



HIV Vaccines

EDCTP Stakeholders' meeting

Antwerp, Belgium

7 September 2007

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1 Introduction

The EDCTP stakeholders' meeting on HIV vaccines is the last of a series of EDCTP stakeholders' meetings. It was organised by EDCTP and the Prince Leopold Institute of Tropical Medicine, Belgium.

The aims of the meeting were to help EDCTP identify and prioritise potential products in the pipeline; advise on potential suitable sites to do trials; and make recommendations on the funding procedure to meet these aims. In addition, EDCTP wanted a preliminary idea of the financial commitment and participation of the Member States for clinical trials on HIV vaccines.

The meeting was chaired by Dr José Esparza, Senior Advisor on HIV Vaccines at the Bill & Melinda Gates Foundation (BMGF). BMGF has been an essential key player in supporting the effort to develop a safe, effective and affordable HIV vaccine. Dr Esparza has been a leader in the international HIV arena for almost two decades and for much of that time has been deeply involved in a number of international activities to promote and facilitate the development of AIDS vaccines, particularly for developing countries.

2 Overview participating organisations

2.1 National Agency for AIDS Research (ANRS)

ANRS is responsible for dispatching public funds among the various groups in all scientific fields doing research on AIDS in France. For over 10 years, the French National Agency for AIDS research (ANRS) has been committed to an original programme of combining basic science and clinical research. The HIV preventive vaccine research programme run by the ANRS covers upstream research for the definition of immunogens, animal models and clinical research to evaluate candidate vaccines.

More information on ANRS can be found at: <http://www.anrs.fr/>

2.2 Bill and Melinda Gates Foundation (BMGF)

The mission of BMGF's Global Health Program is to encourage the development of lifesaving medical advances and to help ensure they reach the people who are disproportionately affected. The BMGF Global Health Program focuses on funding access to existing vaccines, drugs, and other tools to fight diseases common in developing countries and on research to develop health solutions that are effective, affordable and practical.

More information on BMGFs' Global Health program can be found at: <http://www.gatesfoundation.org/GlobalHealth>

2.3 Centres for Disease Control & Prevention (CDC)

As a part of its overall public health mission, CDC provides leadership in helping control the HIV/AIDS epidemic by working with community, state, national and international partners in surveillance, research, prevention and evaluation activities.

More information on CDC can be found at: <http://www.cdc.gov/hiv/>

2.4 European Commission (EC)

The European Commission (EC) is the main funder of EDCTP through Article 169 of the European Treaty. The EC was represented by DG Research.

More information can be found at goals and activities of the European Commission can be found at: http://ec.europa.eu/index_en.htm

2.5 European Developing Countries Clinical Trial Partnership (EDCTP)

EDCTP was represented through the Member State representatives, the Partnership Board (PB), the Developing Countries Coordinating Committee (DCCC), the Executive Director, the Chair of the General Assembly and the Secretariat.

More information on EDCTP can be found at: <http://www.edctp.org>

2.6 International AIDS Vaccine Initiative (IAVI)

IAVI is a global not-for-profit, public-private partnership working to accelerate the development of a vaccine to prevent HIV infection and AIDS. It is the world's only organisation focused solely on the development of an AIDS vaccine. IAVI implements a major part of its research, policy and advocacy programmes in developing countries.

More information on IAVI can be found at: <http://www.iavi.org/>

2.7 Institute of Tropical Medicine (ITM, Belgium)

The Institute of Tropical Medicine in Antwerp (ITM), Belgium is one of the world's leading institutes for training, research and service delivery in tropical medicine and health care in developing countries. The institute plays the role of both the national reference centre for tropical diseases and the regional reference centre for the diagnosis and treatment of HIV/AIDS for Belgian Ministries of Public Health and Social Affairs.

More information on ITM can be found at: <http://www.itg.be/itg/>

2.8 Karolinska Institute, Sweden

Karolinska Institutet is one of Europe's largest medical universities. It is also Sweden's largest centre for medical training and research. Their mission is to improve the health of mankind through research, education and information.

More information on Karolinska institute can be found at: <http://ki.se/ki/jsp/polopoly.jsp?d=130&l=en>

2.9 National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat and ultimately prevent infectious, immunologic and allergic diseases.

More information on NIAID can be found at: <http://www3.niaid.nih.gov/>

2.10 World Health Organisation (WHO)

The World Health Organisation (WHO) was represented by WHO-UNAIDS HIV Vaccine Initiative, which plays a major coordinating role in the HIV vaccine field by conducting and coordinating activities related to product research and development and implementation research for vaccines and delivery devices. Based at WHO headquarters in Geneva, the disease portfolio of the initiative includes tropical

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diseases, HIV/AIDS, tuberculosis, malaria, meningitis, respiratory diseases, diarrhoeal diseases, Japanese encephalitis, cervical cancer and measles.

More information can be found at: http://www.who.int/vaccine_research/about/en/

2.11 Others

Each European Member State was invited to send two representatives; the legal European Network Officer for EDCTP and one researcher representing the HIV vaccine research of that specific Member State.

Governmental representatives (government or research councils) and researchers from Germany, Norway and United Kingdom, France, the Netherlands, Denmark, Norway, Spain, Switzerland, Belgium, Nigeria, Senegal, Kenya, South Africa, Uganda and the U.S.A. were also present.

3 EDCTP Procedures

The Executive Director, Professor Charles Mgone, gave an overview of EDCTP's new strategy where clinical trials are at the centre of all activities and other components important to EDCTP, such as capacity building and networking, are integrated into this framework. It was explained that EDCTP can fund proposals through an open call or a brokering procedure. More information can be found in the Guidelines for Stakeholders' meetings (see Annex 2).

4 Scientific Overview of the Field

Dr Giuseppe Pantaleo from the University of Lausanne presented an overview on the scientific state of the art. In summary it was mentioned that most vaccines developed against other viral diseases are mostly based on antibody responses. In the case of HIV, the induction of broadly neutralising antibody response has been a major challenge that remains to be solved. As a result, the current candidate vaccines are designed to induce cell-mediated immunity. The challenge with such vaccines is their ability to induce a broadly effective and long-lived T-cell response. Dr Pantaleo stressed that these vaccines may be unable to prevent infection but they could decrease the viral load in vaccinated people who become infected, providing individual clinical benefit and perhaps also reducing transmission of the virus in the population.¹

¹ After the meeting took place, Merck announced on 21 Sept 2007 that they were discontinuing trials with their Adeno-vectored vaccines because the interim analysis indicated that this particular candidate vaccine is not capable of preventing infection nor of reducing viral loads.

5 Products in the Pipeline

Dr Saladin Osmanov from WHO-UNAIDS listed several potential vaccines. The following may be ready for phase II trials:

1. MRKAd5 Trivalent vaccine – 70% of participants have a positive response (see footnote).
2. European products:
 - a. Eurovacc (02 DNA C + NYVAC C) -02 DNA C + NYVAC C appear to produce very good cell mediated immune responses and the breadth of response is good².
 - b. Swedish product (Stockholm) – HIVIS DNA + MVA-CMDR – designed to induce cell-mediated immune response.

It was noted that both products are well designed and are worthy of ongoing clinical evaluation. It was indicated that little is known about how these two vaccines compare against each other and other products in terms of immunogenicity; this needs to be evaluated through clinical trials using comparable laboratory assays. It was emphasized that an unbiased approach is necessary regarding the components of the different vaccines, specifically, the HIV sequences to be included in the vaccines or the need to match the vaccine with the virus clades prevalent in the population.

Several Phase I candidates were presented (see presentation also available on the website) and there was a request for trying to put together a coordinated effort.

6 Discussion on Products and Science

The main discussion points are recorded below:

- There is the expectation that a T-cell vaccine will be able to delay progress of the disease. However, better products need to be developed (products that induce cell-mediated immunity and/or protective antibodies) and long-term monitoring is required to determine which candidate vaccines are definitely effective.³
- It was noted that it is also important to explore genetic vaccines since DNA would be a very stable vector.

² Although both Merck and the Eurovacc vaccines are designed to induce cell-mediated immunity, they may have different levels of efficacy. The negative results from the Merck MRKAd5 should be interpreted as a failure of that particular candidate vaccine and not as a failure of the cell-mediated immunity concept or of the Adeno-vector platform. Nevertheless those results emphasize the need to develop a diversified and robust pipeline of candidate vaccines)

³ The failure of the Merck vaccine should also stimulate the exploration of innovative approaches for HIV vaccine development.

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- The European Commission (EC) observer noted that the EC is funding Eurovacc (02 DNA C + NYVAC C) and HIVIS DNA + MVA-CMDR. EC has mostly funded T-cell vaccines (designed to induce cell-mediated immunity).
- In regards to the two vaccines that are in a more advanced stage of evaluation, it was stated that Eurovacc (02 DNA C + NYVAC C) is a homologous prime boost while the Swedish product (HIVIS DNA + MVA-CMDR) is not and it may be sensible to have a comparative trial of the two products. Eurovacc (02 DNA C + NYVAC C) is based on 3 product components whereas HIVIS DNA + MVA-CMDR I is based on 8.
- It was noted that it is too premature to exclude any of the vaccines from further evaluation, rather, comparative trials should be planned in order to assess their relative immunogenicity.
- It was proposed that the least expensive and most expeditious way to determine the comparative effect of these vaccine candidates is through a trial with clinical outcomes as an end point in a three-arm Phase III trial. However it was noted that this may be difficult and very large cohorts would be required.
- The participant from NIH stated that they are supporting four Phase II and one Phase IIb trials. There is a need to compare data from these different clinical trials.
- The importance of conducting phase IIb or phase III efficacy trials in order to define immune correlates of protection was discussed. A panel of global peptides to assess cell-mediated immunity could be useful as a standard in all trials.
- Bionor Immono stated that they have a number of other possible candidates. A multicentre study is being planned in Europe and U.S. to verify results obtained in Oslo.
- Bavarian Nordic stated that they have concepts that could be evaluated in an African context.
- There was support for more advanced trials as it seems high time to test in parallel to assess immune response.
- It was noted that in a recent meeting that was organised by WHO in Paris, the subject of endpoints in clinical trials were discussed in detail. It was proposed that viral load should not be a sole surrogate endpoint and that a combination of both viral load and CD4 count should be included as endpoints in studies. Several studies showed that other surrogate endpoints would also be useful and it was suggested that more research on new surrogate markers was required. In addition, community studies were encouraged.

7 Needs of Africa & in the field of HIV Vaccines

7.1 Presentation by Dr Alashle Abimiku

Dr Alash'le Abimiku from the University of Maryland gave a presentation on the difficulties encountered in Africa in reversing the HIV epidemic. One of the stumbling blocks for clinical trials in Africa is that Western parameters are used for including or excluding people from clinical trials on HIV vaccines.

7.2 Presentation by Dr Pontiano Kaleebu

Dr Pontiano Kaleebu from MRC Uganda gave a presentation on The African AIDS Vaccine Programme (AAVP). AAVP could play a role in helping to open up some new sites.

8 Discussion on Sites

- The chair clarified that there are many definitions of a 'site'. A comprehensive definition includes several parameters: a population within a country with an appropriate epidemiology and able and willing to participate; an appropriate environment including access to appropriate human resources and infrastructure; and the existence of regulatory and ethical framework to enable a clinical trial to be conducted. It is the responsibility of a hosting country to coordinate the appropriate development of a site together rather than the funders.
- It was questioned whether there are too few sites or whether there are too few trials for the sites. It was noted that in reality the sites that very few sites have the capacity to conduct clinical trials.
- There is a tendency to use sites that have been used before rather than open new ones. AAVP was encouraged to coordinate and promote the development of clinical trial sites within Africa.
- Donors must be made to realise that site maintenance is costly and that investing in the sustainability of sites and cohorts are essential.
- Discussions on site capacity must be preceded by examining the need for a trial. The needs should first be analyzed and then a plan made for meeting those needs, including what types of cohorts are required.
- A persistent requirement in the field is the ongoing site support so that research staff is continually employed and can build a career. The research pipeline is unpredictable however a major contribution by donors would be the creation of site stability. One way of achieving this is linking a site to several trials and thus reduces the dependence on one trial for continuous site support.

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- The term “site” was considered inappropriate as it implies ownership. EDCTP promotes the concept of supporting the institution rather than a “site”. It was stated that more than half of site costs are for items such as quality control (which is needed for licensing) rather than costs for maintaining the site itself. Some concern was expressed about the fact that established sites have to compete with less developed sites. Donors were encouraged to communicate amongst each other and not duplicate their efforts.
- The chair added that the BMGF policy is that equipment they fund cannot be used for private purposes but can be used for other public purposes.
- AAVP should encourage African researchers to form partnerships and networks.
- It was stated that a site may need between 2 to 3 million US dollars for maintenance

9 Member States Commitment

- Sweden – has contributed to EDCTP’s common pot and funds can be used for this call
- UK at least 420 pound sterling of new money to put towards this call
- Norway – 6.2m from GLOVAC is available for vaccine research but restricted to Norwegian institutions
- Germany – Very interested in this call but can only fund German researchers or institutions. Have a budget restricted to EDCTP of 1.5m Euro per year
- Denmark – The Danish government and DANIDA have supported several sites for about 20 years. DANIDA has also cofunded a vaccine product in Guinea Bissau (1m Euro) and have a T-cell candidate vaccine.
- ANRS – Has made a commitment to EDCTP to help increase collaboration on clinical trials. There are a number of different tools in Europe. The only way to develop collaboration is to consider phase IIb (proof of concept) trials. ANRS wants to design small phase IIb trials and has a commitment to work with different collaborators to address this goal. ANRS will contribute to this aspect of a project in the call
- Belgium acknowledged that its funding programme is difficult and that the mainstay of its contribution is towards capacity development, not just to EDCTP but also to health system development. Over the next six yrs there will be a development programme valued at 75m Euro for science to strengthen capacity and logistics support. About two-thirds of the funds will be spent in Africa and about half on EDCTP-related activities. Belgium does not have “programmes” – funding is bottom-up based on merit. However, they have currently earmarked approximately 500,000 Euro per year over the next six years
- Spain will only support open calls for proposals rather than brokering and prefers to support joint calls. There is already money in the common pot. Spanish researchers can also apply to Instituto de Salud Carlos III (ISCIII-

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FIS) for new money. Applicants enter an open competition for Spanish funding and would receive funding in cash rather than kind.

Other stakeholders

- IAVI – interested in collaborating with EDCTP on joint projects.
- AAVP – Their only activities with EDCTP have been in advocacy with the African Union and New Partnerships etc would like to explore new ways.
- NIH – have restrictions on what they can fund but are willing to collaborate with EDCTP.
- Eurovacc (02 DNA C + NYVAC C) – goal is to test a vaccine and they would like to do this in close collaboration with African partners.

It was also agreed that there is an absolute need for development agencies to become involved with health system development and science in order to for HIV Vaccines to be evaluated.

Industry

- Bionor Immuno - Industry would participate with its own funds if calls can be designed to do that. Consider looking into how to tune into industry particularly the smaller corporations. Bionor are willing to set aside funds to individual projects that they believe will be successful

The chair asked what kind of commitments was EDCTP expecting from industry in return to the EDCTP support for the trials. Prof Mgone answered that they should make successful vaccines readily accessible and affordable in developing countries and that this would be negotiated with industry up front.

10 Recommendations to EDCTP

Prof. Mgone and Dr Dunstan, the Chair of EDCTP General Assembly explained that brokering as a possible approach was accepted by the GA.

The Spanish representative asked that it was recorded in the report that Spain does not support a brokering approach. The chair added that BMGF also use both approaches and it is better if EDCTP hands are not tied. However, it was emphasized that transparency is of the essence in this matter.

It is important to ensure the pipeline, to support Phase I and also show support to existing African institutions.

It was clarified that the scope of EDCTP also extends to Phase I clinical trials for HIV preventive vaccines only. This has, however, to be conducted in Africa and preferably tied to a phase II programme.

National AIDS vaccine plans in African countries expect that products that are tested in most African countries have been developed outside Africa and in most cases they should have been trialled in the country of origin of the vaccine.

It is necessary to make sure that the protocol is relevant for Africa – this depends on the quality of the proposal and the questions that they ask.

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It was also argued that it seems to be much harder for member states to cofund Phase I rather than Phase II.

Some of the weaknesses of current Phase IIb trials are that analysis are not taking into account many of the lessons learned over the past few years (including some critical question relevant to selected subgroups of the population).

The Cost of different phases for such a clinical trial was discussed; of Phase IIb trials 50m up; for 14m you can fund about 1000 participants for a Phase II. For an efficacy trial costs are about 6k per participant in SA and 8k per participants in less developed countries; for a Phase I/II the cost is about 12k per participant (250 individuals. – 3m Euro). This excludes trial management, immunology and product production.

It was urged that EDCTP has an opportunity to take a new approach. They are also perfectly positioned to present this as a scientific rather than a political issue.

It was argued that there is a window of opportunity - a need to do a Phase IIb trial now or it may never be done and that a three-arm trial might be the best way forward.

Possible candidates for a phase II trial were discussed. It may not only be the Swedish (HIVIS DNA + MVA-CMDR) and Eurovacc (02 DNA C + NYVAC C) candidates, though the door should be left open for other possibilities

Alternatively, EDCTP could use this opportunity to promote some of the studies that might fill the gaps. Phase I trials could also be repeated in particular in particular groups like adolescents.

It was suggested that EDCTP could go for an open call, but the call text could opt for groups that collaborate, encourage people to work together.

Summary of Recommendations to EDCTP

- EDCTP should fund this topic
- An open call seems to have more support
- There are 2 products for Phase II and potentially phase IIb
- Another option is to support Phase I with a number of different candidates.

Conclusions

Although there was no clear cut conclusions, bearing in mind the scope and merit of EDCTP as well as the current landscape, the majority of the opinion seemed to favour conducting a phase II preventive vaccine trial. This bore in the mind that currently the USA is favouring one approach, that is Adr5 and that the world needs to have alternatives; this became much more evident with the recent results from the Merck vaccine. Bearing in mind that the other advanced alternatives namely 02 DNA C + NYVAC C and HIVIS DNA + MVA-CMDR are almost ready to go into phase II trials in Africa and are at almost similar stages of development a three-arm trial of 02 DNA C + NYVAC C and HIVIS DNA + MVA-CMDR and control would be very pragmatic. Nevertheless, all factors should be taken into account before making the final decision.

Annexes

Annex 1: Hosting country contribution to the stakeholder meeting

Estimate of all costs covered by hosting country	
Item	Amount
Travel	0
Hotel	0
Catering	695
Administration support (8,5 days of staff involvement during preparation, event end follow up)	2.010
Venue	0
Other (graphic and technical department)	320
Sum	3025

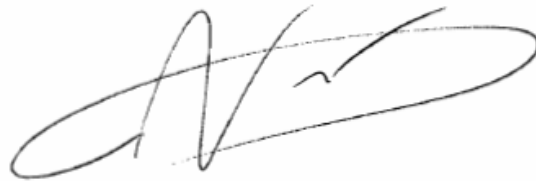
Signed by organising Member State:

Name

Dirk Von der Reest

Date

10 October 07



Annex 2: EDCTP Guidelines for Stakeholder meetings

Introduction

This document aims to describe all aspects related to the aim, organisation and outcome of the EDCTP stakeholder meetings. EDCTP aims to organise 2 types of stakeholder meetings: 7 meetings will focus on disease specific topics and one meeting will concentrate on Nodes of Excellence. The disease-specific topics will have a focus on products in the pipeline. These topics are listed below:

- Malaria treatment and malaria in pregnancy (combined meeting)
- Malaria vaccines
- TB treatment
- TB vaccines
- HIV treatment
- HIV vaccines
- HIV microbicides

The Nodes of excellence meeting will focus on the integrated approach of EDCTP towards the establishment of regional nodes of excellence in sub-Saharan Africa with particular focus on reference laboratories and centres specialised in data management encompassing clinical trials design, conduct, and analysis skills, building on sites with existing capacities and competences in these areas.

These guidelines aim to describe the generic approach towards organising both types of meetings. All stakeholder meetings on disease related topics will be hosted by one of the participating European Member States whereas the stakeholder meeting about Nodes of Excellence will be hosted by one of the African partners participating in EDCTP. The expected outcome, communication aspects, timelines and financial issues concerning stakeholder meetings will be clarified. In addition the role of the hosting member state, the organising committee including the independent chair as well as the expected list of participants are described.

To ensure transparency these guidelines are made public and the EDCTP Secretariat will ensure that the implementation will be carried out and documented correctly.

Aim and objectives of a stakeholder meeting

A stakeholder meeting is a one day meeting. It is the start of a process that leads towards EDCTP funding one or more projects through a call or brokering procedure.

The expected outcome of these meetings is:

1. To make recommendations to EDCTP for:
 - The development of cooperative projects and coordination of efforts
 - Priorities for EDCTP:
 - for disease specific topics EDCTP requires priorities in terms of product and sites whereas
 - for nodes of excellence EDCTP needs priorities in terms of sites, location as well as required skills and capacity
2. Expression of a willingness of the various stakeholders to contribute to the topic both in financial as well as practical terms. These will be followed up by the EDCTP secretariat.
3. Establishment of trust in the EDCTP approach with our stakeholders.

The meetings with a disease-specific topic will have the following objectives:

- Identify products in the pipeline
- Identify potential suitable sites to do the trial
- Recommend priority in terms of product and sites
- Recommend if the funding procedure is a call or brokering or no-go
- Recommend EDCTP timelines concerning the initiation of funding for each topic area

The stakeholder meeting on Nodes of Excellence has similar priorities:

- Identify potential sites
- Identify needs in terms of skills and capacity

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- Recommend priorities in terms of needs and sites
- Recommend if the funding procedure is a call or brokering or no-go
- Recommend EDCTP timelines concerning the initiation of funding

Organisational aspects

All stakeholder meetings on disease-related topics will be hosted by one of the participating European Member States whereas the stakeholder meeting about Nodes of Excellence will be hosted by one of the African partners participating in EDCTP.

All meetings will be organised by an Organising Committee that consists of:

- An independent expert to chair
- A representative of the hosting country. For the European Member States this is the European Networking Officer (ENO) representing the country while for the Nodes of Excellence meeting this role should be fulfilled by the relevant member of the Developing Country Coordinating Committee (DCCC),
- The Partnership Board (PB) and DCCC disease experts
- The Executive Director and Operations Manager from the EDCTP Secretariat

The independent chair will be identified by EDCTP Secretariat, PB and DCCC representatives of the organising committee before the date of the stakeholder meeting is set. The candidate will be approved by the GA in a written procedure. If the hosting country is identified before a chair is selected the representative of the hosting country will also be involved in selecting the chair. The Terms of reference for the Independent chair are the following:

To work with the EDCTP stakeholders' meeting planning group to ensure that the meeting is planned and implemented transparently avoiding or declaring any conflict of interest to give an optimal, independent and objective advice to the EDCTP. This, via the EDCTP Secretariat should take into account the following:

1. The presence of appropriate representation of all significant bodies including industry, private-public partnerships and other stakeholders that are relevant to the topic; ensuring that the representation at the meeting is sufficiently senior to contribute with authority
2. There are appropriate and effective arrangements for conducting the meeting including drafting and approving of the agenda; noting of the attendance; ensuring of adequate participation and deliberation of all the relevant issues
3. Provision in an agreed timescale of a good quality report of the meeting.

Travel and hotels are arranged in close collaboration between the hosting country and the EDCTP Secretariat and the hosting country is expected to play an active role in this. The hosting country should organise location, catering and administrative support as well as assist delegates with their visa requirements. In addition the hosting country is responsible for sending out the invitations to participants. The final list of participants to be invited will be provided by the EDCTP Secretariat in collaboration with the Organising Committee.

Participants

It is a requirement that the following parties are represented at the stakeholder meeting:

- Funders both from the European Member States and if applicable third parties. Each European Member State will be asked to send one representative. It is up to the individual country to accept this invitation or not
- Product developers, Public Private Partnerships and/or industry (disease specific topics only)
- Representatives of African sites that have the capacity to carry out phase II or III trials
- Experts in the field. Each European Member State may bring one expert of their own choosing
- Independent experts if applicable.

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Most participants will be identified by the Organising Committee with the exception of the representatives of the European Member States. Each European Member State is free to send one expert in the field and one representative of their funding body of their own choosing.

It is normally expected that a stakeholder meeting will have no more than around 40 participants.

Invitations to the participants need to go out at least 6 weeks in advance.

Agenda

The agenda for the stakeholder meeting is set by the Organising Committee using the format developed by the EDCTP Secretariat. The generic format for the meetings on disease specific topics is shown below.

EDCTP Stakeholder Meeting

Topic
location, date 2007
Address
Contact

Agenda items	By	Timelines
<i>Coffee/Tea</i>	<i>All</i>	
1.0 Welcome by host	host	
2.0 Approval of the Agenda	All	
3.0 Science and products 3.1 Scientific overview of the field 3.2 Products in the pipeline: relevant stakeholder (more added if required) More added if required		
Coffee break	All	
4.0 Discussion on products and science	All	
5.0 Sites in Africa 5.1 Relevant stakeholder (more added if required) 5.3 DCCC		
Lunch	All	
6.0 Discussion on sites	all	
7.0 EDCTP procedures	SEC	
8.0 Recommendations on how to proceed in terms of products, sites and funding procedure	all	
9.0 Summary of recommendation	Chair	

Communication

Because EDCTP stakeholder meetings should demonstrate transparency and independence it is important that the meetings are widely advertised and that the hosting country does not have a perceived conflict of interest with the topic. EDCTP will however, not publish a call for participants. The advertisements for the stakeholder meetings will focus on announcement of topics, locations, aims and dates. They should list a contact address and encourage those that would like more information to make contact. If someone contacts EDCTP with a wish to participate, this request will be passed on to the Organising Committee who will make a decision.

Advertising of the stakeholder meetings will be through the following means:

- Internet:
 - EDCTP website
 - Requesting constituency members to publish at their websites
 - Other relevant websites
- Paper advertisement:
 - Publishing of adverts in Lancet as soon as all the dates are set
- Ask EDCTP constituencies to communicate to appropriate parties
- If the opportunity arises mention of EDCTP stakeholder meetings in presentations or meetings

Timelines

The dates for the various stakeholder meetings will be set as soon as the independent chair and hosting country have been identified and once the chair agrees to the Terms of

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Reference. It is expected that the stakeholder meetings for TB vaccines, malaria vaccines, HIV vaccines and HIV treatment will take place during the first quarter of 2007. The stakeholder meetings for Nodes of Excellence, malaria treatment/pregnancy, TB treatment and HIV microbicides are scheduled for the second quarter of 2007.

Financial issues

If the stakeholder meeting is hosted by a European country, it is expected that this country will at least as a minimum cover the costs for use of the location, catering during the meeting, administrative support and any other local expenses. If the hosting country is African these costs need to be discussed with the EDCTP Finance Manager. EDCTP will normally pay for travel and hotel for external participants as well as for PB and DCCC members. EDCTP expects that the European Member states will at least pay for travel and hotel of the participants they delegate. EDCTP will pay for travel and hotel of European MS participants and experts only if the European Member State is unable to do so.

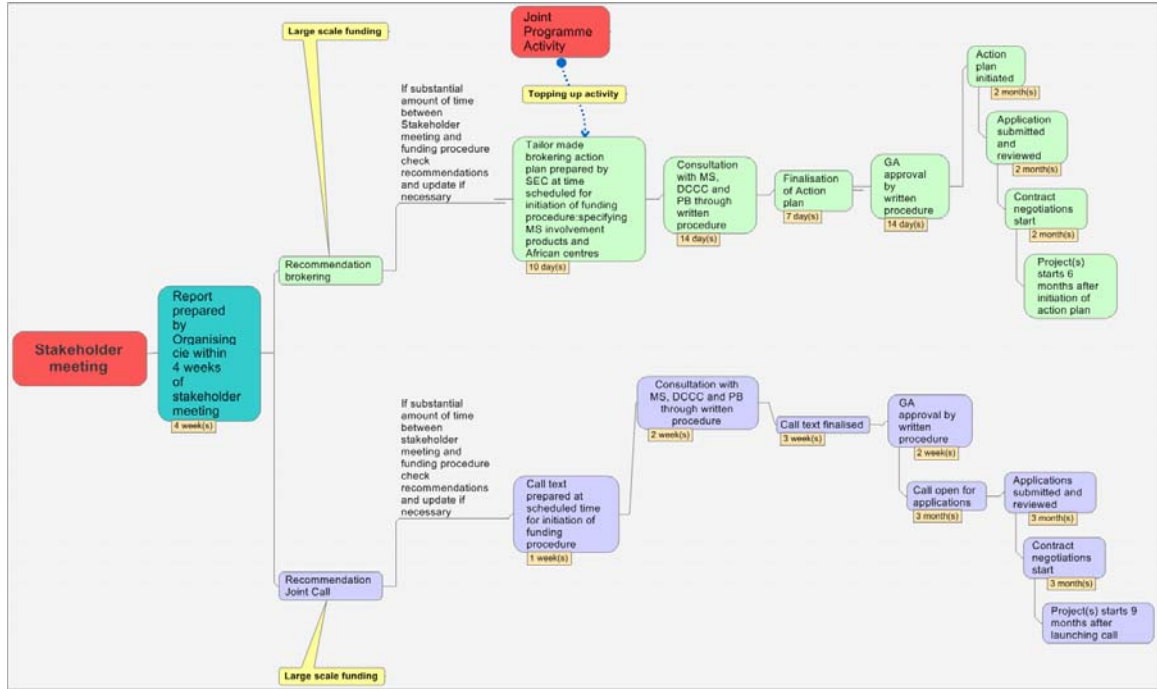
Outcome/follow up

The organising committee will produce a report of the meeting within 4 weeks. The report will be presented to EDCTP. EDCTP will initiate its funding procedures at the appropriate time after considering the report. The timing for launching calls or brokering initiatives can range from 2007-2009 depending on the on the availability of products and sites. A final list of expected dates for initiation of funding procedures will be prepared after all stakeholder meetings have taken place. The diagram below summarises both funding procedures. More information on the EDCTP funding procedures can be found at the website.

A summary of both procedures is described below:

- *Call for proposals*
A call text is drafted based on the recommendations that came out of the stakeholder meeting. After consultation of the various EDCTP constituencies and approval of the General Assembly the call will be published. An EDCTP call is normally open for applications for a period of 3 months. The applications are then checked against the eligibility criteria as defined in the call text and eligible applications will be reviewed by at least 2 external experts as well as the EDCTP Scientific Review Committee (SRC). The SRC ranks the applications and makes a recommendation for funding. This recommendation is examined by the PB which ensures the quality of the review procedure and also assess if the proposal is in line with the EDCTP strategy. The PB make the final recommendation for funding to the General Assembly who approve the application.
- *Brokering*
A brokering action plan is prepared by the EDCTP Secretariat and requires to be approved by the General Assembly after consultation with the EDCTP constituencies. The action plan will be initiated resulting in an application for funding. This application is checked for eligibility as described in the brokering action plan and reviewed by at least two external experts as well as the relevant EDCTP SRC. The SRC make a recommendation for funding or rejection which is examined by the PB which examines both the procedure as well as the alignment of the project with the EDCTP strategy. Upon recommendation of the PB the GA make the decision to fund the project or not.

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Annex 3: Instructions for presentations

Expected outcome of the meeting

The expected outcome of the EDCTP stakeholder meetings is to make recommendations to EDCTP for:

- The development of cooperative projects and coordination of efforts
- Priorities for EDCTP in terms of product and sites
- Expression of a willingness of the various stakeholders to contribute to the topic both in financial as well as practical terms.
- Establishment of trust in the EDCTP approach with our stakeholders

The stakeholder meeting is considered the start of a process that leads towards EDCTP funding of one or more projects through an open call or brokering.

Audience

The audience will be a mixture of experts in the field and people who represent funding agencies and may not have a scientific/medical background. Therefore we would like to suggest that your presentation should be aimed at a general audience.

Expected contents of your presentation

Given the expected outcome of the meeting and the composition of the audience EDCTP would like to provide you some points regarding the expected contents of your presentation.

If you talk about science and products

- A short introduction on the organisation you are representing
- Without going into too much scientific details basic information about the products in the pipeline:
 - Basic principles of the product
 - Status with respect to clinical testing: what has been done/what is ongoing and what is planned/needed
 - Availability of the product
 - Restrictions with respect to the use of the product: is it only available for persons associated with your organisation/is it for sale?

In addition to the presentation could you provide a short summary document on each product that should enable the participants to the meeting to assess its scientific validity and potential.

If you talk about sites in Africa

- A short introduction on the organisation you are representing
- Basic information about the sites you are representing:
 - Capacity and trial experience
 - Commitment to other trials/availability to do the trial
 - Local tuberculosis situation

Duration of your presentation

The time available per presentation is limited to 15 minutes. The presentations will be followed by an initial discussion of 1 hour.

Annex 4: Agenda**EDCTP Stakeholder Meeting****HIV Vaccines**

Antwerp, 7 September 2007

10:00-16:30

Aim of the meeting:

- Identify and prioritise potential products in the pipeline
- Identify potential suitable sites to do the trial
- Recommend if the funding procedure of EDCTP will be an open call, brokering or whether EDCTP should fund this topic at all
- Recommend EDCTP's timeline concerning the initiation of funding for this topic

Agenda items	By	Timelines
1.0 Welcome	Prof Charles Mgone, Prof Bruno Gryseels Chair, Dr Jose Esparza	10:00 - 10:15
2.0 Approval of the Agenda	All	10:15 - 10:20
3.0 EDCTP procedures	Prof Charles Mgone	10:20 - 10:35
4.0 Scientific overview of the field	Dr Giuseppe Pantaleo	10:35 - 10:55
5.0 Products in the pipeline	Dr Saladin Osmanov	10:55 - 11:15
<i>Coffee break</i>		11:15 - 11:35
6.0 Discussion on products and science	All	11:35 - 12:20
7.0 Needs of Africa and in field of HIV vaccines	Dr Alashle Abimiku Dr Pontiano Kaleebu	12:20 - 12:40 12:40 - 13:00
<i>Lunch</i>		13:00 - 13:45
8.0 Discussion on sites	All	13:45 - 14:30
9.0 Member States commitment	Member State representatives	14:30 - 14:45
10.0 Concluding remarks on sites	Chair	14:45 - 15:15
11.0 Recommendations to EDCTP	All	15:15 - 16:00
12.0 Summary of recommendations	Chair	16:00 - 16:20
Closing Remarks	Chair	16:20 - 16:30

Annex 5: List of participants

EDCTP HIV vaccine stakeholder meeting Antwerp, 07 Sept 2007			
	Last name	First name	Organisation
1	ABIMIKU-KORENTZEN	Alash'le	Institute of Human Virology, University of Maryland School of Medicine, U.S.A
2	AGWALE	Simon	Innovative Biotech, Nigeria - Chair of EDCTP's Developing Countries Coordinating Committee (DCCC)
3	ALACAMI	Jose	National Centre for Microbiology (CNM), Instituto de Salud Carlos III, Majadahonda-Spain
4	BONT DE	Jean	International Aids Vaccine Initiative (IAVI)
5	BOSMA	Sofie	International Aids Vaccine Initiative (IAVI)
6	CHEN	Robert	Centres for Disease Control & Prevention
7	COLES	David	EDCTP Secretariat
8	de ANDRES MEDINA	Rafael	Fund for Health Research (FIS), Instituto de Salud Carlos III, Madrid, Spain Member of EDCTP's European Network of National Programmes (ENNP)
9	DEBRE	Patrice	Hospital Pitie Salpetriere, France - Chair of EDCTP's Partnership Board
10	DING	Song	Eurovacc (02 DNA C + NYVAC C) c/o IATEC, The Netherlands
11	DONNERS	Helen	Institute of Tropical Medicine, Belgium
12	DUNSTAN	Diana	MRC London UK - Chair of EDCTP's General Assembly (GA)
13	ESPARZA	Jose Gilberto	Bill and Melinda Gates Foundation (BMGF)
14	FAST	Patricia	International Aids Vaccine Initiative (IAVI)
15	FLORES	Jorge	National Institute of Allergy and Infectious Diseases
16	FOMSGAARD	Anders	Staten Serum Institute, Denmark
17	GOTCH	Frances	Imperial College, UK
18	GRYSEELS	Bruno	Institute of Tropical Medicine, Belgium - member of EDCTP's GA
19	HAIN	Johannes	Bavarian Nordic GmbH, Germany
20	van HAM	Guido	Institute of Tropical Medicine, Antwerp
21	HEROK	Claudia	Bundesministerium fur Bildung und Forschung, Germany - Member of EDCTP's ENNP
22	HOELSCHER	Michael	University of Munich, Germany
23	JAOKO	Walter	Kenya Aids Vaccine Initiative- Member of EDCTP's DCCC

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24	KAMANU ELIAS	Nnemdi	Projects Manager, EDCTP
25	KALEEBU	Pontiano	MRC Uganda
26	LAFORT	Yves	University of Gent, Belgium
27	LEVENDAL	Elise	MRC, South African Aids Vaccine Initiative
28	LEVY	Yves	ANRS / Hospital Henri Mondor, France
29	LIU	Margaret	ProTherImmune. U.S.A
30	MBOUP	Souleymane	Université Cheikh Anta DIOP, Senegal - Member of EDCTP's PB
31	MGONE	Charles	Executive Director, EDCTP
32	MOCUMBI	Pascoal	High Representative, EDCTP
33	NDUMBE	Peter	Centre for the Study and Control of Communicable Diseases, Cameroon - Member of EDCTP's DCCC
34	de OLIVEIRA	Vanessa	Project Officer, EDCTP
35	OLUFEMI	Olutayo Samuel	Sagamu Community on HIV/Aids Information Centres, Nigeria
36	OSMANOV	Saladin Kamilovitch	WHO - UNAIDS
37	PANTALEO	Giuseppe	Centre Hospitalier Universitaire Vaudois (CHUV)
38	ROMARIS	Manuel	European Commission
39	ROOST, VAN DE	Dirk	Institute of Tropical Medicine, Belgium
40	RUSSELL	Nina	Bill and Melinda Gates Foundation
41	SANDSTROM	Eric	Department of Infectious Diseases, Karolinska University Hospital, Sweden
42	SAUNIERE	Anne	ANRS, France
43	SORENSEN	Birger	Bionor Immuno, Norway
44	TARRAGONA	Tony	Imperial College, UK
45	WEBER	Jonathan	Imperial College, UK
46	WAHREN	Britta	Karolinska Institute, Sweden
47	Winkel	Klaus	Staten Serum Institute, Denmark - Member of EDCTP's ENNP
48	ZIJENAH	Lynn	University of Zimbabwe Medical School - Member of EDCTP's DCCC