



Regional Networks of Excellence for Conducting Clinical Trials

EDCTP Stakeholders' meeting

Douala, Cameroon

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2

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EDCTP

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1. Introduction

The main goal of EDCTP (European and Developing Countries Clinical Trials Partnership) is to alleviate poverty in developing countries, particularly in the sub-Saharan Africa, through health improvement. To achieve this EDCTP focuses on the three main poverty related diseases (PRDs), namely HIV/AIDS, malaria and tuberculosis, through which the programme supports conducting of clinical trials to accelerate development of new or improved intervention tools. To ensure commitment, ownership, synergy and optimal use of resources, this is done in partnership with the sub-Saharan countries and through the integration and coordination of European national programmes on research and development in PRDs. It is however, recognised that generally there is a lack of capacity in sub-Saharan Africa to conduct clinical trials under best practices that follow ICH-GCP, GCLP and other internationally recognised guidelines. Moreover, it is known that the health research ethics review mechanism and the regulatory framework in sub-Saharan Africa is far from being adequate. Recognising these deficiencies, EDCTP aims to secure an enabling environment for conducting clinical trials that follow best practices. This includes establishing Regional Networks of Excellence for Conducting Clinical Trials.

Objectives:

1. To identify sub-Saharan institutions for strengthening to become part of a regional network of excellence for training and conducting clinical research
2. To support the identified centres to develop essential skills in applied sciences related to the study and control of major poverty related diseases, GCP, GLP, data management and specialised laboratory techniques.
3. To enable the identified centres to become regional network coordinators and promoters of intra-regional collaboration and networks
4. To identify potential sub-Saharan centres to participate in the regional networks of excellence with the aim of strengthening them through south-south mentorship
5. To enhance research collaboration and networking between African institutions coordinated by the identified centres and northern partners.

The stakeholder meeting on Regional Networks of Excellence for Conducting Clinical Trials was part of a series of such meeting organised by EDCTP in the light of its new strategy for funding projects. This is based on focusing on conducting clinical trials using best practices as the centre piece and cornerstone of its activities and capacity development and networking as means of achieving this in a sustainable manner. The aim of this meeting, which was hosted by Cameroon, was to make recommendations to EDCTP in terms of selection and funding of successful sites to fill the role of EDCTP Networks of Excellence. The meeting was chaired by Professor Francis Nkrumah. He is an emeritus professor and former director of Noguchi Memorial Institute for Medical Research, University of Ghana in Accra. Prof. Nkrumah serves as an advisor and expert to many scientific and international groups and has extensive experience on capacity building issues in Africa.

2. Participants

2.1.1 Kenya Medical Research Institute (KEMRI)

KEMRI-Wellcome Research Programme has a long-standing commitment to scientific capacity strengthening, and has established itself as an internationally renowned research centre tackling malaria and other important infectious diseases. KEMRI was represented by Professor Kevin Marsh, the Programme's Director, who is stationed at Kilifi.

More information can be found at <http://www.kemri-wellcome.org/>

2.1.2 African Malaria Network Trust (AMANET)

The mission of AMANET is to promote capacity strengthening and enhance performance and impact of Africa malaria R&D. AMANET is based in Tanzania. Its objectives include:

1. Creation of global awareness of the Africa malaria disaster
2. Promotion of cooperation and collaboration with stakeholders
3. Advancement of essential human capacity for research development of malaria interventions
4. Determining needs and characterising of potential sites for testing malaria interventions
5. Strengthening of infrastructure and provision of equipment to prospective trial sites
6. Sponsoring clinical trials
7. Promotion of good governance and networking of malaria R&D and training institutions.

AMANET was invited because of its role in training and capacity building in conduct of malaria trials. Professor Wen Kilama represented AMANET at this meeting.

More information can be found at <http://www.amanet-trust.org/>

2.1.3 Medical Research Council / Uganda Virus Research Institute (MRC/UVRI)

The Medical Research Council / Uganda Virus Research Institute (MRC/UVRI) is based Entebbe, Uganda. It is a collaborative project of governments of Uganda and the United Kingdom. The unit conducts large-scale epidemiological and intervention studies, clinical trials, virological and immunological research and behavioural studies on HIV/AIDS.

Dr Anatoli Kamali represented MRC/UVRI in the meeting.

More information can be found at: <http://www.mrc.ac.uk>

2.1.4 European Commission (EC)

The EC was invited as a funder of the EDCTP programme and was represented by Dr Dario Zanon and Professor Adetokunbo Lucas, a member of an Independent EDCTP Review Committee.

More information can be found at <http://ec.europa.eu/dgs/research/>

2.1.5 Institut Pasteur

The Institut Pasteur is a not-for-profit private foundation dedicated to the study of biology, microorganisms, diseases and vaccines. Over the years, the foundation has been responsible for breakthrough discoveries that have enabled medical science to control such virulent diseases as diphtheria, tetanus, tuberculosis, poliomyelitis, influenza, yellow fever and plague. Institut Pasteur is one of the world's leading networks of research centres eight of which are in Africa in Algeria, Senegal, Cote d'Ivoire, Madagascar, Morocco, Tunisia, Niger and Cameroon.

A representative of Institut Pasteur from Yaoundé, Cameroon was present in the meeting.

More information can be found at: www.pasteur.fr/

2.1.6 Development agency representatives

Two European government representatives attended the meeting. These were Dr Gerd Eppel of German Technical Cooperation (GTZ) of Cameroon and Dr Jean-Pierre Lamarque of French Embassy in Yaoundé, Cameroon.

2.1.7 European and Developing Countries Clinical Trial Partnership (EDCTP)

EDCTP was represented through the Member State representatives; ten European Network Officers (ENO), five members of the Partnership Board (PB), nine members of the Developing Countries Coordinating Committee (DCCC) and three members of the Secretariat.

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

2.1.8 Scientists

A consultant physician, Dr Sinata Koulla-Shiro represented the Central Hospital of Yaoundé in Cameroon.

3. DCCC position paper on Nodes of Excellence

Following the recommendation of the PB and DCCC, EDCTP has decided to fund the establishing of Regional Networks of Excellence for Conducting Clinical Trials on the three poverty related diseases (HIV/AIDS, malaria and tuberculosis). The purpose of this strategy is to create and maintain sufficient capacity within Africa to design and conduct clinical research with a focus on the poverty-related diseases. This is towards achieving its goal in accelerating the development of new or improved drugs, vaccines and other tools for treatment and prevention of these diseases. It also aims generally to raise the quality of research and clinical practice in these and other fields in the sub-Saharan Africa.

To kick-start the meeting the Chairman presented a background paper narrating the need for centres or nodes of excellence. This was followed by presentations from Secretariat, DCCC and ENNP. DCCC recognises the fact that it is not currently feasible to find centres in Africa that have all the expertise and capacity to meet the objectives spelt above. Centres specialised in one or more of the required expertise can be granted the status of a centre of excellence provided they will be able to support other centres on a regional basis. To realise this, the following strategy was therefore suggested by DCCC for discussion and adoption:

1. Identification and strengthening of the capacities of selected African institutions to conduct and host training in specific, but fundamental areas of clinical research on poverty-related diseases
2. Accreditation of centres as regional hubs or Nodes of Excellence for capacity building and conduct of clinical trials
3. Conducting of regional workshops to identify talents in clinical research and support them to develop research proposals for their trainees including on-job training

4. Supporting of the identified Nodes of Excellence to establish fellowships and exchange programs in partnership with other institutions within their region.

The mode of funding to Nodes of Excellence can either be through brokering or open calls. The decision of which one to follow is dependent on consultation with several stakeholders and PB.

4. Discussion

The discussions whose main thrust was to determine what EDCTP wants as structure and activities of Nodes of Excellence and how to select and fund the nodes covered the following areas:

Definition and purpose of the Nodes of Excellence

There was a lively debate on what terminology to use for the envisaged centres. It was suggested that the term “Excellence” may be construed to depict elitism and be replaced “Collaboration”. There was, however no strong opinion to change this. It was also suggested and agreed that instead of focusing on centres or nodes the concept should be built around networks with one of the centres taking on the coordinating role. It was eventually agreed that the concept should be to establish Regional Networks of Excellence for Conducting Clinical Trials.

Regarding the purpose and functions of the networks of excellence it was also discussed at length that there was a need to balance training as a capacity development activity with the actual conducting of clinical trials. It was agreed that capacity should not be developed just for the sake of it since this will lead to waste and brain drain. As originally conceptualised expertise in nodes of excellence should include addressing weakness that hamper the conduct of clinical trials. Among these include:

- Post-doctoral career development
- Data safety monitoring
- Basic epidemiological studies
- Project management
- Basic sciences
- GCP, GCLP and other skills required to conduct clinical trials.

It was also agreed that since most centres or institutions in sub-Saharan Africa may not have the capacity and skills required for managing all types of clinical trials including the necessary laboratory investigations, data management, trial monitoring and quality assurance, it is pragmatic to form consortia of institutions or centres that will complement each other.

A review highlighting potential centres for the regional networks was presented and discussed. However, it was agreed that the most effective way is to allow the centres themselves to forge these regional networks of collaboration. To facilitate this EDCTP could support regional workshops. Alternatively EDCTP could do this through an open call.

Sustainability

It was agreed that for the Nodes of Excellence to be effective their sustainability must be a priority and built into the plan for establishing them. It was also agreed that to be viable these centres should be able to conduct all types of clinical trials rather than limited to specific types of trials. It was strongly urged that they should have the backing of their governments. DCCC members and EDCTP Africa Office were urged to leverage for

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African government backing and support of these networks and centres including seeking for financial support.

Member states commitment

Generally there were positive responses and support for this initiative from all member states that were represented at the stakeholders' meeting. These include Belgium, Denmark, France, Germany, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom. All indicated that they would support a call for Networks of Excellence for Conducting Clinical Trials and were to look into means of doing this. In the case of Germany and Spain it was however, indicated that this would only be possible if their nationals were to participate in the networks. France pointed out that they would be ready to support a centres in Senegal if chosen to be part of the network. Sweden indicated that they will support the call through the funds that they have already committed to EDCTP and United Kingdom confirmed that they have already earmarked GBP 800,000 to be used for the call.

5. Recommendations to EDCTP

The following recommendations were made:

1. Regional networks of excellence should be based according to geographical representation and sited in Eastern, Western, Southern and Central Africa. Each network must include at least three institutions or centres from three different sub-Saharan African countries. These centres must have complimentary expertise across the three diseases (HIV/AIDS, malaria and tuberculosis) and in other fields.
2. All centres and institutions within the networks will collectively be responsible for identifying needs and gaps within the network and choose a coordinating institution, which must be a public institution that is owned by sub-Saharan African country. The network will collectively use their combined strength to promote identified weaker institution(s) in the region to the level that these weak institutions could participate in multicentre clinical trials
3. The four networks should also work in collaboration and complimentary with each other
4. EDCTP should thrive to get more north-south collaboration and funding to support this initiative including approaching development agencies
5. A call for proposal should be sent out in August 2007. It should be a one-stage process with an extended deadline to allow time for the formation of the networks.

6. EDCTP procedures

Overview EDCTP procedures

EDCTP can fund proposals through an open call or a brokering procedure. Both were explained to the audience. More information can be found in the Guidelines for Stakeholder meetings (see annex 1).

Annexes

Annex 1: 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 to 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

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- 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
- 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:

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- 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.

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

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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 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*

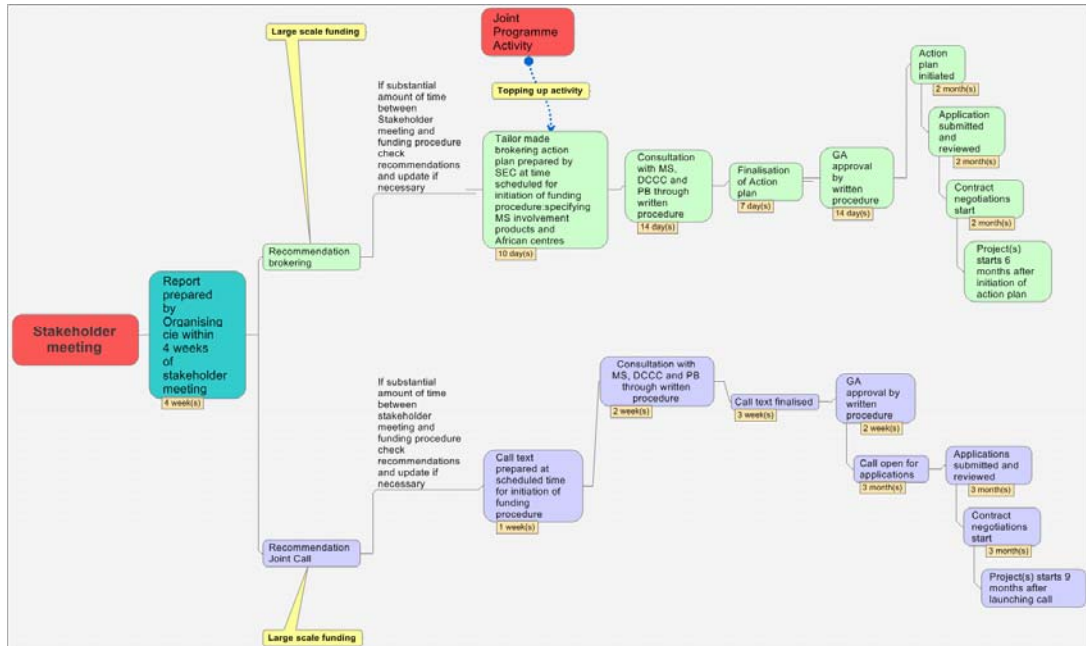
A call text is drafted based on the recommendations that came out of the stakeholder meeting. After consultation of the various EDCTP constituencies and approval of the General Assembly the call will be published. An EDCTP call is normally open for applications for a period of 3 months. The applications 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

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makes the final recommendation for funding to the General Assembly who approves 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 2: Agenda for EDCTP Stakeholder Meeting Nodes of Excellence, Douala, 8 May 2007

Aim of the meeting:

- Recommend priorities for EDCTP in terms of sites: location, required skills and capacity
- 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 |
|--|--|--------------------|
| <i>Coffee/Tea</i> | <i>All</i> | <i>9:00 – 9:15</i> |
| 1.0 Welcome | Peter Ndumbe, Awono Ambene, Charles Mgone | 9.15-9.30 |
| 2.0 Approval of the Agenda | All | |
| 3.0 Objectives of stakeholders meeting and expected out comes | Francis Nkrumah | 9.35-9.45 |
| 4.0 Funds available and EDCTP procedures | Tom Nyirenda | 9.45-10.00 |
| 5.0 Required capacity and activities 5.1 DCCC contribution 5.2 ENNP contribution: mechanism of support 5.3 Contribution of other players: donors, regional economic communities, academic institutions etc | Andrew Kitua Laura Brum As many as will be present | 10.00-10.40 |
| Coffee break | | 10.40-11.00 |
| 5.4 Discussion on Required capacity and activities | All | 11.00-11.45 |
| 6.0 Mechanism of identification and location of Nodes of Excellence 6.1 DCCC's and PB's role 6.3 Roles of committees outside EDCTP constituencies | All | 11.45-12.30 |
| Lunch | | 12.30-13.30 |
| 6.4 Discussion on location of Nodes of Excellence/distribution in Africa | All | 13.30-14.30 |
| 7.0 Recommendations on how to proceed in terms of selection of nodes and funding procedure 7.1 Brain storming on strategies, methodology and expected output 7.2 Discussion on ways of enhancing synergy with other funding organisations with similar goals 7.3 Sustainability plan and involvement of African governments | All | 14:30-15.40 |
| Coffee break | | 15.40-16.00 |
| 8.0 Summary of recommendations | Chair | 16:00-17:00 |

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Annex 3: List of participants

| No. | Name | Capacity | Organisation / Country |
|------------|-------------------------|-----------------------------------|-------------------------------|
| 1 | Francis Nkrumah | Meeting Chairman | Noguchi / Ghana |
| 2 | Patrice Debre | PB (Chair) | France |
| 3 | Peter Smith | PB (Vice Chair) | UK |
| 4 | Souleymane Mboup | PB (second vice Chair) | Senegal |
| 5 | Peter Kremsner | PB member | Germany |
| 6 | Juhani Eskola | PB member | Finland |
| 7 | Simon Agwale | DCCC (Chair) | Nigeria |
| 8 | Christine Manyando | DCCC (Vice Chair) | Zambia |
| 9 | Peter Ndumbe | DCCC (2 nd Vice Chair) | Cameroon |
| 10 | Awono Ambene | DCCC member | OCEAC - Cameroon |
| 11 | Lynn Zijenah | DCCC member | Zimbabwe |
| 12 | Mathieu Ndounga | DCCC member | Congo |
| 13 | Andrew Kitua | DCCC member | Tanzania |
| 14 | Tumani Corrah | DCCC member | Gambia |
| 15 | Walter Jaoko | DCCC member | Kenya |
| 16 | Laura Brum | ENNP (Chair) | Portugal |
| 17 | Dirk van der Roost | ENNP (Vice Chair) | Belgium |
| 18 | Claire Newland | ENNP member | UK |
| 19 | Klaus Winkel | ENNP member | Denmark |
| 20 | Olof Stendahl | ENNP member | Sweden |
| 21 | Claudia Herok | ENNP member | Germany |
| 22 | Bernadette Murgue | NNP member | France |
| 23 | Judith Kroon | ENNP member | Netherlands |
| 24 | Christoph Meier | ENNP member | Switzerland |
| 25 | Raphel de Andres Medina | ENNP member | Spain* |
| 26 | Vic Arendt | ENNP member | Luxembourg |
| 27 | Charles Mgone | EDCTP secretariat (ED) | EDCTP |
| 28 | David Coles | EDCTP secretariat | EDCTP |
| 29 | Thomas Nyirenda | EDCTP secretariat | EDCTP |
| 30 | Wen Kilama | Expert | AMANET |
| 31 | Kevin Marsh | Expert | KEMRI - Kenya |
| 32 | Jocelyne Rocour | Expert | Pasteur Inst - Cameroon |
| 33 | Dario Zanon | Expert | EC |
| 34 | Adetokunbo Lucas | Expert - consultant | EC |
| 35 | Jean- Pierre Lamarque | Government rep | French Embassy - Cameroon |
| 36 | Gerd Eppel | Development Agency rep | GTZ - Cameroon |
| 37 | Anatoli Kamali | Expert | MRC / UVRI - Uganda |
| 38 | Sinata Koulla-Shiro | Expert | Central Hospital – Yaoundé |

* Apologise for late arrival and contribution only in constituency meetings

Conference organising support staff:

- 1) Ms Caroline Scholtz (EDCTP secretariat, Den Haag – Netherlands)
- 2) Ms Deidre Raubenheimer (MRC, Cape Town – South Africa)
- 3) Mr Deon Salomo (MRC, Cape Town – South Africa)

Annex 4: Discussion paper – Professor F Nkrumah

Nodes of Excellence Stakeholders Meeting, Douala, Cameroon, 8 May 2007

The EDCTP guidelines for stakeholder meetings stipulates that one meeting is dedicated to the Nodes of Excellence (NoE) concept as developed by the Developing Countries Coordinating Committee (DCCC). The NoE stakeholder meeting is intended to focus on developing an integrated approach towards the establishment of regional NoE in sub-Saharan Africa with the primary objective of enhancing capacity building (institutional & human resource) for the formulation and conduct of clinical trials. It is further envisaged that establishment of such NoE would equally strengthen scientific and institutional capacities in Africa to address poverty related diseases in general or diseases of high burden still prevalent on the continent. EDCTP has committed itself to the establishment of these regional NoE to accelerate the development of new or improved drugs, vaccines and other tools for the treatment and prevention of these diseases and to raise the level of clinical practice.

The aim of the planned stakeholder meeting in Douala will be to make recommendations to EDCTP in terms of starting the process that leads to selection, funding and establishment of such NoE in sub-Saharan Africa.

Issues for Discussion:

- Identification and selection of potential sites and institutions.
- Site selection criteria and selection processes (by invitation, application?) will need to be defined and agreed on. Factors such as geographic distribution language (Anglophone, francophone), comparative advantages (e.g. existing capacities and infrastructure) will have to be taken into consideration. Is it envisaged that NoE sites be functionally disease specific in nature or multi-disease in scope of activities? Identification of needs in terms of skills, infrastructure and overall site capacity will have to be established. A (5-year) Site Strategic development plan may be requested.

Training and human resource development

A substantial part of the budget should be allocated to training and manpower development; especially to fill in identified gaps. Short-term (workshops) and long-term (degree) programmes will need to be developed. These should include:

- basic and applied health sciences,
- clinical research and conduct of clinical trials (GCP, GLP, research ethics, data management)
- epidemiology, statistics, and social sciences
- health systems research

Networking and Linkages

Networking and linkage mechanisms among the NoE sites and their affiliates and partners (south-south networks) will be crucial and will need to be developed as early as possible through establishment of communications and information shearing systems. Collaborations with Northern partners (north-south networks) will need to be elaborated on, especially the conditionality for such collaborations. African scientists in the Diaspora (and there are many out there!) should be identified and encouraged to participate in these programme linkages which can provide them with opportunities for eventual re-entry.

Funding and funding mechanisms

EDCTP

EDCTP has initially earmarked up to 2.5 million euros per NoE (initially four Nodes are envisaged) but additional co-funding from EDCTP member states and other developing agencies will be required for the full implementation of the initiative.

Sustainability

African leadership, ownership and sustainability of NoE can only be achieved through national and regional commitment and support. (National governments and other regional organisations such as NEPAD and AU). Advocacy at the highest levels of governments, particularly in countries where NoE will be sited, will have to be vigorously pursued since majority of academic and research institutions in Africa are public entities. Mechanisms for support from NEPAD and AU will have to be explored.

Collaboration with other R&D Programmes and Initiatives

A number of R& D programmes emphasizing or having components in capacity building and institutional strengthening are already in existence or have been recently initiated in the Africa region. These include: WHO Special Programme for Research and Training in Tropical Diseases (TDR); African Malaria Network Trust (AMANET); Gates Malaria Partnership etc. A broader collaborative network of institutions and their sponsors will need to be put in place to complement each other in training and capacity building.

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Annex 5: Presentations

Annex 5.1: Aims and objectives of the meeting – Charles Mgone

Annex 5.2: Funds available and EDCTP procedures – Tom Nyirenda

Annex 5.3: South-south Networking: Need for Nodes of Excellence – Andrew Kitua

Annex 5.4: Report from ENNP – Laura Brum

Annex 5.5: Identification of credible clinical trial sites in Africa – Simon Agwale