South Africa
Phone +27 21 938 0819
Fax +27 21 938 0569