



European & Developing Countries Clinical Trials Partnership

JOINING FORCES

EDCTP CURRENT AND
PROSPECTIVE PARTNER
COUNTRIES MEETING REPORT

15 MAY 2012



Towards the second EDCTP programme

The process of expanding the European membership of EDCTP in preparation for EDCTP2 has begun with a meeting of current and prospective European partner countries. The aim of expanding EDCTP membership is to leverage European national research programmes relevant to poverty-related and neglected infectious diseases.

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 14 European Union Member States plus Norway and Switzerland with 47 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 January 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	– 2
1. Executive summary	– 3
2. The EDCTP experience	– 5
Introduction	– 5
Preparations for Horizon 2020: the Danish presidency	– 5
EDCTP strategy and operations	– 5
Experiences of current EDCTP partner countries	– 7
Germany: national research stimulated	– 7
France: national research priorities	– 7
Ghana: opportunities created	– 8
Spain: leveraging funding resources	– 9
Belgium: research partnerships	– 9
Netherlands: embedding a national programme	– 10
3. The case for EDCTP2	– 11
Dialogue with prospective partner countries	– 11
Strategic Business Plan for EDCTP2	– 14
EDCTP2 and the EU process	– 15
4. Conclusions and next steps	– 17
Annex 1. List of participants	– 19

Acronyms and abbreviations

ANRS	Agence Nationale de Recherche sur le Sida (National Agency for AIDS Research)
CSA	Coordination and Support Action grant
DfID	UK Department for International Development
EDCTP ₂	second phase of EDCTP's programme, which will begin in 2014
EEIG	European Economic Interest Grouping
ERA	European Research Area
EU	European Union
GA	EDCTP General Assembly
Horizon 2020	financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness
INSERM	Institut National de la Santé et de la Recherche Médicale (National Institute of Health and Medical Research)
LSHTM	London School of Hygiene and Tropical Medicine
MRC	Medical Research Council
MSc	master's degree in science
NACCAP	the Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases
NIDs	neglected infectious diseases
NoE	EDCTP-funded Networks of Excellence
PDPs	product development partnerships
PRDs	poverty-related diseases
UNITAID	an international facility for the purchase of drugs against HIV/AIDS, tuberculosis and malaria
WHO AFRO	World Health Organization Regional Office for Africa

1. Executive summary

Preparations for a second phase of the European & Developing Countries Clinical Trials Partnership (EDCTP₂) are currently underway and EDCTP₂ is expected to be funded by and start in parallel with Horizon 2020 in January 2014. The EDCTP programme goals will be realised through cooperative partner country joint programmes with a common research administration and funding. This will include alignment and integration of scientific activities and resources and, more specifically a common peer-review, co-financing, projects oversight, and monitoring and evaluation framework.

As stated in the EDCTP₂ Strategic Business Plan, all European partner countries have acknowledged the value of EDCTP₁ to developing their own national programme of intervention studies to develop new products to fight HIV/AIDS, tuberculosis and malaria. Moreover, the programme has been one of the few international initiatives to have developed real partnership with African scientists giving ownership and leadership to those on the ground in disease-endemic countries.

The objectives for national programme networking and coordination at the European level are:

- Coordination of research objectives, strategies and activities in the European partner countries
- Cooperation to promote efficiency, complementarities and avoid duplication
- Creation of synergies and added value
- Collaboration and brokering between national programmes.

In support to these preparations, this meeting hosted national representatives from current members of the European & Developing Countries Clinical Trials Partnership (EDCTP) together with prospective partner countries including Czech Republic, Finland, Hungary,

Latvia and the Slovak Republic. It was organised by EDCTP and the European Commission and hosted by Statens Serum Institut with the support of the Danish Presidency of the European Union, represented by the Danish Ministry for Science, Innovation and Higher Education.

The aim of this meeting was to provide information on the strategic opportunities and benefits offered by participation in the EDCTP₂ programme and to provide a forum for discussion between current and prospective EDCTP partner countries.

The following areas were addressed:

- Preparations for Horizon 2020 under the Danish Presidency; expected milestones under the forthcoming presidencies of Cyprus and Ireland
- The strategic and operational aspects of the current EDCTP programme
- The experiences of current EDCTP partner countries, from the perspective of Germany, France and Ghana
- The achievements of EDCTP in the context of the European Research Area (ERA)
- The strategic benefits and opportunities for partner countries; their roles and responsibilities
- The current status of preparations for EDCTP₂ and next steps.

This meeting was to begin the process of expanding the European membership of EDCTP in preparation for EDCTP₂ as a way to leverage investment in European national research programmes of relevance to poverty-related diseases. Through the course of the discussion, a number of areas were identified which will be addressed as part of the activities in the period 2012-2014 when EDCTP is preparing for the second programme. In parallel with the legislative process, the European Commission, the EDCTP Secretariat, and

current member states will work to streamline governance structures, simplify and harmonise rules and processes governing participation such as cofunding, as well as engaging with stakeholders globally to ensure that EDCTP continues to address the research priorities and health needs of all stakeholders in Africa and Europe.

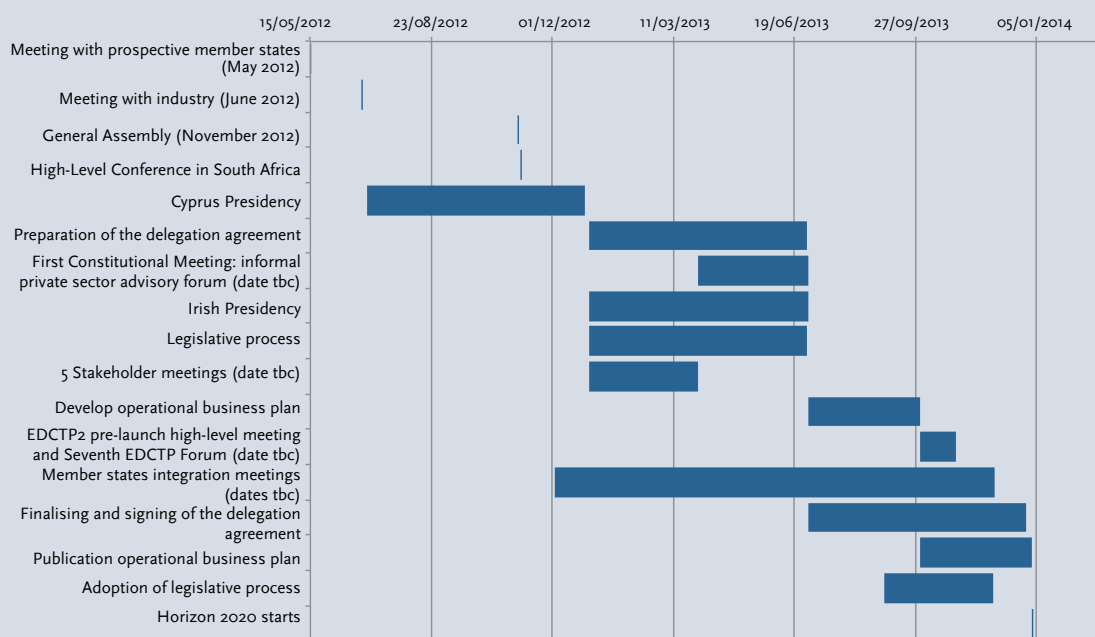


Figure 1. Overview of the key public milestones in the preparations for EDCTP2

2. The EDCTP experience

Introduction

This meeting brought together national representatives from current and prospective member states of the European & Developing Countries Clinical Trials Partnership (EDCTP). It was organised by EDCTP and the European Commission and hosted by Statens Serum Institut with the support of the Danish Presidency of the European Union. The Danish presidency was represented by the Danish Ministry for Science, Innovation and Higher Education. The aim of this meeting was to provide information on the strategic opportunities and benefits offered by participation in the EDCTP₂ programme and to provide a forum for discussion between current and prospective EDCTP partner countries. The goal was to begin the process to expand European membership of EDCTP in preparation for EDCTP₂ and thereby leverage investments in European national research programmes of relevance to poverty-related diseases (PRDs).

The meeting followed on from the Consensus Meeting hosted by the Belgian EU Presidency in September 2010, at which the current EDCTP partner countries agreed that a second phase of the programme should be sought. Preparations for a second phase of the European & Developing Countries Clinical Trials Partnership (EDCTP₂) are currently underway and EDCTP₂ is expected to be funded by and start in parallel with Horizon 2020 in January 2014.

Preparations for Horizon 2020: the Danish presidency

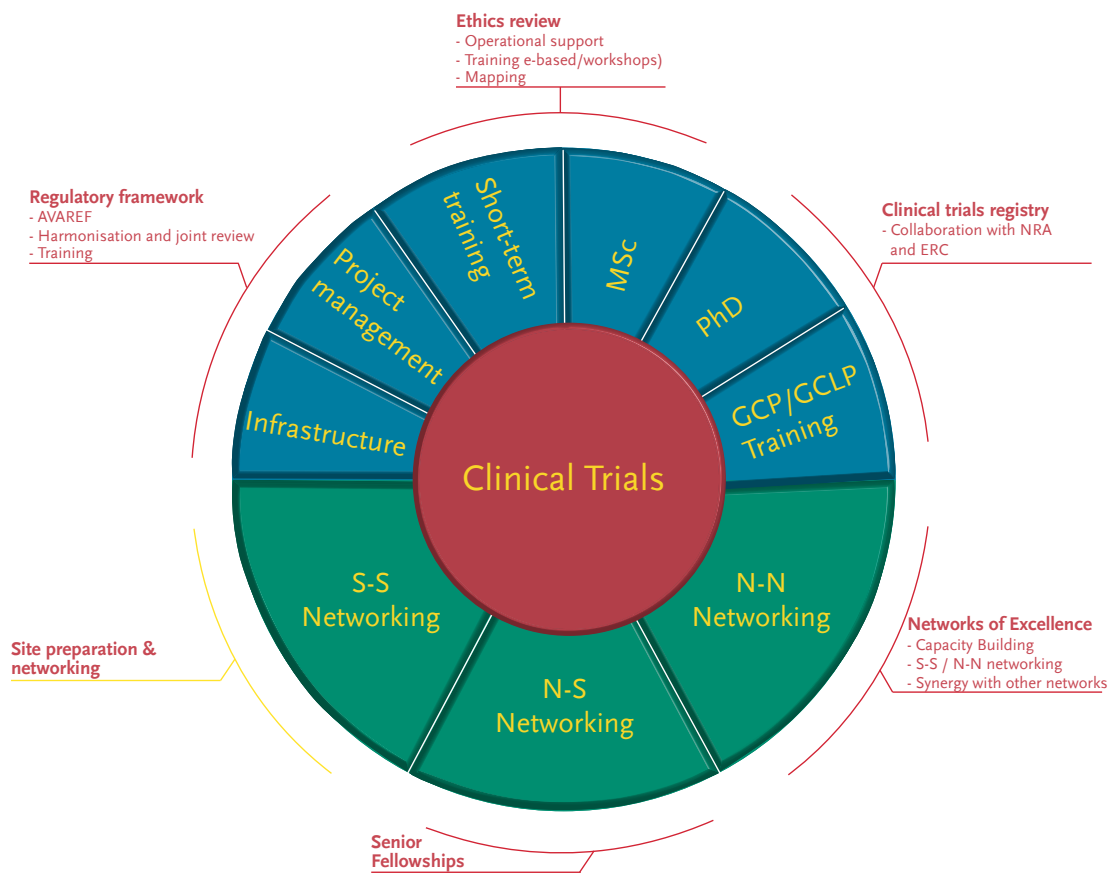
Dr Kim Brinckmann, Head of Division, Centre for Globalisation, Danish Ministry for Science, Innovation and Higher Education, welcomed all participants on behalf of the Danish Presidency and gave a short overview of the preparations for Horizon 2020 under the Danish Presidency.

Dr Brinckmann underlined that the new EU Framework Programme for Research and Innovation Horizon 2020 is one of the political priorities for the Presidency. In the current phase of the decision-making process on Horizon 2020 the Presidency has achieved a partial general agreement between European Union (EU) Member States with regard to the scope and objectives of Horizon 2020 although the budgetary envelope has not yet been addressed. One of the objectives is to widen the participation in the programme by new EU Member States and to increase opportunities for broader participation in European research programmes. Dr Brinckmann endorsed EDCTP as a positive example of research collaboration and underlined the Danish support for the preparations for EDCTP₂.

EDCTP strategy and operations

Professor Hannah Akuffo, Chair of the EDCTP-EEIG General Assembly and Lead Specialist for research cooperation at the Swedish International Development Agency introduced EDCTP, explaining that its main goal is to accelerate research and development of new or improved intervention tools against HIV/AIDS, tuberculosis and malaria with a focus on sub-Saharan Africa. She gave an overview of EDCTP's legal and governance structure, which seeks to ensure the broad participation of European and African scientists and policy makers both at the regional and national level. Although the focus is on supporting excellence in phase II and phase III clinical research in the field of poverty-related diseases, she highlighted the importance of EDCTP's investment in capacity development for research in ensuring that activities take place in a sustainable and ethical manner.

Professor Charles Mgone, the EDCTP Executive Director, continued the introduction to EDCTP with an overview of the scope of the programme, its strategy and the various funding schemes used. He stressed that EDCTP's



core business is the funding of clinical trials of new interventions against HIV/AIDS, tuberculosis and malaria which will enable promising products to proceed along the pipeline and into the settings where they can have the greatest impact. He noted that most funded clinical research projects under the current programme were phase II and phase III studies, but phase Ib and IV studies were also supported. In terms of the second phase of the EDCTP programme, it is expected that a larger number of phase III studies will be funded in order to maximise the benefits of the first phase and leverage funding from multiple sources. In addition, given the increasing evidence and recognition of the burden of neglected infectious diseases, EDCTP2 will expand to support research in this area.

Building on Professor Akuffo's introduction to the strategic importance of capacity building, Professor Mgone noted that the EDCTP model integrates capacity building within the clinical

trials in order to enable that the conduct of trials are done according to the best practices and regulatory requirements. For the same reason EDCTP also supports sub-Saharan countries and institutions to enable them to develop their regulatory capabilities. Identifying a gap in terms of opportunities for south-south networking within regions, the EDCTP Networks of Excellence (NoE) were established to support the long-term aim of a more robust clinical trial infrastructure in eastern, western, central and southern Africa.

Professor Mgone described the various EDCTP grant schemes which are used to fund projects. These included integrated projects; fellowships and training grants; grants to strengthen the ethics and regulatory framework; Networks of Excellence; and grants to enhance coordination and integration of European research projects. More information about EDCTP grant schemes are available on the [EDCTP website](#).

Experiences of current EDCTP partner countries

Germany: national research stimulated

Dr Detlef Böcking, who represents the Project Management Agency DLR on behalf of the German Federal Ministry for Education and Research, began by presenting a snapshot of the situation of research funding for poverty-related and neglected infectious diseases in Germany before EDCTP. He then identified the ways in which EDCTP had contributed to the development of a more coherent environment for national research in poverty-related diseases, noting the number of institutions and initiatives which had since developed. He underlined the opportunities afforded by EDCTP for German researchers to collaborate more easily with researchers across and beyond Europe, and in a more focused way compared with other framework programme activities such as networking of thematic programmes within the European Research Area (ERA-NETS). Although Germany did not have an established research tradition in this area, significant financial commitment from Germany had resulted in good return on investment. He concluded that a comparison between the national background a decade ago and today indicated that participation in EDCTP had contributed to stronger research for poverty-related and neglected infectious diseases and greater commitment to research in partnership with other European and African countries. Finally, he added that the participation in EDCTP has led to stronger programmes in HIV/AIDS, tuberculosis and malaria together with a greater focus on global health supported national needs, particularly in relation to issues such as migration and microbial resistance.

He concluded noting Germany's endorsement of the second EDCTP programme which is a core feature of Germany's commitment to fighting poverty-related and neglected

infectious diseases. This position is illustrated in the *Concept for Research Funding: Neglected and Poverty-Related Diseases* published by the Ministry for Education and Research in July 2011.

France: national research priorities

Professor Patrice Debré, INSERM (National Institute for Health and Medical Research, France) reviewed the experience of EDCTP in the context of France and identifying opportunities for the second phase. He began by presenting the French research landscape from the perspective of international and national global health priorities. He noted that there are presently six organisations in France devoted to the fight against the three diseases (both advocacy and operational) and that national priorities for global health are closely linked to the work of these organisations.

He commented that there is still need for better interactions between the different organisations working with the disease priorities of EDCTP at the international level. For example EDCTP, UNITAID and the Global Fund cover the trajectory from 'bench to bed' and he suggested that greater interaction among these organisations would be beneficial.

Professor Debré referred to the magnitude of French contribution to global health, highlighting that the three diseases, a commitment to Francophone countries, and sub-Saharan Africa were all priorities. He reported that between 2000 and 2011, the French contribution to the three major poverty-related diseases doubled. Both the Global Fund and UNITAID received significant amounts from French Ministries – while the contribution to EDCTP was much smaller. He attributed this to the weaker position of research in the context of international cooperation. Professor Debré explained that most relevant French research institutions are not in a position to contribute directly to EDCTP as most of these are financed

rather than funding agencies. Only ANRS, the national agency for funding research relevant to HIV/AIDS and viral hepatitis has an annual budget of 50 million Euros and is in a position to do this.

This introduction served to illustrate the ways in which national science policies and politics influence the form of the relationship with EDCTP. Currently, in spite of the active research programmes across sub-Saharan Africa and Asia, French ministries do not have the budgets to contribute to the EDCTP ‘common pot’, and the traditional EDCTP grant scheme makes it difficult for French researchers to participate as their home institutions have very limited budgets for international cooperation in research. From this perspective, he recommended the Joint Calls by Member States scheme (based on [EDCTP stakeholder meetings](#), see subsequent discussion) as the best way to network and to integrate European research activities. Under this scheme funds are provided by the partner countries and EDCTP administers the grants. He stressed the need for EDCTP to carefully consider national research priorities (even in terms of cross-cutting areas such as maternal and child health) when developing policy and recommended the stakeholder meetings as the best forum to further research collaboration.

He concluded noting that one of the difficulties that had arisen was the division of responsibility between funder and sponsor in the EDCTP structure.

He underlined the need for stronger links between EDCTP and other international agencies and European initiatives in the second phase, and the potential opportunity associated with moving to phase IV clinical trials in relation to these efforts.

Ghana: opportunities created

Professor John Gyapong, Pro-Vice-Chancellor (Research Innovation & Development), University of Ghana and GA member representing WHO AFRO, decided to present his contribution by focusing on his analysis on Ghana. He began by illustrating the breadth of EDCTP activities in Ghana which include clinical trials, capacity building and research ethics support. He reported that his presentation was prepared following discussions with some of the scientists who were part of EDCTP funded-projects in different ways and he reported some of their perspectives and experiences. He noted the importance of international collaboration and foreign funding for research in Ghana, in creating opportunities for research that would otherwise not exist. He emphasised the importance of EDCTP in funding expensive clinical trials where national funds are scarce. He emphasised that for African scientists, EDCTP provides the opportunity “to get real work done” which provides evidence to strengthen the national environment for health and add value to health service delivery. Beyond phase II and phase III trials, EDCTP has also supported a number of evaluations which provide valuable opportunities to pose research questions which juxtapose research with healthcare service delivery.

Professor Gyapong stressed the importance of capacity building as a way to develop the next generation of scientists, emphasising the importance of specific skills such as grant proposal writing and scientific publications. He emphasised that this process contributes to a growing confidence in the capacity to conduct research. He furthermore underlined that projects such as the grant which enabled the MSc in clinical trials training programme to be developed at the University of Ghana in conjunction with LSHTM had been an opportunity to train clinical research scientists from all over Africa. As well as building capacity in Ghana, this enabled Ghana to contribute to

strengthening the whole sub-Saharan African research environment.

Another area where he reported impact was in the field of health research ethics through strengthening of Institutional Review Boards. This improved coordination at the national level by increasing collaboration between national research ethicists, while supporting individual institutions.

Reflecting on the end of the first phase of EDCTP, Professor Gyapong reported that many of the Ghanaian centres which conduct clinical trials have well established and well managed research activities. The investment of four grants in research ethics paid off as well where monitoring of programmes by ethics review and regulatory bodies has become routine practise in Ghana. He suggested that it is now time to reflect on further collaboration between the ethics committees/institutional review boards and to consider how future monitoring of research activities can be most effective.

Concluding, he commented that the feedback on EDCTP he had received from conversations with members of the national research community was positive and EDCTP is well known within the major institutions. The only area, he concluded, where intensified work is needed is to improve EDCTP's visibility at the political level, in the Ministry of Science and Technology and the Ministry of Health.

Spain: leveraging funding resources

Further contributions were received from Dr Rafael de Andrés Medina, Instituto Carlos III, the GA representative from Spain who drew on his personal experience of involvement with EDCTP. He suggested that EDCTP acted to stimulate contributions from different partner countries towards clinical research in the field of HIV/AIDS, tuberculosis and malaria and that this was an important sign of its value as a mechanism to leverage multiple sources of

funding from Europe, African and third parties. He noted that contributions to the field of poverty-related diseases reported annually by the member states were significant and that there was great potential in the second phase to reallocate and channel those funds according to EDCTP's priorities. Without EDCTP, there would not have been the significant leverage provided by the European Union. Referring to the integration of member states he noted the increasing level of integration over the life of the EDCTP programme which indicated its growing importance. Finally, he commented on the importance to frame EDCTP and the preparation for EDCTP2 within the context of the political strategy for [Horizon 2020](#) and the [EU Communication on Global Health](#).

He underlined the importance of the achievement of the joint programme and the European Economic Interest Group (EEIG) as the instrument to implement this, noting that building up mutual trust and operations had taken time and should not be underestimated as an achievement. The networks were not just north-south, but also north-north and south-south. Further alignment of national priorities and expansion to include even more partners would contribute to an even stronger programme in the future and the eventual sustainability of the research outcomes.

Belgium: research partnerships

Dr Dirk van der Roost, Institute for Tropical Medicine, Belgium, framed the EDCTP approach in the context of current thinking on development and research partnerships. He commented that after a difficult start the organisation has learned to deal with the complexities of conducting research in partnership with European and African researchers and institutions. In a sense EDCTP is a 'third generation initiative' because it places partnership "Europe-Europe" and "Europe-Africa" at the core of its strategy.

Referring to the Paris Declaration and Accra Agenda for Action, he said EDCTP was striving to work according to the principles of ownership, alignment, harmonisation, mutual accountability and clear goals. The second EDCTP programme would be an opportunity to pursue this partnership further and to offer a common European response to African demands based on jointly identified priorities and forms of collaboration.

He suggested that it would be in the national interest of the prospective new partner countries to participate in the partnership, particularly in view of the far-reaching effects of poverty-related diseases and the pandemic character of HIV and tuberculosis. EDCTP offers a structure for research collaboration with strong African counterparts and mechanisms for institutional capacity development in Africa, for example through the Networks of Excellence. The stakeholder meetings and the Seventh EDCTP Forum in 2013 will offer potential European partner countries concrete opportunities to network and explore the possibilities of involvement in EDCTP.

Netherlands: embedding a national programme

Dr Eva Rijkers, Netherlands Organisation for Scientific Research, presented the Dutch contribution to and participation in EDCTP, which was mainly through the pivotal NACCAP programme, the Netherlands-African Partnership for Capacity Development and Clinical interventions against Poverty-related diseases. The programme was established and developed in parallel with EDCTP. It ran two proposals independently of EDCTP and funded four research partnership programmes. After EDCTP became an established programme, the Dutch contribution was channelled to EDCTP for specific calls and in this way the national programme became embedded within EDCTP with Dutch researchers encouraged to apply through the partnership. The Dutch

contribution has been approximately 20 million Euros from the budget of the Ministry of Foreign Affairs.

Drawing on the Dutch experience, she identified the important reasons to participate actively in EDCTP:

- Greater collaboration between European countries
- Greater collaboration between African countries
- North-south collaboration, harmonisation and alignment
- Increased possibility of demand driven research.

Dr Rijkers concluded that in the current political situation EDCTP remains a strategic partner for pursuing health research and contributing to the global health development agenda although currently the Netherlands seem to be moving away from the direct involvement and direct cash contributions and in the current financial situation that is unlikely to change further.

3. The case for EDCTP₂

Dialogue with prospective partner countries

Dr Eva Rijkers chaired a round of questions, comments and discussions. The discussions focused on the case for joining, national experiences of the programme, and areas where current members saw opportunities for further development in the second phase. Questions raised included the more practical aspects of participation, forms of contributions which could be recognised as cofunding, and opportunities for EDCTP activities to be linked to existing national research and disease control programmes thereby contributing to strengthened European integration.

In terms of making the case for joining, attendees were informed that EDCTP offered opportunities to conduct research which individual countries cannot fund or deliver. From the UK perspective, it was commented that the strategic reason for Medical Research Council (MRC) and Department for International Development (DfID) to be involved in the programme is that:

- It gives access to joint research funding. EDCTP is a unique global programme which has delivered in terms of developing research infrastructure in Europe and Africa to facilitate multi-country, multi-site clinical research
- Looking forward, EDCTP will be an important political asset for the EU. Future research on Neglected Infectious Diseases (NIDs) in the second programme will be able to build on the experience and infrastructure of the first phase
- Even though issues of procedure, management and funding mechanisms can be challenging the prize is the clinical trials that can be delivered in partnership
- For new countries which value research capacity, EDCTP is contributing to a

strengthened 'African Research Area' as well as [European Research Area](#).

The importance of participation in EDCTP for prospective partner countries with development policy agendas was also underlined. Participants commented that the EDCTP programme has a strong impact on the scientific community in Africa, at the country level as well as in the region. EDCTP has leveraged many African research institutions that participate in this programme. Within the various regions in Africa, research centres are networking and collaborating with each other. Governments know EDCTP and are committed but the problem is that the governments are not yet making firm financial commitments.

Subsequent discussion focused on how EDCTP activities could contribute to better alignment of individual programmes both within Europe and between Europe and Africa. It was suggested that the European offer and the African demand should be better connected. Three steps forward were suggested:

- That each country should set its own scientific priorities which should then be reviewed in concert
- These priorities should be submitted to the scientific advisory bodies of EDCTP
- That these bodies would then make priorities which would inform the stakeholder meetings.

The need to explore common ground and ways to collaborate was also emphasised. It was also suggested that greater involvement from the development agencies, for example through the inclusion of the European Commissioner for Development would improve alignment between research institutions and national healthcare delivery systems.

Comments from prospective partner countries raised the question of how new members could

ensure a good level of integration and participation for their national researchers. Professor Mgone noted that contributions to a common pot are not a prerequisite for participation and that researchers from non-partner countries could still participate in research projects, but it may be difficult for them to receive funding from other partner countries. The condition is that their participation must include at least two European partner countries that contribute to the funding of the project, such as in the case of the US. Third parties may also bring funding and there is no limit to their involvement. However, membership has the advantage of enabling countries not only to participate but also to bring visibility and influence to EDCTP decision-making. It was emphasised that much remains to be done with regard to integration and new members will be essential to this process. The EDCTP programme aims to further European research integration and collaboration and funding schemes have been developed to stimulate further integration as a means to allow for best use of current funds. It was also added that in-kind contributions were a valuable mechanism for contributing where human resources are available while there is limited funding.

The importance of the stakeholder meetings in contributing to preparing for a greater level of integration was highlighted. It was noted that EDCTP would organise stakeholder meetings to prepare for the second phase of the programme to which new potential partner countries could contribute. Through discussion of the state of research a shared view on where to put the emphasis in future research was developed.

The question of whether the scientific remit of EDCTP would include areas such as diarrhoeal and acute respiratory infections research in the context of maternal and child health was raised. In response, it was emphasised that the decision making process in EDCTP is

participatory at all levels and the present scope of the programme is likely to be focused on poverty-related diseases with an expansion to neglected infectious diseases. It was also commented that many calls for proposals have a wide scope and resulting projects such as the malaria in pregnancy studies are relevant for cross-cutting areas such as maternal and child health. Potential tension between national research priorities and the scope of the EDCTP programme can often be resolved.

Current EDCTP members were eager to hear more from the participants from the new partner countries on their expectations and requirements from participation in the EDCTP programme. A representative from Latvia explained that the decision to prepare for participation through an observer status had been taken at the political level but that further information was still required on various aspects such as the rules and processes related to cofunding. In response, it was emphasised that countries would be able to contribute through the work of its scientists, not just through cash funding to EDCTP. National funding could also be used to support the work of scientists participating in larger research activities. This could include participation in research on drug resistance and epidemiology. Comments from other participants remarked on the potential opportunities for both researchers and institutions afforded by participation in large international studies as well as capacity building and networking activities. Further information was requested on how countries could become more involved in preparation. The representative from the Czech Republic commented that whilst the Czech Republic has the scientific capacity and expertise to participate, further steps will need to be taken including building political support by explaining the benefits of participation in EDCTP (the question was whether this should be focused at the Ministries of Health, Foreign Affairs or Education) and identifying

appropriate institutional actors to support that participation.

In response to some of the points raised, further information was provided on the subject of participation and funding, particularly national contributions.

- At the inception of EDCTP the European Commission had funded EDCTP with 200 million Euros to be spent over 5 years. The EDCTP member states were expected to match this support euro for euro, either in cash or in kind. At the same time EDCTP was to leverage third parties, mainly from the private sector, to support EDCTP. In addition to their funds channelled through EDCTP, participating member states also had to continue spending on EDCTP-relevant research at the level of 2003 expenditure. For the second programme, there had been discussions about whether the focus would be on contributions to a common pot or to a virtual common pot but it was expected to retain a degree of flexibility in how they structured their contribution to EDCTP. This would also reflect the differing levels of independence of agencies to contribute to a common pot
- For example, currently the UK Department for International Development or the Swedish International Development Agency are both in positions to contribute cash to be administered directly via EDCTP. The latter supports African scientists and Swedish researchers, but can also give funding to other countries
- It was noted that some countries contribute in-kind, but are trying to progress to a common pot approach
- From the European Commission, there was indication that a common pot approach will not be insisted upon and that there will be flexibility in terms of both cash and in-kind contributions

- It is likely that in-kind contributions will have to be clearly visible to ensure greater transparency and accountability. However the value of the common pot for Africa was underlined.

Some additional points were raised regarding the legal entity, the EEIG, in which members are individually and collectively liable. However, it was emphasised that EDCTP is shielded from a major liability risk by the decision that EDCTP cannot act as the sponsor of clinical trials.

Regarding the potential political commitments from prospective partner countries, there was consensus that in a number of countries the scientific communities were sensitive to the issue but the concern at the moment was the financial situation. However, a number of country representatives present reported strong political will to participate subject to any financial and legal obstacles being addressed. Further consultation will continue the dialogue with the countries represented at the meeting – Czech Republic, Finland, Hungary, Latvia and Slovak Republic – as well as with countries with which EDCTP has previously met but who were not able to attend such as Bulgaria, Cyprus, Estonia, Lithuania, Malta, Poland, Romania and Slovenia.

Strategic Business Plan for EDCTP2

Dr Mark Palmer, Head of International Strategy, MRC UK reiterated the UK's support to EDCTP2 and the importance of negotiation with more interested parties as a way to ensure that the final programme is valuable and has impact.

Dr Palmer introduced the background of the Strategic Business Plan for EDCTP2 to illustrate the progress that had been made, and outlined the future process. At the Consensus Meeting that was held on 27-28 September 2010 in Brussels, the EDCTP-EEIG partner countries, Latvia (observer partner country), African representatives and the European Commission unanimously agreed to continue with the EDCTP programme.

There was a consensus that the second phase of the programme should be bigger and more ambitious covering a period of up to twelve years divided into three terms. While still focusing on the current scope of HIV/AIDS, tuberculosis and malaria phase II and III clinical trials, the programme would gradually expand to all clinical trial phases (I-IV), health service optimisation research, other neglected infectious diseases, increased membership in Europe and collaborating with other developing countries besides sub-Saharan Africa. The decision was made that the second phase would make a clear start under the next framework programme, Horizon 2020.

The participating member states under the Belgium presidency of the European Union presented their intention to continue with EDCTP to the EU Competitiveness Council on 26 November 2010. Following that meeting, a [Strategic Business Plan \(SBP\)](#) for the second phase of the European & Developing Countries Clinical Trials Partnership programme, EDCTP2, 2014-2024 has been drafted through

an extended dialogue between partner countries. This was facilitated by a drafting committee comprising members from Germany, Ghana, Latvia, Spain and the United Kingdom.

As part of this process, the partner countries presented their country's indicative financial commitments in the second half of 2011. They made a commitment that matched the 500 million Euros the European Commission was prepared to invest. By maintaining current levels of expenditure the partner countries would likely be able to keep this commitment. They also expressed their commitment to exploring future mechanisms to increase cooperation between national programmes with the objective of greater integration of European national programmes within the scope of EDCTP. The Strategic Business Plan provides the foundation to the legislative process which will take place in Brussels in 2012 and 2013.

Although the EDCTP programme formally ended with Framework Programme 6, the partner countries continued to fund EDCTP activities beyond 2010. Additionally, the programme was granted a no-cost extension till 2015. This extension allowed for time to reflect on what the second programme would have to look like and also to prepare for it. In February 2012, the European Commission awarded EDCTP a grant to prepare for the transition to a second programme. The project is called 'EDCTP-Plus: Laying the Foundations for the EDCTP2 Programme'. Its activities will be carried out in the period 2012-2014. In parallel with these activities, monitoring and evaluation of ongoing trials will enable EDCTP and its stakeholders to review the outcomes of the first programme and consider where best to focus in the next phase.

In summary, Dr Palmer concluded that the Strategic Business Plan well positions EDCTP to play its role in a fight against global problems. The budget of 500 million Euros from

the member states has been carefully considered and the idea is that the commitment that has been made is feasible. It was decided to restrict its scope still to sub-Saharan Africa. However, if work needed to be done elsewhere there is a degree of flexibility. He commented that Product Development Partnerships (PDPs) are considered important partners to move products forward along the pipeline. The programme will maintain an integrated approach and will not be exclusively focused on clinical trials but also about building research capacity and a regulatory environment in a way that is active and facilitates research. This approach would in future also allow for more work on health systems optimisation and implementation research to ensure products can be put into practice. Importantly, the scope will be expanded to neglected infectious diseases with special attention to comorbidities. There were also further discussions about new joint activities such as training. On the legal side, the current planning assumes that there will be continuity as an EEIG but at present the process for Horizon 2020 is of major importance in informing the timeframe.

EDCTP2 and the EU process

Dr Line Matthiessen, Head of Unit Infectious Diseases and Public Health at the European Commission Directorate-General for Research & Innovation, began by emphasising that both the Commissioner and the Director General for Research and Innovation have a very positive view of EDCTP as a new way to address global health issues, work in partnership with developing countries and as a better way to use scarce research resources. EDCTP has allowed Europe to take a lead in launching large-scale clinical trials and without it a number of clinical trials would not have been launched.

Dr Matthiessen gave a short overview of the next steps towards EDCTP2 at the European level. A high-level conference will be held in Cape Town, South Africa, in November 2012 to discuss the content of the second programme with African, European and international participants from policy, industry, patient organisations, non-governmental organisations and research. The European legislative process for Horizon 2020 is underway. Currently, the European Commission prepares the proposal for the second phase of the EDCTP programme. This will be based to a large extent on the EDCTP Strategic Business Plan. At the end of 2012 or in early 2013, this proposal will be sent to the European Parliament and the Council. It is foreseen that the proposal will request that the EU contribute 500 million Euros to EDCTP2 to match the expected contribution of the member states.

She also noted that one of the supporting documents is the EDCTP Impact Assessment. Dr Gianpietro van de Goor, European Commission Directorate General for Research & Innovation, explained the character and function of this document. Impact assessments are common practice since 2004 and a prerequisite for evidence based policy. The aim of the assessment is to provide a baseline on the current status, what further action is needed and why. The ex-ante impact assessment explains what impact can be expected from the launch of EDCTP II. It analyses what EDCTP1 has achieved; what the current situation is with regards to the burden of the poverty-related diseases and the lack of efficacious medical interventions; the 'critical mass' required for the EEIG (funding commitment) as well as the lack of research capacity in Africa.

The proposal for EDCTP2 will be debated after the decisive debates on Horizon 2020. Dr Matthiessen reminded the current and prospective EDCTP partner countries that to some extent they will take two key decisions this year:

to be part of EDCTP and fully participate, and to support the proposal from the European Commission which is the indirect decision that allows the EU to participate with 500 million Euros from Horizon 2020. She urged the representatives from the prospective partner countries to ensure their ministers are fully informed and aware of EDCTP.

4. Conclusions and next steps

Dr Isabella Beretta, State Secretariat for Education and Research SER, Switzerland, gave a summary, highlighting key points and issues which had been raised during the discussion and which would shape the process for the next steps:

- EDCTP2 is bound to a political process, but both European and African policymakers are not well informed. There is an information gap
- Further clarity is needed in relation to the various ways of financing participation in EDCTP2 (both at project and programme level), but the financial mechanisms will remain flexible
- Questions remain on how best to prioritise and balance European offer and African demand
- The issue of how financial commitment can be secured at the national level is also pressing
- There is a need for exchanging experiences. It is important to analyse and discuss what is the potential of new partner countries and what they have to offer as well as what EDCTP can offer to the new partner countries that join the platform
- The legal aspects mentioned had focused on the area of liabilities, but this issue had been largely addressed in the first programme
- The need for EDCTP to act where it can add value (by harmonising and integrating research efforts and scarce resources)
- The need for the (potential) partner countries to be proactive and inform and further the internal policy discussion.

Professor Mgone commented that the process, indicated in the graph Figure 1, is clear although the dates are not yet known and the timing will depend on the political process. There are no hard milestones which can impact on the decision of new partner countries to join. Most importantly, policymakers

in the European and African countries should be informed about the added value of joining or supporting EDCTP. Ministers or ministries should be allowed to argue for EDCTP if they want to strengthen its case.

The Secretariat is already preparing for the second phase through EDCTP-Plus, the Coordination and Support Action (CSA) grant, particularly with regard to 1) the mapping of relevant research efforts in European and African countries, including EU-12 countries and 2) the preparation of the stakeholder meetings. Ultimately, these and other activities will feed into the preparation of an operational business plan in mid-2013. It was agreed that it would be helpful if the representatives could advise or assist regarding the collection of moderately detailed data on national research activities, national actors and national funding schemes for research in poverty-related diseases and neglected infectious diseases.

Dr Detlef Böcking offered to be a contact for potential new partner countries who seek detailed information on aspects of EDCTP activities or its programme. Dr Michael Makanga, EDCTP Director of South-South Cooperation and Head of Africa Office, directed the current and prospective partner countries to the EDCTP website as a source of information on EDCTP and especially its projects in the section '[Our work](#)'. The EDCTP through its database of contacts will engage in active communication with potential new partner countries and update country representatives on EDCTP activities and funding opportunities on a regular basis. A follow up meeting will be planned linked to High-level conference on the second programme of EDCTP in Cape Town, November 2012.

Professor Akuffo encouraged the potential new partner countries to communicate their questions to the EDCTP Secretariat or directly to the representatives of the partner countries.

She pointed out that currently Latvia was involved in EDCTP as an observer. Finally, she commented that whilst the framework and the strategic business plan for EDCTP2 were set, EDCTP will remain flexible. She remarked that it has direction but also room for new partner countries to leave their mark and be equal partners.

She thanked all the participants for their contributions and closed the meeting.

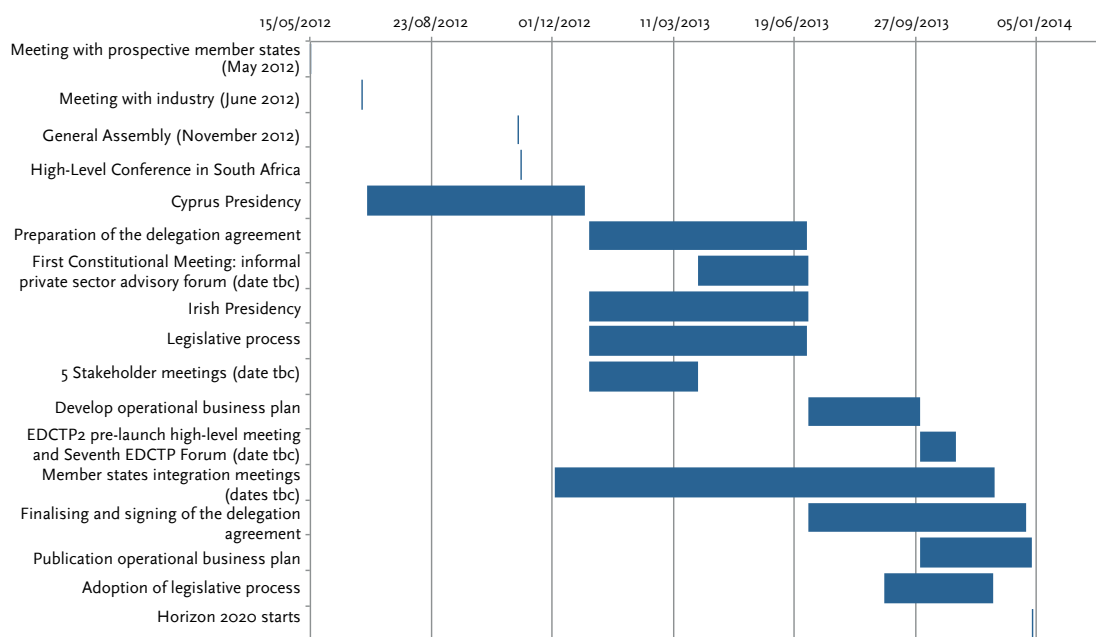


Figure 1. Overview of the key public milestones in the preparations for EDCTP2

Annex 1. List of participants

Name	Affiliation
Akuffo, Hannah	EDCTP, Chair General Assembly (Sweden)
Ashorn, Per	University of Tampere (Finland)
Barry, Abdoulie	EDCTP, Director of Finance and Administration (The Netherlands)
Beattie, Pauline	EDCTP, Operations Manager (The Netherlands)
Beretta, Isabella	State Secretariat for Education and Research (Switzerland)
Berkis, Uldis	Latvian Academy of Sciences, Riga Stradins University (Latvia)
Böcking, Detlef	Deutschen Zentrum für Luft und Raumfahrt e.V. (Germany)
Brinckman, Kim	Danish Ministry for Science, Innovation and Higher Education (Denmark)
Debré, Patrice	Hôpital Potié Salpêtrière (France)
Dieye, Alioune	EDCTP, Chair Developing Countries Coordinating Committee (Senegal)
Endresen, Marit	Norwegian Directorate for Health and Social Affairs (Norway)
Goor, Gianpietro van de	European Commission (Belgium)
Gyapong, John	Research Innovation & Development, University of Ghana (Ghana)
Jaffar, Shabbar	EDCTP, Partnership Board Chairperson (United Kingdom)
Janko, Christa	EDCTP, Private Sector Relations Coordinator (Austria)
Jepsen, Søren	Statens Serum Institut (Denmark)
Klashorst, Gert Onne van de	EDCTP, Communications Officer (The Netherlands)
Lopez Pena, Tomás	Instituto de Salud Carlos III (Spain)
Makanga, Michael	EDCTP, Director of South-South Collaboration and Head of Africa Office (South Africa)
Mathewson, Sophie	EDCTP, Networking Officer (The Netherlands)
Matthiessen-Guyader, Line	European Commission (Belgium)
Medina, Rafael de Andres	Instituto de Salud Carlos III (Spain)
Mgone, Charles	EDCTP, Executive Director (The Netherlands)
Mocumbi, Pascoal	EDCTP, High Representative (The Netherlands)
Murovska, Modra	Microbiology and Virology Institute (Latvia)
Oberfrank, Ferenc	Hungarian Academy of Sciences (Hungary)
Palmer, Mark	EDCTP Vice-Chairperson, Medical Research Council (United Kingdom)
Rijkers, Eva	Netherlands Organisation for Scientific Research (The Netherlands)
Roost, Dirk van der	Institute for Tropical Medicine (Belgium)
Sanne, Arne-Petter	Norwegian Directorate for Health and Social Affairs (Norway)
Stanekova, Danica	Slovak Medical University (Slovakia)
Stehlíkova, Džamila	The National Institute of Public Health (Czech Republic)

Colophon

The Hague, September 2012
European & Developing Countries
Clinical Trials Partnership

Reporting and editing: EDCTP Secretariat
Design: Sam Gobin, www.samgobin.nl

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

