Assessment of the need for a renewed European and Developing Countries Clinical Trials Partnership (EDCTP) initiative

Analysis of Results from the Public Consultation

Final Version

July 2012

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ACRONYMS

AIDS	Acquired Immuno-Deficiency Syndrome
AO	EDCTP Africa Office
ARV	Antiretroviral Treatment
AU	African Union
CT	Clinical Trials
DC	Developing Country
DCCC	Developing Countries Coordinating Committee
EAC	East African Community
EC	European Commission
ECCAS	Economic Community of Central-African States
ECOWAS	Economic Community of West African States
EDCTP	European and Developing Countries Clinical Trials Partnership
EEIG	European Economic Interest Group
EU	European Union
EP	European Parliament
FDA	Food and Drug Administration
FP7	Seventh Framework program for Research and Technological Development
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
IASG	Impact Assessment Steering Group
IEE	Independent External Expert
IGAD	Intergovernmental Authority on Development
IRB	Institutional Review Board
IPR	Intellectual Property Right
MDG	Millennium Development Goal

MEP	Member of the European Parliament
MS	Member State of the EU
MRC	Medical Research Council
MTCT	Mother to Child Transmission
NEPAD	New Partnership for Africa's Development
NID	Neglected Infectious Disease
NIH	National Institute of Health (USA)
NN	North-North Networking
NP	National Programme
PB	Partnership Board
PDP	Product-Development Partnership
PRD	Poverty-Related Disease
PPP	Public Private Partnership
R&D	Research and Development
RCT	Randomised Clinical Trials
SADC	Southern African Development Community
SSA	Sub-Saharan Africa
TB	Tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organisation
WHO/AFRO	WHO Regional Office for Africa

1. INTRODUCTION

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in September 2003 by 15 European countries with the aim to develop capacity building for clinical trials and new clinical interventions to address the needs of sub-Saharan Africa in the fields of HIV/AIDS, malaria and tuberculosis. Created in terms of Article 169 of the Treaty (since re-numbered as Article 185 of the Treaty on the Functioning of the European Union), the EDCTP aims to improve integration of research from different European Member States in the field of poverty related diseases.

Procedural Issues and Consultation of Interested Parties

The objectives and scope of the Consultation were defined in the Roadmap, Public Consultation document and Terms of Reference published at the launch of the consultation. These included the scope of any new initiative, the development of the possible future policy options, and the identification of key issues to be put forward for consideration in the consultation.

Input of other Commission Services

An Inter-Service Advisory Group (ISAG) was set up under the responsibility of DG-RTD, Infectious Diseases Unit. DG-SG, SJ, BEPA, ECFIN, ENTR, ENV, SANCO, JRC, INFSO, REGIO, EAC, JLS, RELEX, TRADE, DEV, ELARG, AIDCO, ECHO and ESTAT were invited to participate. The ISAG participated in the definition and development of the key issues and the future policy options, and supported the consultation process. Its role was to offer guidance, input and assistance to the impact assessment process and to ensure streamlined policy actions across all services.

Method

Stakeholders were alerted to the consultation process by online publication on the 'Your Voice in Europe' webpage. In addition, a personal email signed by the head of the EC Health Directorate for Research was sent to relevant mailing lists held by DG RTD, the EDCTP Secretariat and other EU services.

A questionnaire was developed to assess support for the different policy options identified and to canvass stakeholders' opinions in other areas of particular interest.

The consultation was divided into 9 sections and consisted of 19 questions:

A. Respondent Profile

B. Activities, Scientific Strategy and Management

C. Funding

D. Policy Options

E. Third Parties

F. Ethics and Intellectual Property Rights Policy

G. Social and Economic Impact

H. Governance Structure

I. General Remarks

The questionnaire was open from 8th April until 22nd June 2010.

2. SUMMARY

Respondent Profile

Of the 235 answers received, 137 (58.5%) were from Europe, 64 (27%) from Africa and 34 (14.5%) from other geographic areas. The majority of the answers (175, 75%) were received as personal opinions, 48 (20%) represented the view of an organization/company and 12 (5%) were from public authorities. The majority of respondents were male.

Of individual respondents the three main categories were researchers (96 people, 55%), interested citizens (20 people, 11%), and employees of a public organisation (19 people, 11%). Concerning the category 'organisation/company', the three main categories were private non-profit organisations (15 people, 31%), public organisations (12 people, 25%), and private for-profit organisations (9 people, 13%).

We received 12 contributions as questionnaires from public authorities. Eleven (92%) were from a centralised governmental body.

Activities

Clinical Trials

Respondents felt there should be a high level of support for clinical trials in Tuberculosis (88%), HIV/AIDS (85%) and Malaria (83%).

Capacity-Building

When asked about capacity building in a new EDCTP initiative, 88% of respondents felt that there should be a high level of support for these activities.

Networking

Respondents felt that 'South-South networking' and 'North-South networking' should receive the highest levels of support (76% and 74% respectively). In contrast, 49% of respondents felt that 'North-North networking' should receive a high level of support in a future EDCTP initiative (23% favoured a medium level of support and 26% favoured a low level of support).

Advocacy, Governance and Communications

Sixty-three percent of respondents felt that 'Advocacy' should receive a high level of support in a new EDCTP initiative. For the categories 'Communication' and 'Governance' 58% and 51% of respondents respectively felt that there should be a high level of support for these activities.

Scientific Strategy

Support for Phase I and Phase IV Clinical Trials

Seventy-nine percent of respondents agreed that a new EDCTP initiative should be broadened to support clinical trials in Phase I and Phase IV, with 17% as 'disagree' and 4% answering 'Don't know'.

Geographical Areas of Focus

In response to the statement that a new EDCTP should expand to additional geographic areas, 57% of respondents agreed, 40% disagreed and 3% answered 'Don't know'.

Disease Scope

In response to the statement that ‘the EDCTP should investigate other infectious diseases in addition to the three major poverty-related diseases’, 65% of respondents agreed, 31% disagreed and 4% answered 'Don't know'.

Additional Research Priorities

In response to the question that if a new EDCTP initiative were to be extended which one of the following areas should be prioritised, 71% of respondents favoured public health, 21% favoured basic research and 8% favoured other areas.

Management

Submission and Evaluation of Proposals

Eighty-seven per cent of people agreed that a new EDCTP initiative should review the way it handles proposals and publish revised procedural guidelines on its website, 7% responded 'Don't know' and 6% disagreed.

Funding

Co-funding Arrangements

In response to the statement that 'the successor to EDCTP should better define co-funding arrangements at the start of the programme', 91% of respondents agreed, 5% disagreed and 4% answered 'Don't know'.

Member States’ Commitments

In response to the statement that 'each member state should make a formal commitment for a minimum annual payment throughout the life of a new EDCTP initiative', 85% agreed, 9% disagreed and 6% responded 'Don't know'.

A Single Fund

Eighty-one percent of respondents agreed with the statement that 'to reduce operational complexity a new EDCTP initiative should simplify and streamline co-funding, by creating a single fund', 11% disagreed and 8% responded 'Don't know'.

Policy Options

Of the four defined policy options, 71% of respondents favoured 'Expanded Scope', 12% favoured 'Business as Usual', 9% favoured 'Programme based' and 2% favoured 'No European Union policy'. A further 5% of respondents' preference was for 'A Different Option' which they then defined.

Third Parties

This question asked the extent to which the future EDCTP initiative should collaborate with the following third parties: international funding bodies, large pharma/biotech companies/industry and Small or Medium Enterprises (SMEs).

In relation to international funding bodies, 83% of respondents felt that there should be a high level of engagement (12% favoured a 'medium level of engagement' and 4% favoured 'low level of engagement).

In relation to large pharma/biotech companies/industry, 57% favoured a high level of engagement, 23% favoured a medium level of engagement and 17% favoured a low level of engagement.

Finally, in relation to SMEs, 55% favoured a high level of engagement (24% favoured a medium level of engagement and 18% favoured a low level of engagement).

Ethics and Intellectual Property Rights Policy

Ethics

The statement addressed the question of whether an EDCTP-specific research ethics committee, composed of African and European experts, might simplify and accelerate the process of ethical clearance. Sixty-four percent of respondents agreed, 32% disagreed and 4% responded 'Don't know'.

Intellectual Property Rights

In response to the statement that 'a new EDCTP initiative should have a balanced, clear and comprehensive Intellectual Property Rights policy', 91% agreed, 6% disagreed and 3% responded 'Don't know'.

Social and Economic Impact

Social Impacts

In terms of the social impacts of a new EDCTP initiative, respondents felt that it should have a high level of impact on ensuring access to the products of research findings (87%) and improving health care benefits and equal treatments (87%). They also felt it should have a high level of impact on improving public understanding of clinical trials (74%), promoting cultural exchange through research (72%) and improving public awareness of ethics (72%).

Economic Impact

Respondents felt that EDCTP should have a high level of impact on promoting collaboration between research and development funding institutions (86%), promoting academic research (81%) and facilitating the introduction and dissemination of new products, technologies and production methods (80%).

Sixty-eight percent of respondents answered that a new EDCTP initiative should have a high level of impact on reducing the cost of clinical trials, and 48% of respondents felt that EDCTP should have a high level of impact on both promoting industrial research and facilitating job creation.

Governance Structure

In relation to defined features of the governance structures of EDCTP, respondents felt that simplifying the governance structure (74%) and clarifying the political and financial mandate (71%) were high level priorities. Fifty-four percent of respondents felt that the revision of the legal structure to incorporate voting rights for African government representatives was a high priority. Forty-six percent felt that the restriction of decision-making to Member States who provide financial or other resources was a high priority.

3. RESULTS

Methodological note regarding the presentation of results

Question B1

Answers were classified on a scale of 1 to 5 (1=Low level support; 5=High level support) including the option 'Don't know'**.**

To facilitate the analysis of results the first and second answers were added together and classified as 'Low level of support'; the third answer was considered 'Medium level of support' and the fourth and fifth category of responses were added together and classified as 'High level of support'.

Question B2-B4; B6; C1-C3; F1-F2

The range of answers was 'strongly agree', 'agree', 'disagree', 'strongly disagree' and included the option 'Don't know'.

To facilitate the analysis of results the first and second answer ('strongly agree', 'agree') were added together and classified as 'Agree'; the third and fourth category of responses ('disagree', 'strongly disagree') were added together and classified as 'Disagree'.

Question E1

Answers on a scale of 1 to 5 (1=Low level of engagement; 5=High level of engagement) including the option 'Don't know'.

To facilitate the analysis of results the first and second answer were added together and classified as 'Low level of engagement'; the third category of responses were classified as 'Medium level of engagement' and the fourth and fifth answers were added together as 'High level of engagement'.

Question G1-G2

Answers were classified on a scale of 1 to 5 (1=Low level impact; 5=High level of impact) including the option 'Don't know'**.**

To facilitate the analysis of results the first and second answer were added together and classified as 'Low level of impact'; the third category of responses were classified as 'Medium level of impact' and the fourth and fifth answers were added together as 'High level of impact'.

Question H1

Answers on a scale of 1 to 5 (1=Low level of priority; 5=High level of priority) including the option 'Don't know'.

To facilitate the analysis of results, the first and second answer were added together and classified as 'Low level of priority'; the third category of responses were classified as 'Medium level of priority' and the fourth and fifth answers were added together and classified as 'High level of priority'.

Open Questions

The following questions were open questions: B1 (final part), B5 (final part), D1 (final part) and E2.

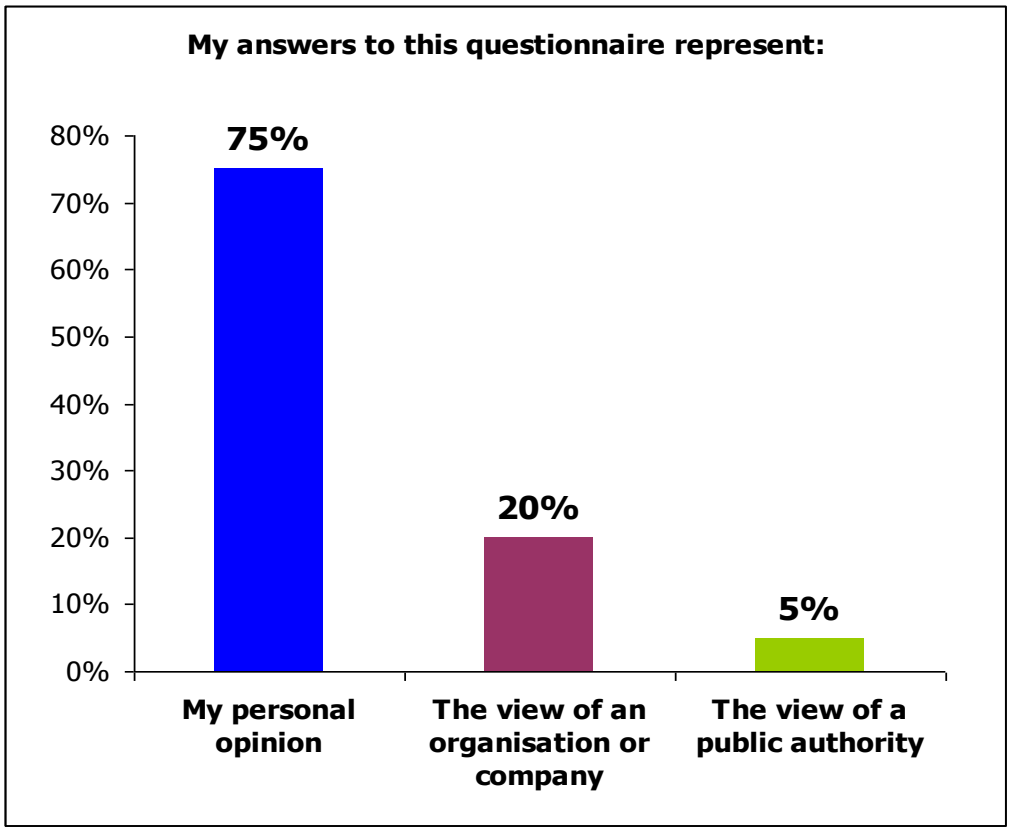
General Remarks

Section I was for the addition of general remarks.

A. Respondent Profile

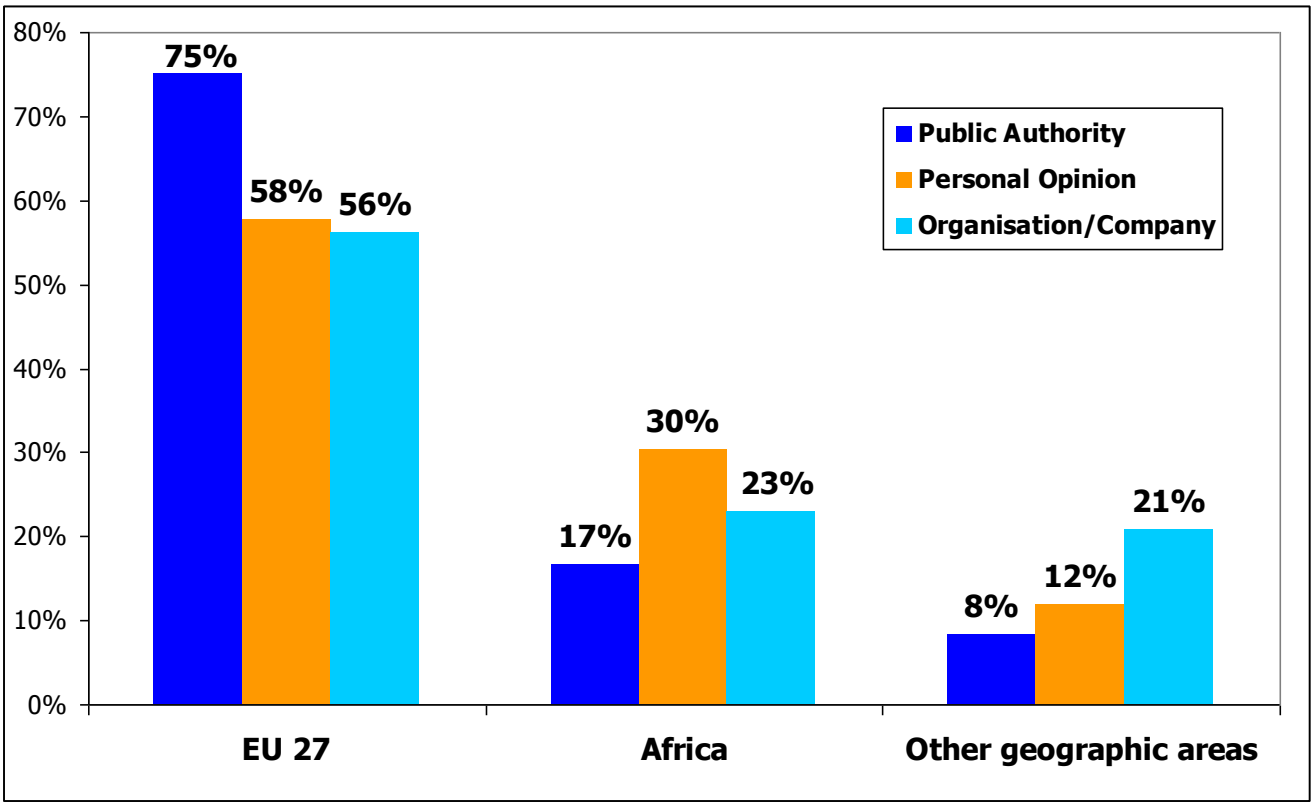
Respondents were asked to categorise their submissions as a personal view, view of organisation or company, or view of public authority. For further identification, each respondent was then asked to give personal or corporate details, although these were not compulsory.

The majority of the answers were received as personal opinions (175, 75%), 48 (20%) represented the view of an organization/company and 12 (5%) were from public authorities.



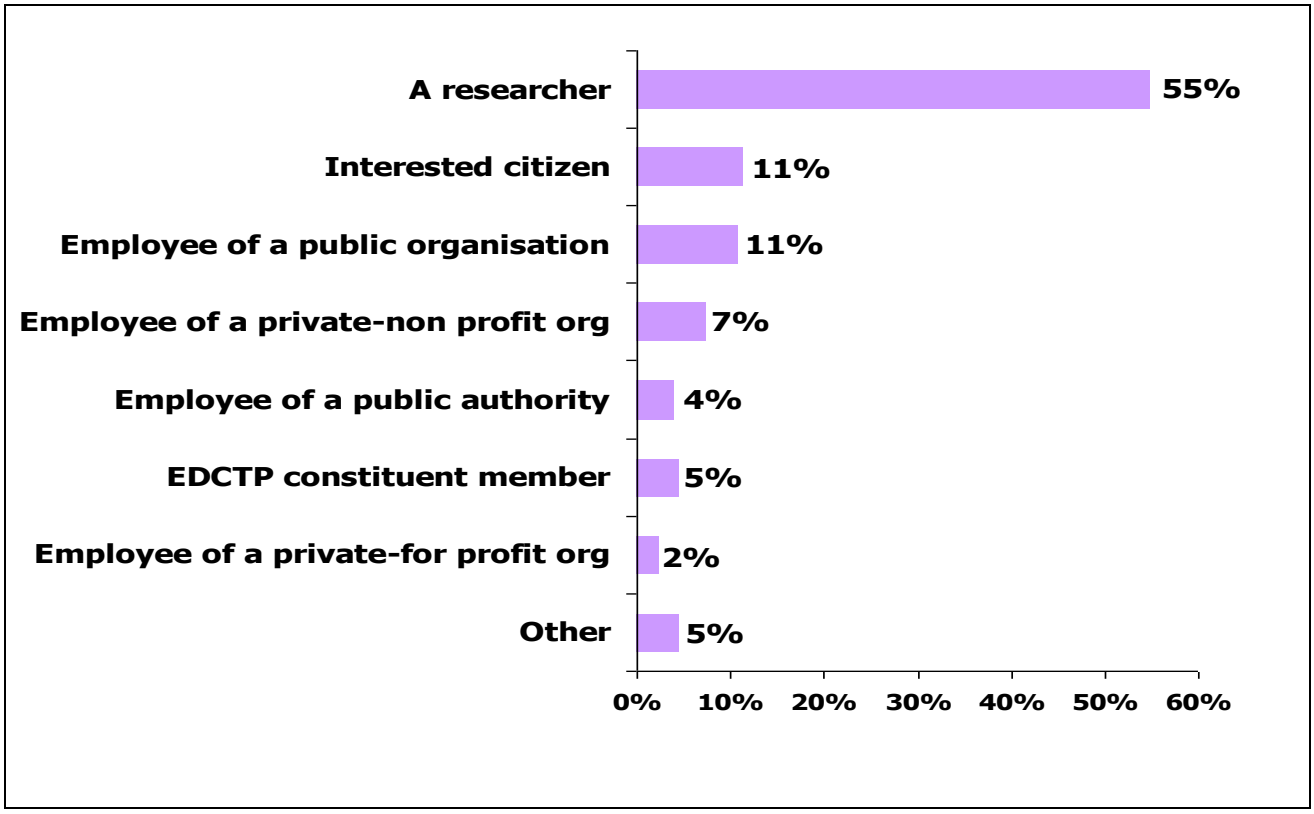
Profile of respondents by geographical location

Of the 235 answers received, 137 (58.5%) were from Europe, 64 (27%) from Africa and 34 (14.5%) from other geographic areas. The table below illustrates the respondent profile (public authority, personal opinion and organisation/company) by geographical area.



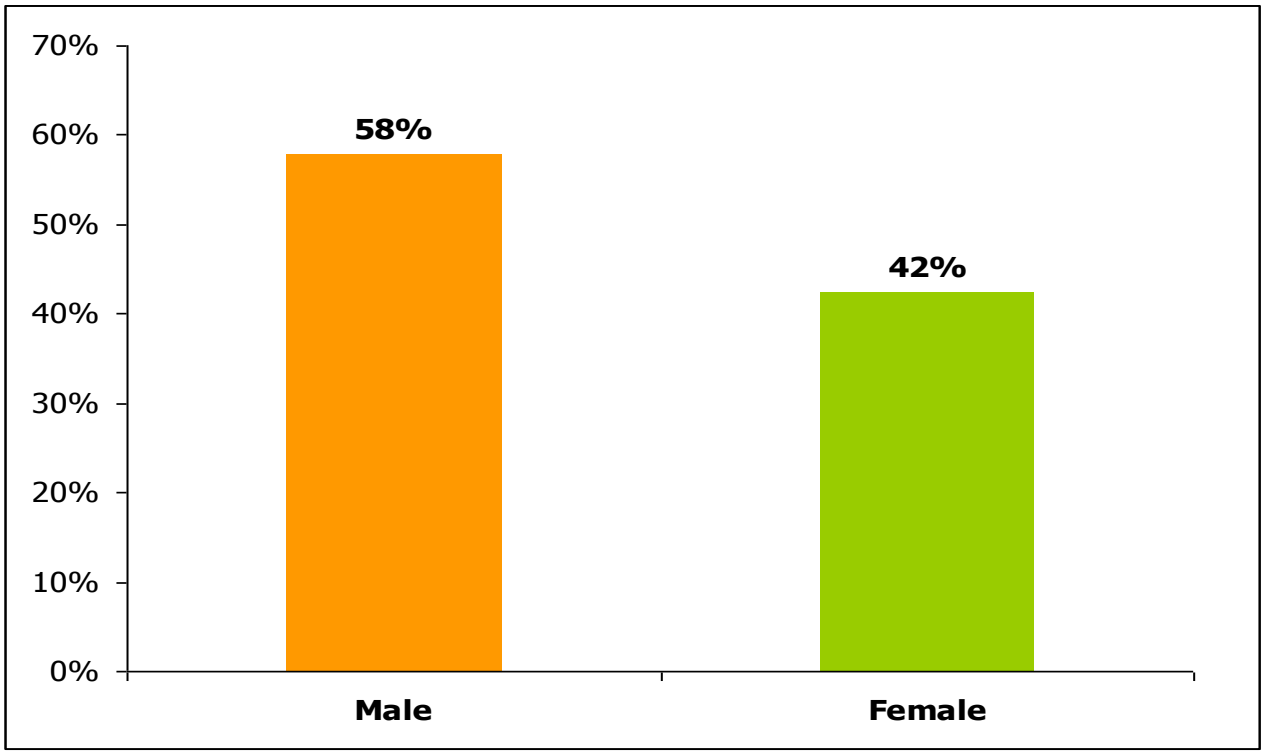
Profile of individual respondents

For the category 'individuals', respondents were asked to characterise their interest in the EDCTP in terms of the following categories:

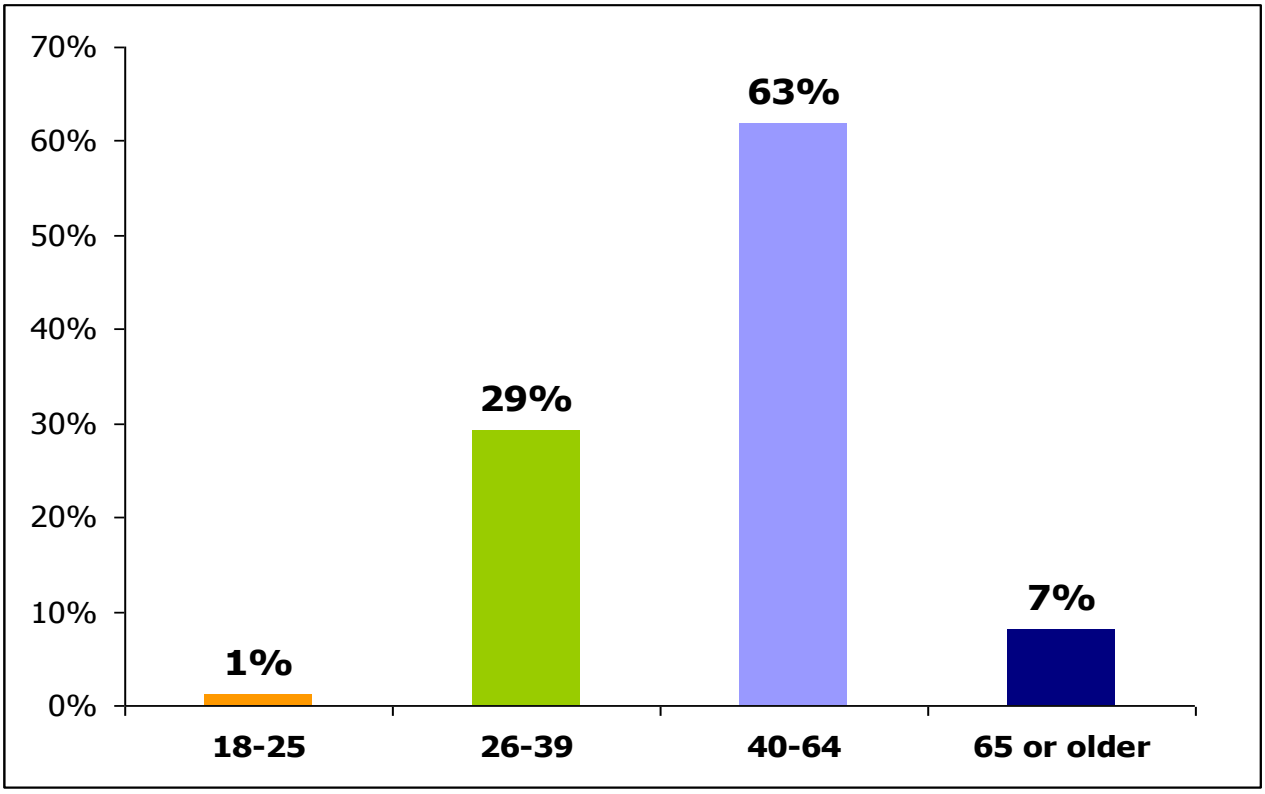


Age and gender of individual respondents

The gender distribution is summarised in the chart attached. The majority of respondents were male.

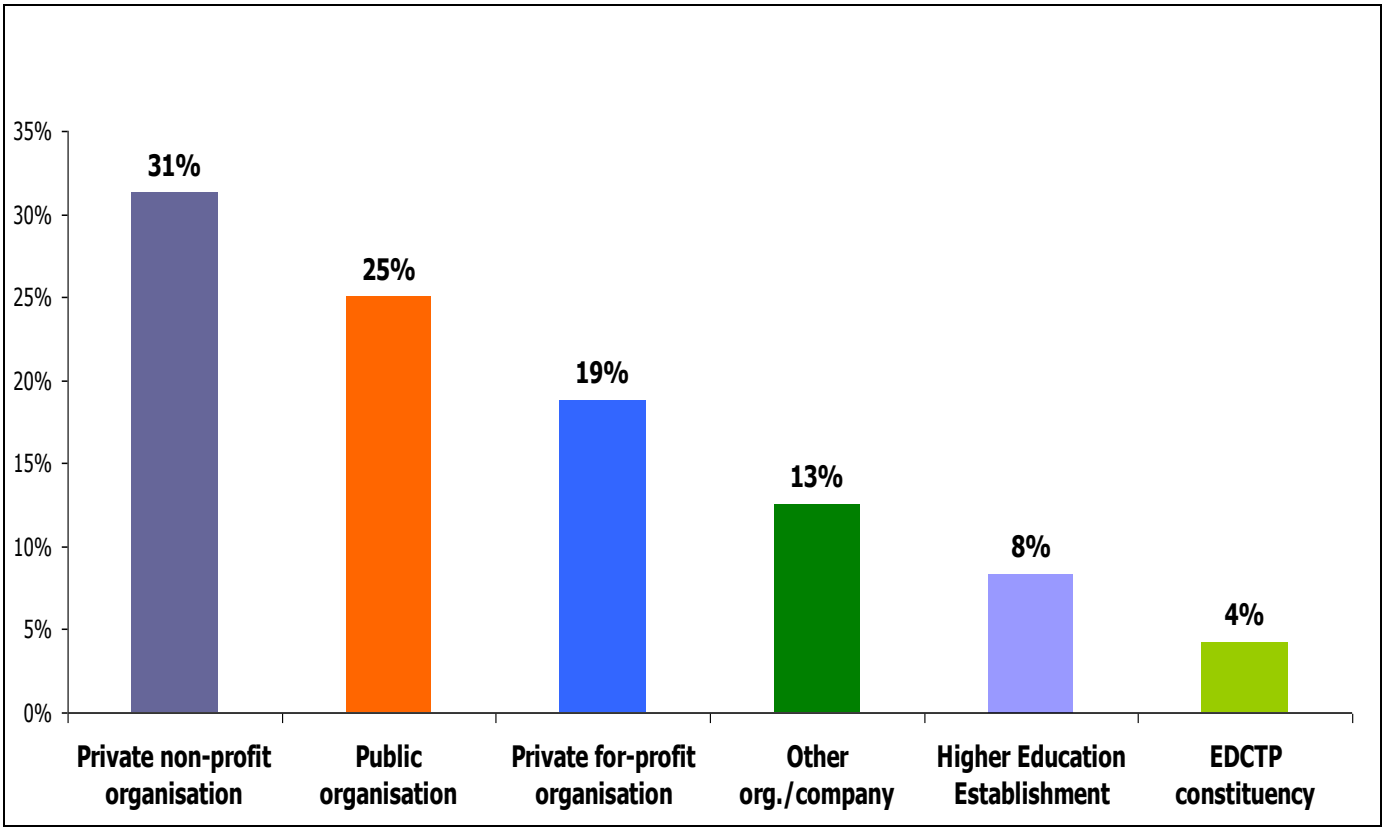


Seventy-four respondents (63%) were aged 40-64, 35 respondents (29%) were aged 26-39, 7 respondents (6%) were aged 65 or older and finally 2 responses were received from persons aged 18-25 (2%).



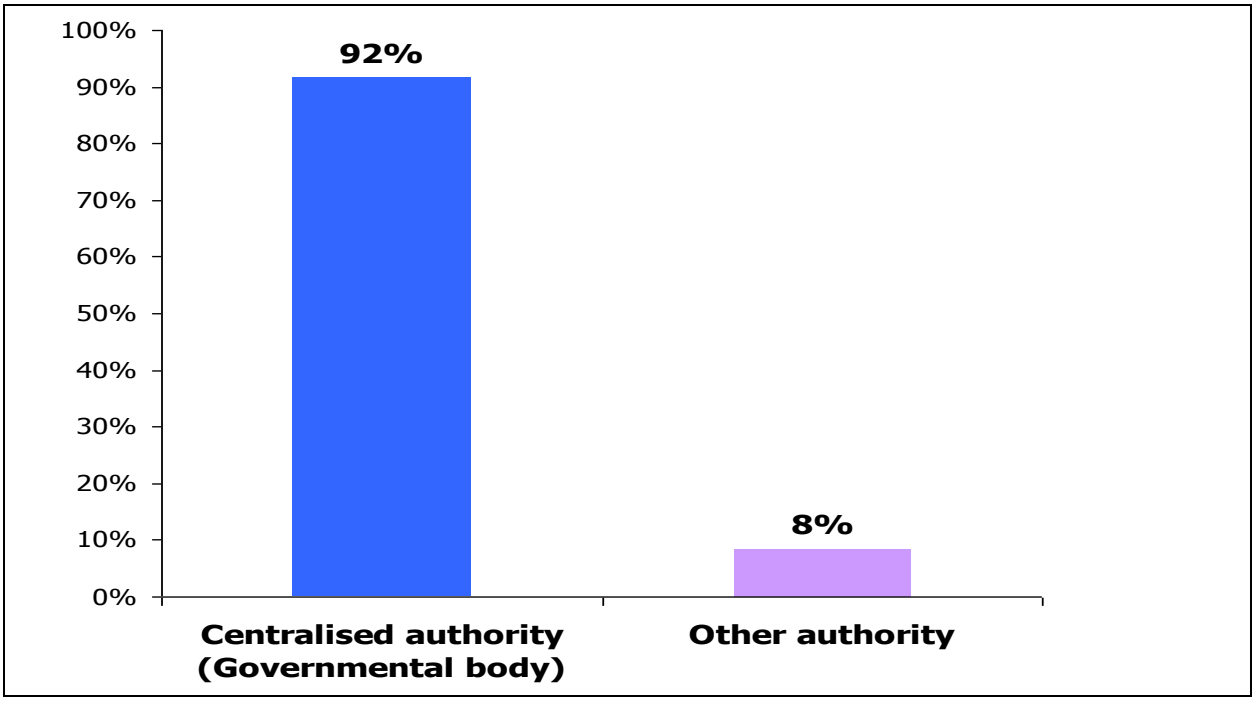
Profile of organisation/company responses

For the category 'organisations/companies', respondents were asked to supply the name, country and email of the organisation. Respondents were also asked to define their organisation in terms of the following categories:



Profile of public authority responses

For the category 'public authorities' the name, country and type of public authority (centralised or decentralised) was requested.



B. Activities, Scientific Strategy and Management

B1. Programme activities

The main activities of the EDCTP are: i) research and training activities to support clinical trials; ii) capacity building in Africa; iii) networking and coordination and iv) ensuring visibility and sustainability of the EDCTP programme.

Which of these activities should be supported by a new EDCTP initiative and to what extent?

Clinical Trials

- Research and training activities to support HIV/AIDS clinical trials
- Research and training activities to support malaria clinical trials
- Research and training activities to support tuberculosis clinical trials

Capacity Building

- Strengthening of African capacity to undertake clinical trials

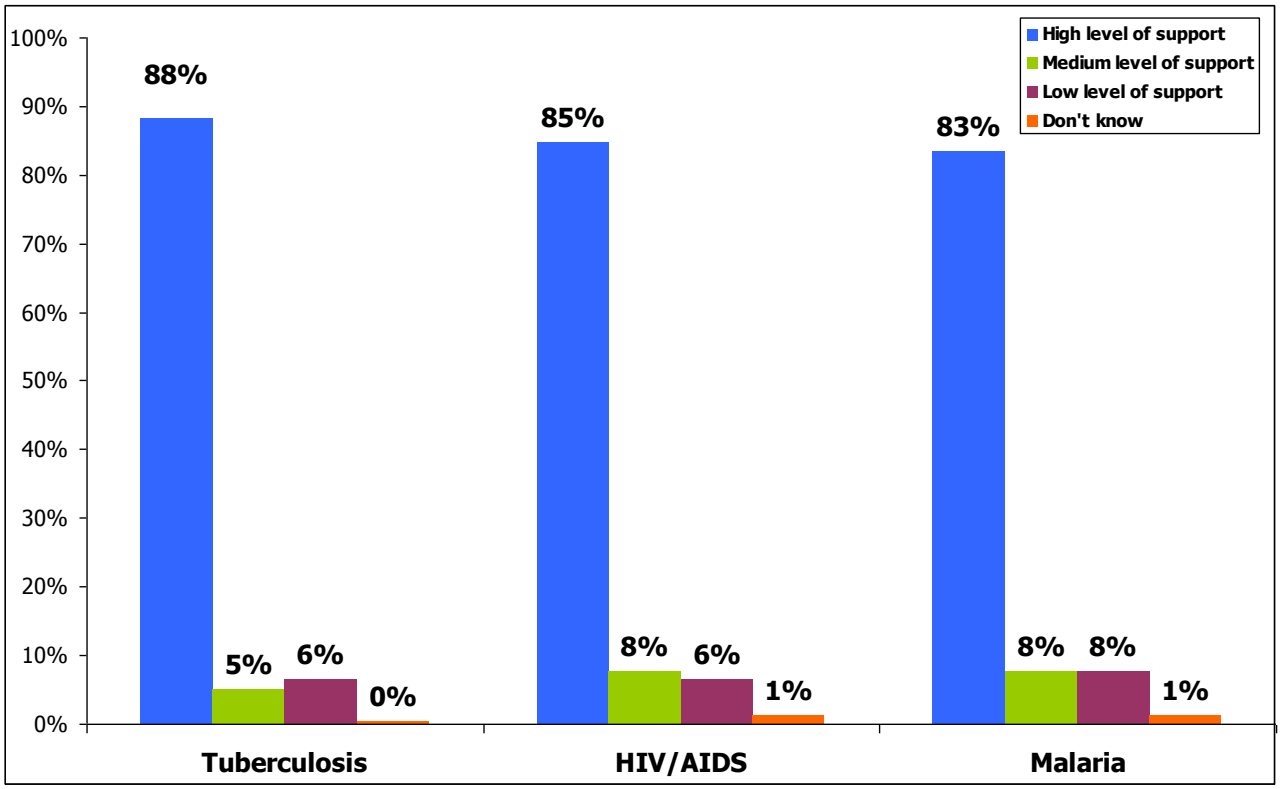
Networking

- Networking and coordination of European national research programmes with their partners in the South (North-South networking)
- Networking and coordination between European national research programmes (North-North networking)
- Networking and coordination between African national research programmes (South-South networking)

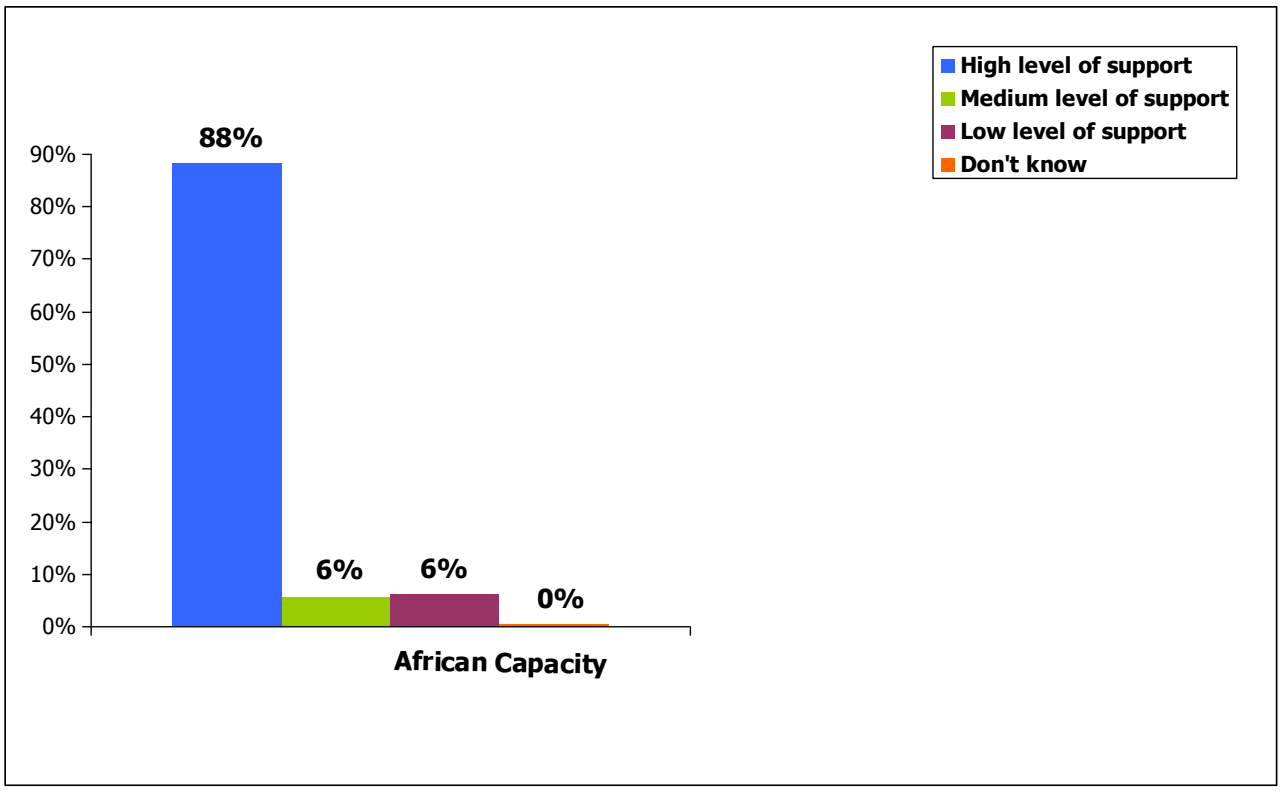
Advocacy, Governance, Communications

- Advocacy and fundraising
- Governance structure
- Communications

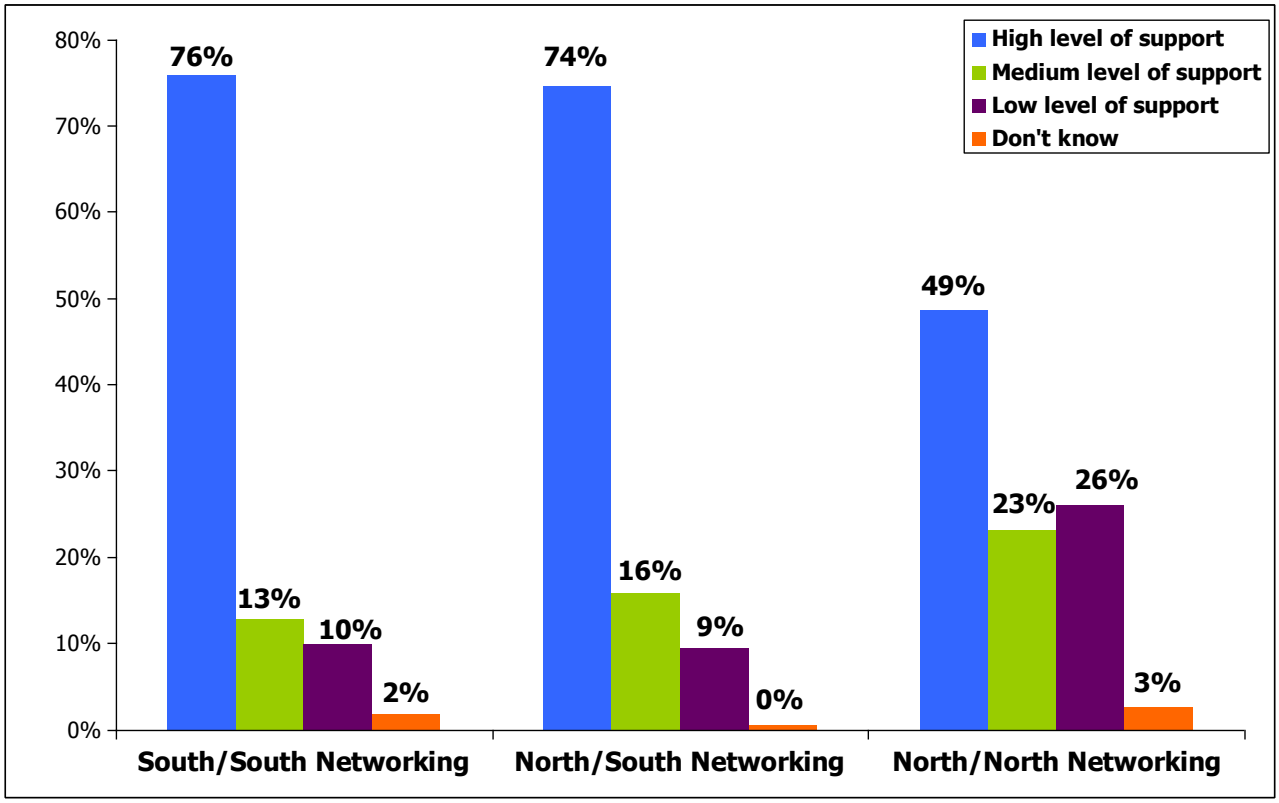
CLINICAL TRIALS



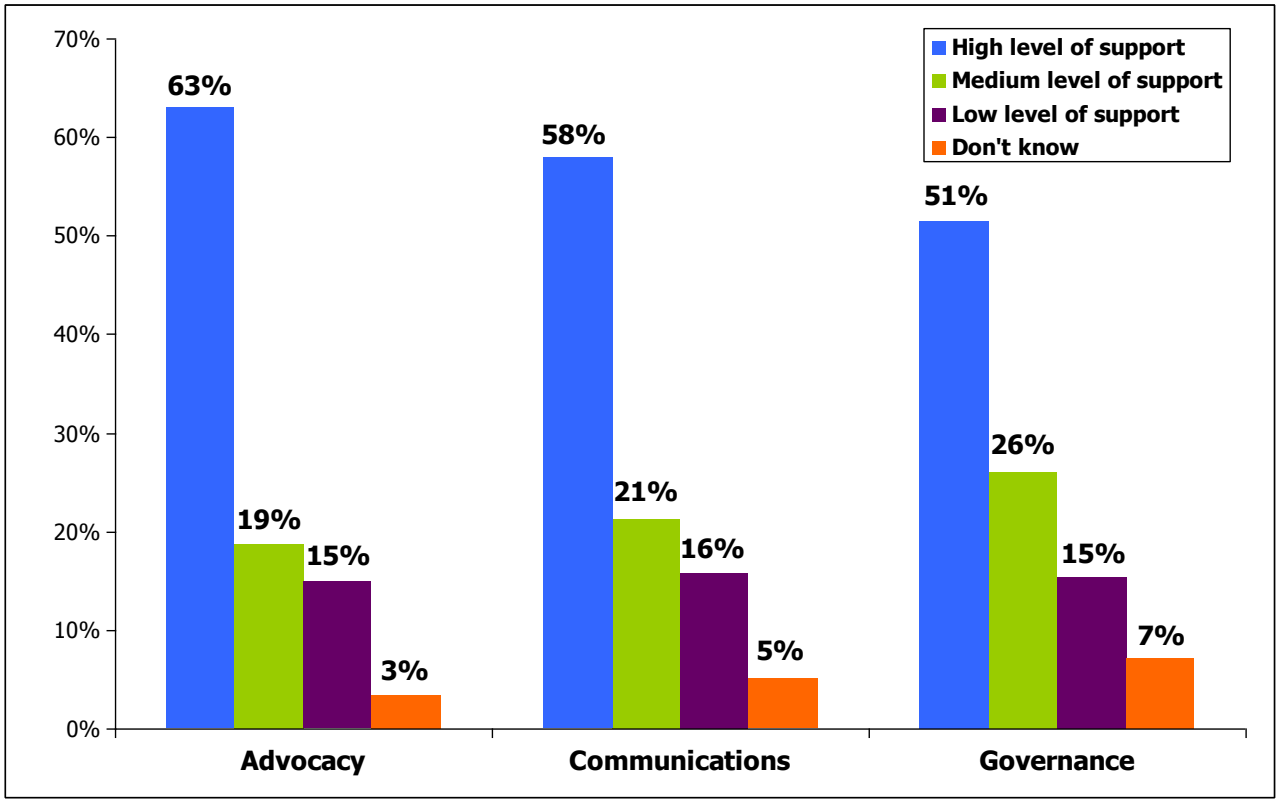
CAPACITY BUILDING



NETWORKING



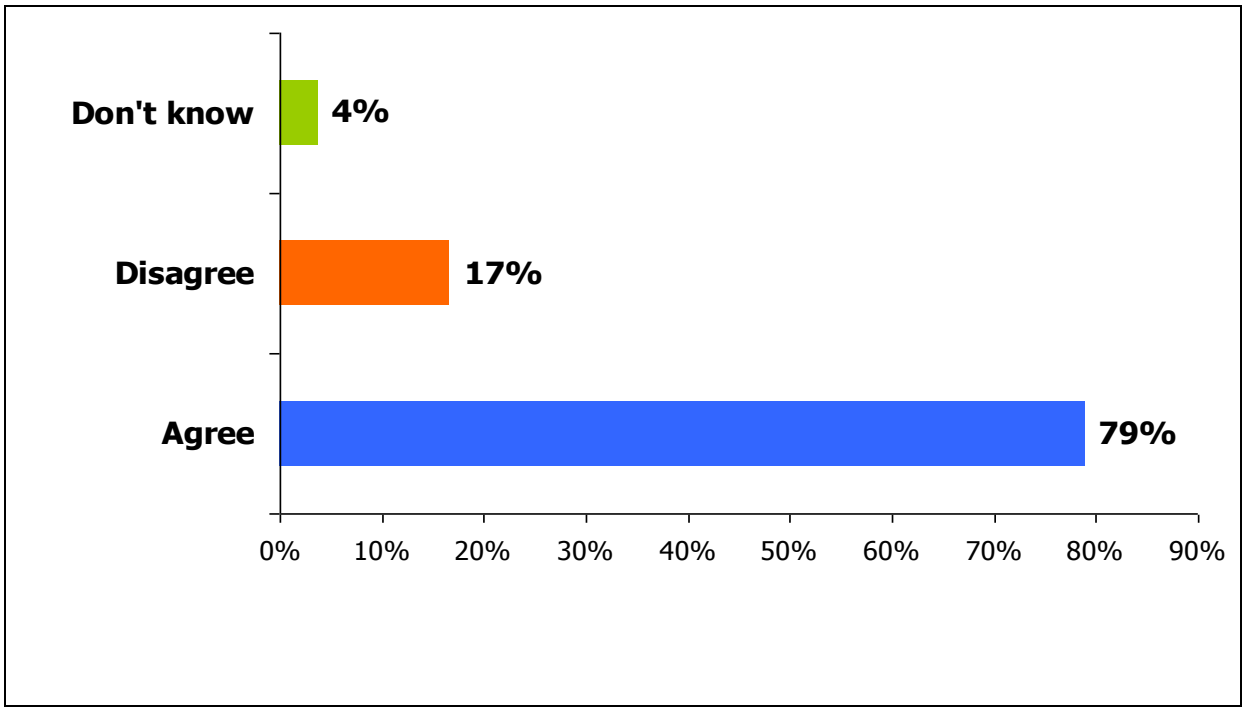
ADVOCACY, GOVERNANCE, COMMUNICATIONS



B2. Phases of clinical trials

The main objective of the EDCTP is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries. Many of the current EDCTP studies focus on the pre-registration phase clinical trials (Phase II and III).

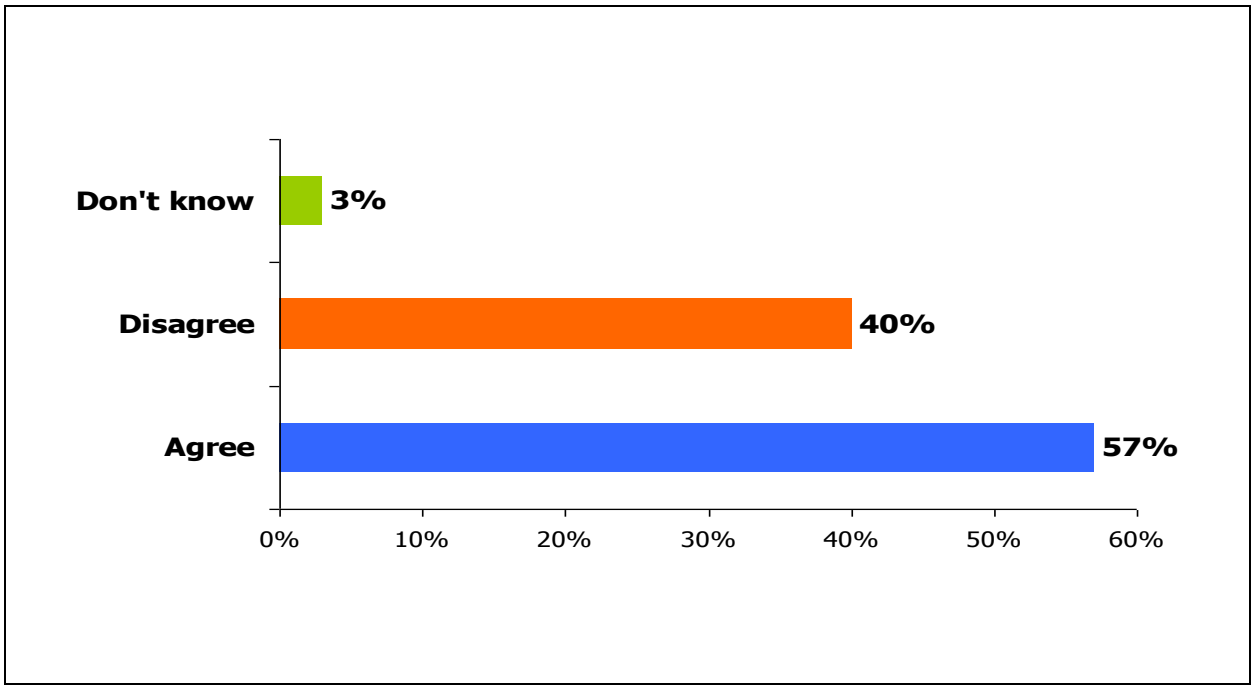
A new EDCTP initiative should be broadened to support clinical trials in Phase I and Phase IV.



B3. Areas of geographical interest

HIV/AIDS, tuberculosis and malaria are a major cause and consequence of disease burden in developing countries, particularly sub-Saharan Africa. During the current EDCTP programme, no activities have been carried out in regions other than Africa.

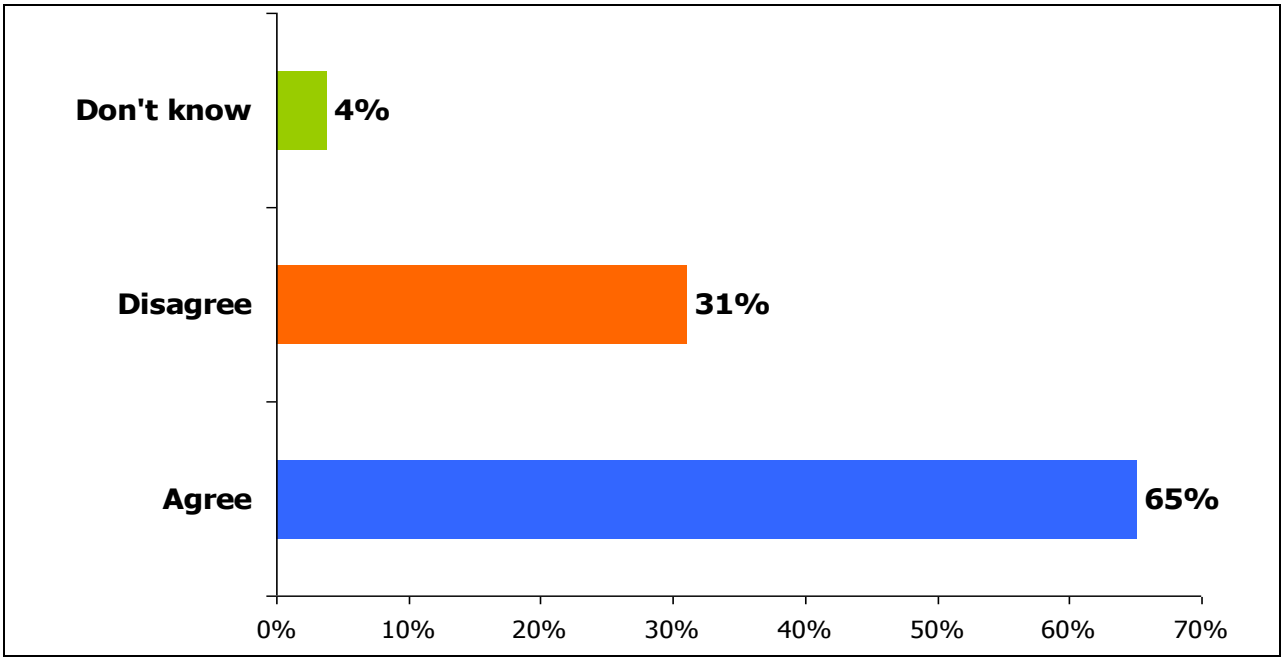
A new EDCTP initiative should expand to additional geographic areas.



B4. Disease scope

The current EDCTP is focused on the three major poverty related diseases: HIV/AIDS, malaria and tuberculosis.

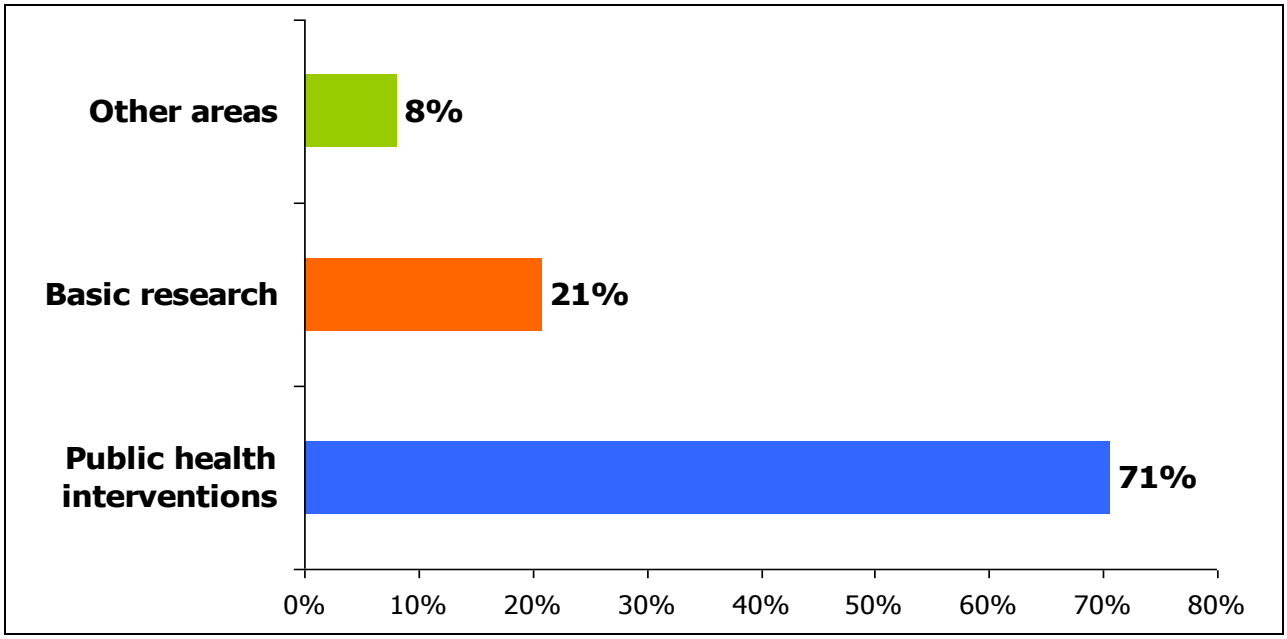
A new EDCTP should investigate other infectious diseases in addition to the three Poverty-related diseases.



B5. Research priorities

The current EDCTP is focused on the three major poverty related diseases: HIV/AIDS, malaria and tuberculosis.

If a new EDCTP initiative were to be extended to new areas of research which one of the following areas should be prioritised?

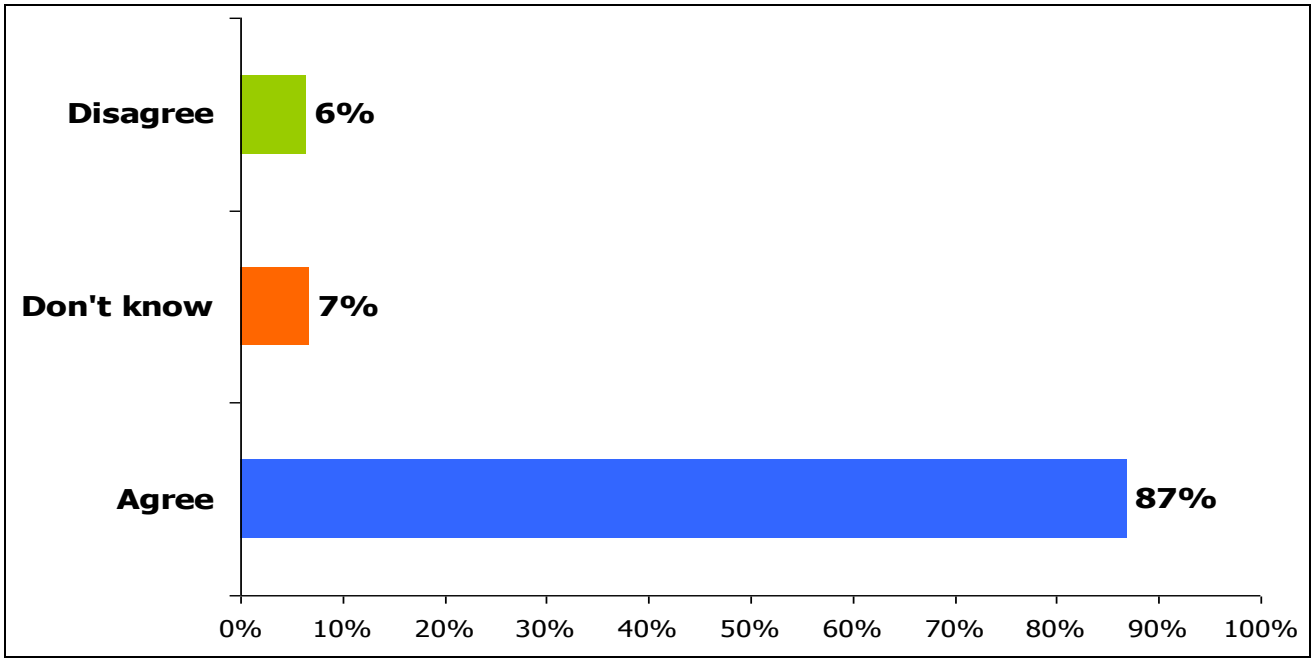


B6. Submission and evaluation of the proposals

There has been some criticism of the handling of the EDCTP proposals. For example few of the projects included outcome evaluation measures and a number of researchers are involved simultaneously in multiple

projects which may limit other researchers from participating. It has been suggested that revised procedural guidelines should be published on the website.

The new EDCTP initiative should review the way it handles the proposals and publish revised procedural guidelines on its website**.**

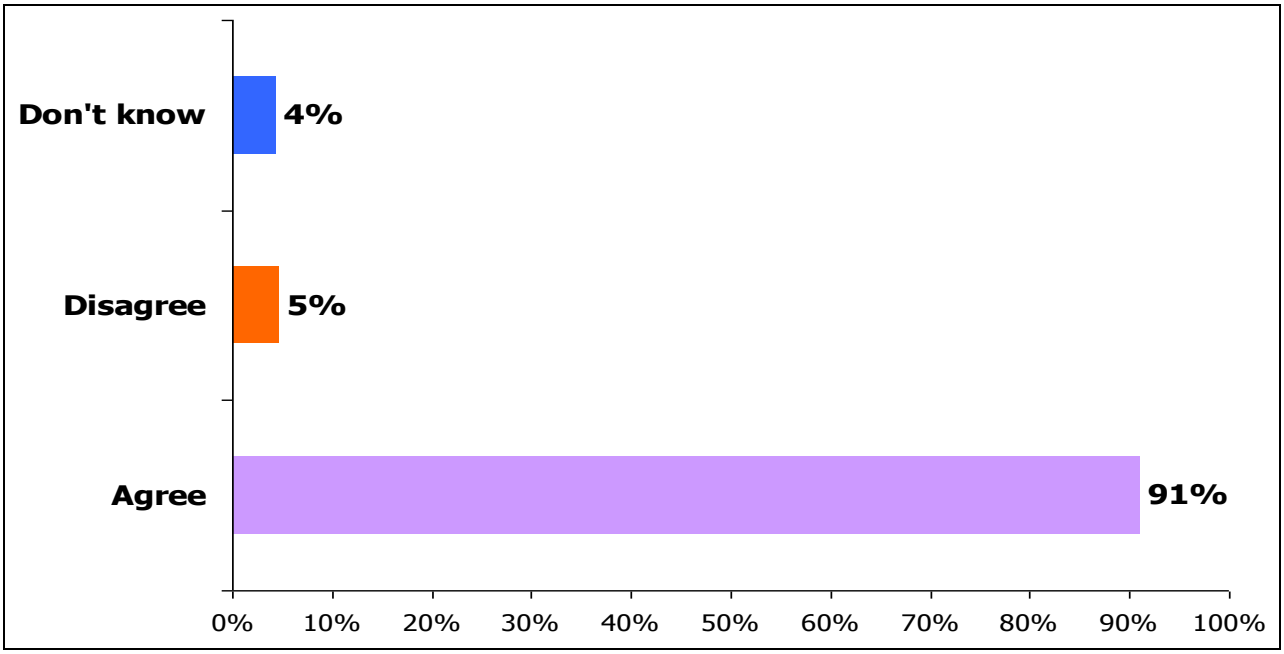


C. Funding

C1. Co-funding arrangements

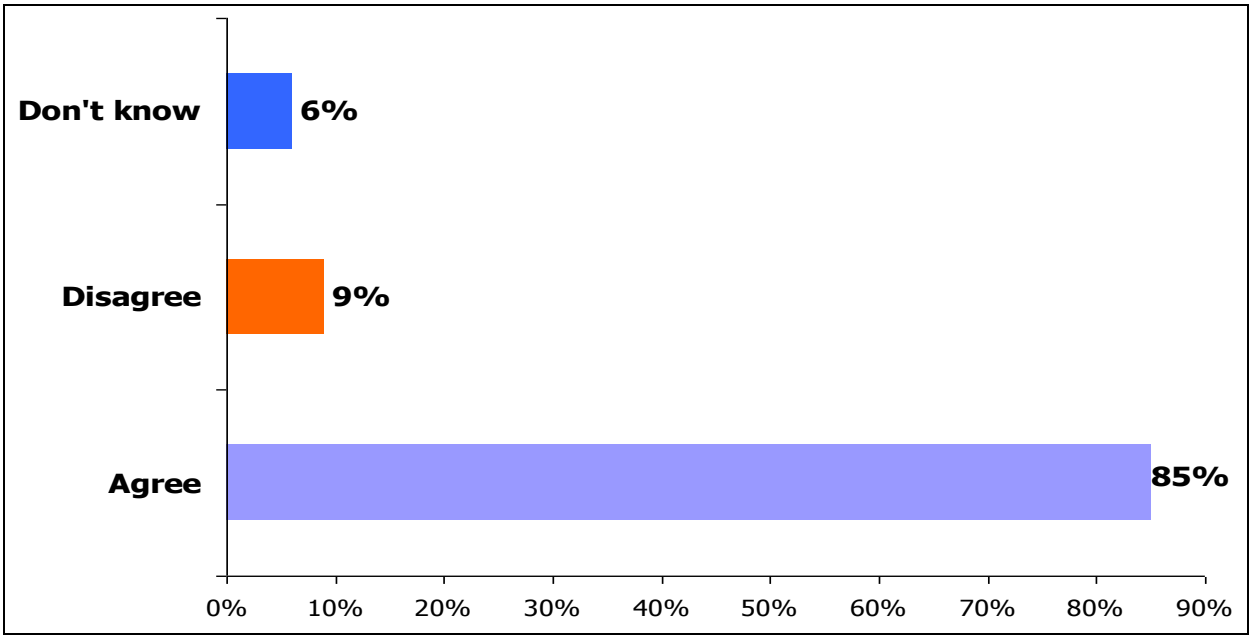
The EDCTP has not yet succeeded in integrating Member State clinical trials programmes. The current co-funding arrangements constitute a major source of difficulties and confusion, generating multiple evaluations and unnecessary administrative delays and costs.

In order to address this, the successor to EDCTP should better define co-funding arrangements at the start of the programme.



C2. Member State's commitments

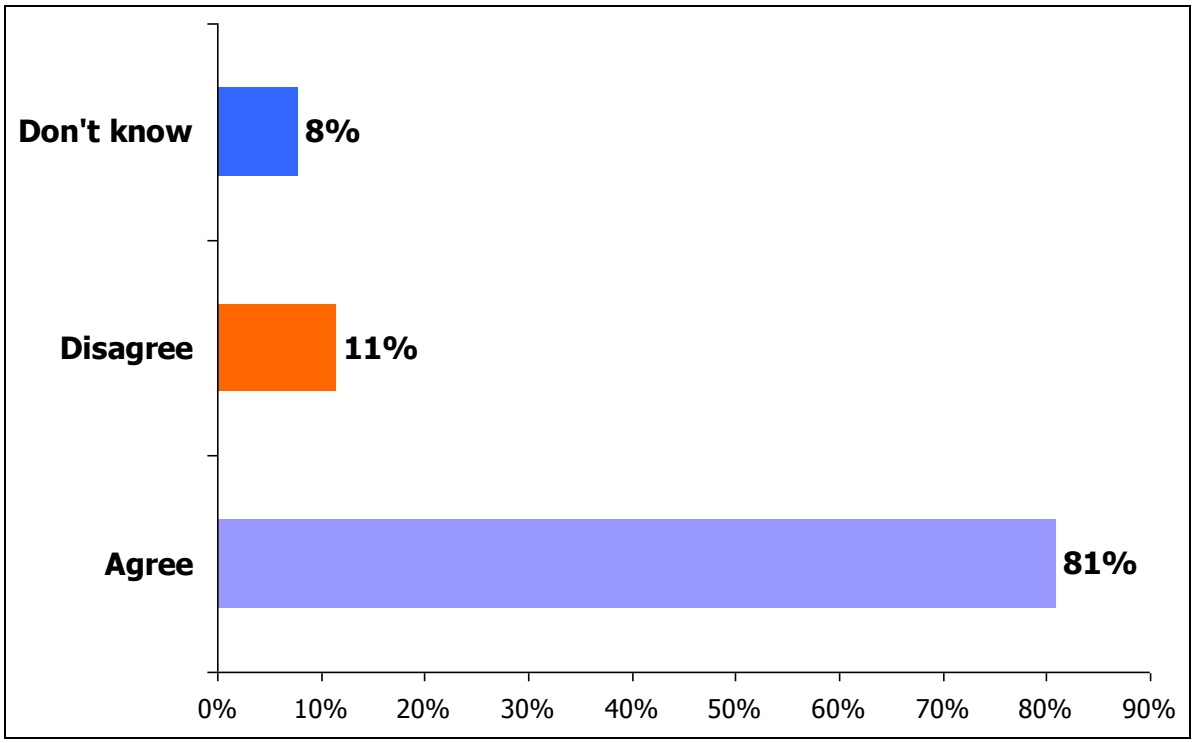
Each Member State should make a formal commitment for a minimum annual payment throughout the life of a new EDCTP initiative.



C3. A single fund

Co-funding could be simplified if Member State contributions were made to a single fund. A 'common pot' creates a single fund for the programme and its projects, and the criteria for project funding do not include consideration of the origin of funds to the 'common pot'.

In order to reduce operational complexity, a new EDCTP initiative should simplify and streamline co-funding, by creating a single fund.



D. Policy Options

D1. EDCTP future options

Four options can be envisaged for the future of the EDCTP programme:

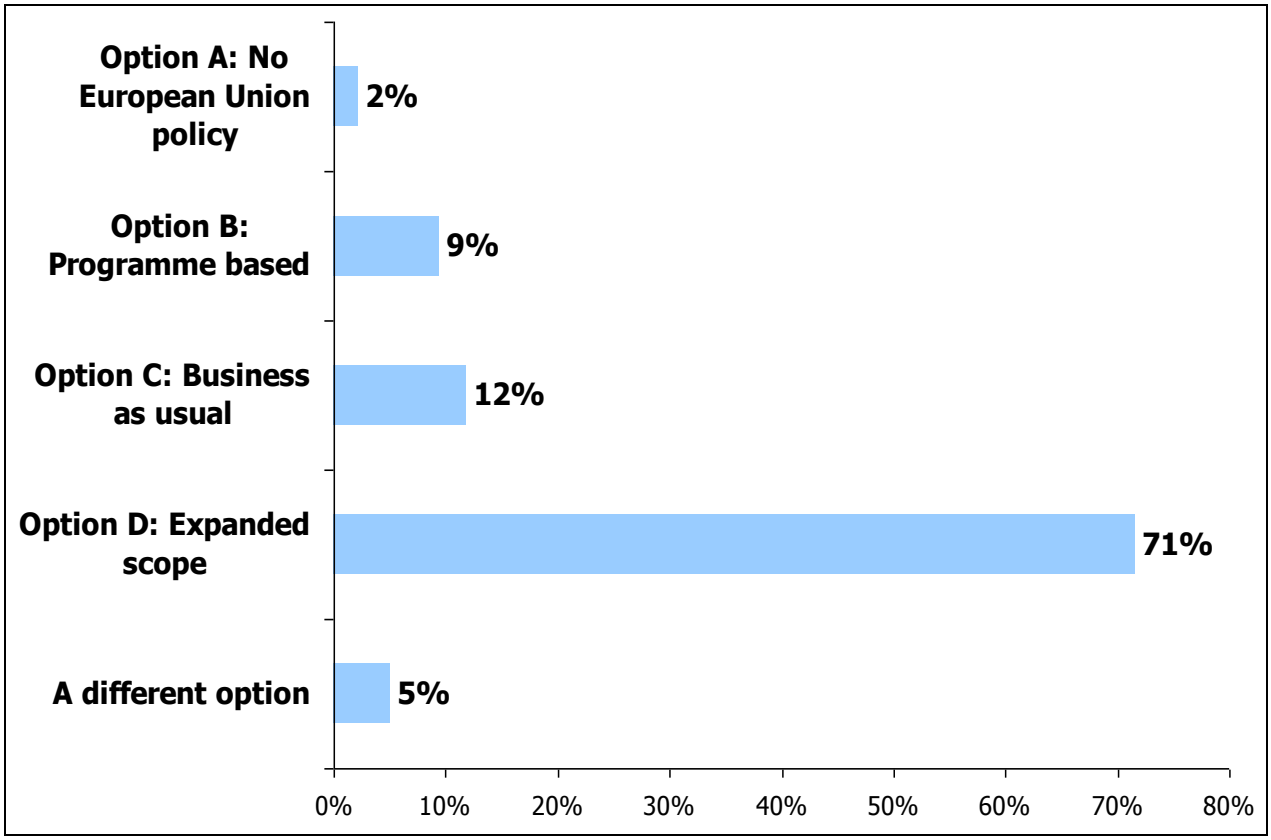
Option A: "No European Union policy". No European Union decision establishing a successor programme to the current EDCTP after the expiration of its current funding phase. No provision is made in EU research policies or funding to support EDCTP objectives, either in terms of clinical trials or the integration of Member State research programmes.

Option B: "Programme based". No European Union decision establishing a successor programme to the current EDCTP after the expiration of its current funding phase. Provision is made in EU research policies and funding to support EDCTP objectives in terms of clinical trials but not the integration of Member State research programmes.

Option C: "Business as usual". A new European Union decision establishes a successor programme to the current EDCTP under the same terms as the original (Article 185 (ex-169) of the Treaty on the Functioning of the EU). Current EDCTP objectives on clinical trials and the integration of Member State research programmes are maintained. The successor takes account of the recommendations provided in the 2007 and 2009 evaluation reports.

Option D: "Expanded scope". As in Option C, a new European Union decision establishes a successor programme to the EDCTP under the same terms. The successor takes account of the recommendations provided in the 2007 and 2009 evaluation reports. The scope of the programme is expanded to include some or all of the following: (i) other diseases, (ii) other stages of clinical trials, (iii) other geographical areas.

Which is your preferred opinion?

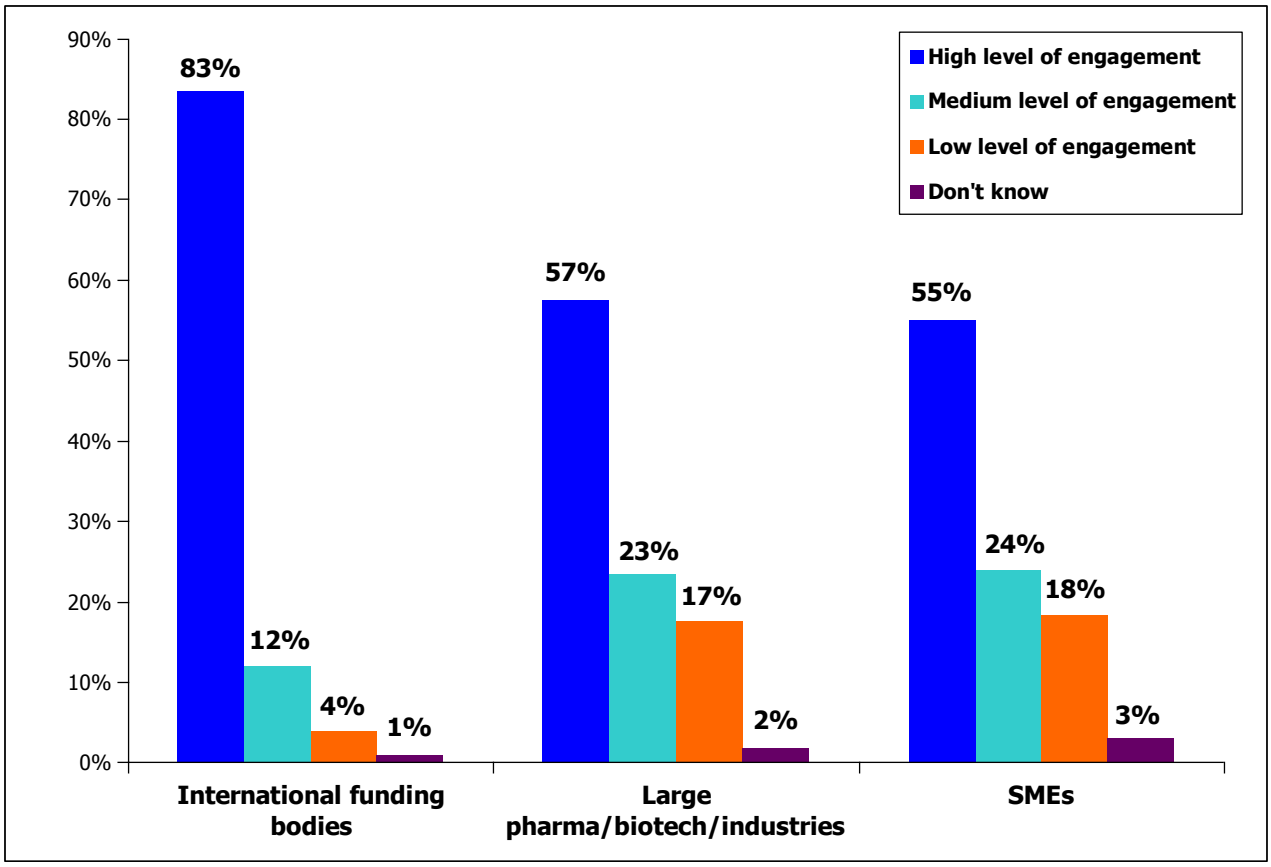


E. Third Parties

E1. Partnerships

The involvement of third parties such as Small and Medium Enterprises and large pharmaceutical, biotech and industrial companies is important in the development of new products. In addition, in view of the high cost of clinical trials, it has been recommended that a new EDCTP initiative should collaborate more closely with major international funding bodies.

To what extent should a future EDCTP initiative work closely with the following third parties?



F. Ethics and Intellectual Property Rights Policy

F1. Ethics

The current EDCTP requires that all proposals to conduct clinical trials have ethical clearance from the national ethics board(s) in the country or countries in which the trial(s) will take place. This requirement can slow the project approval process.

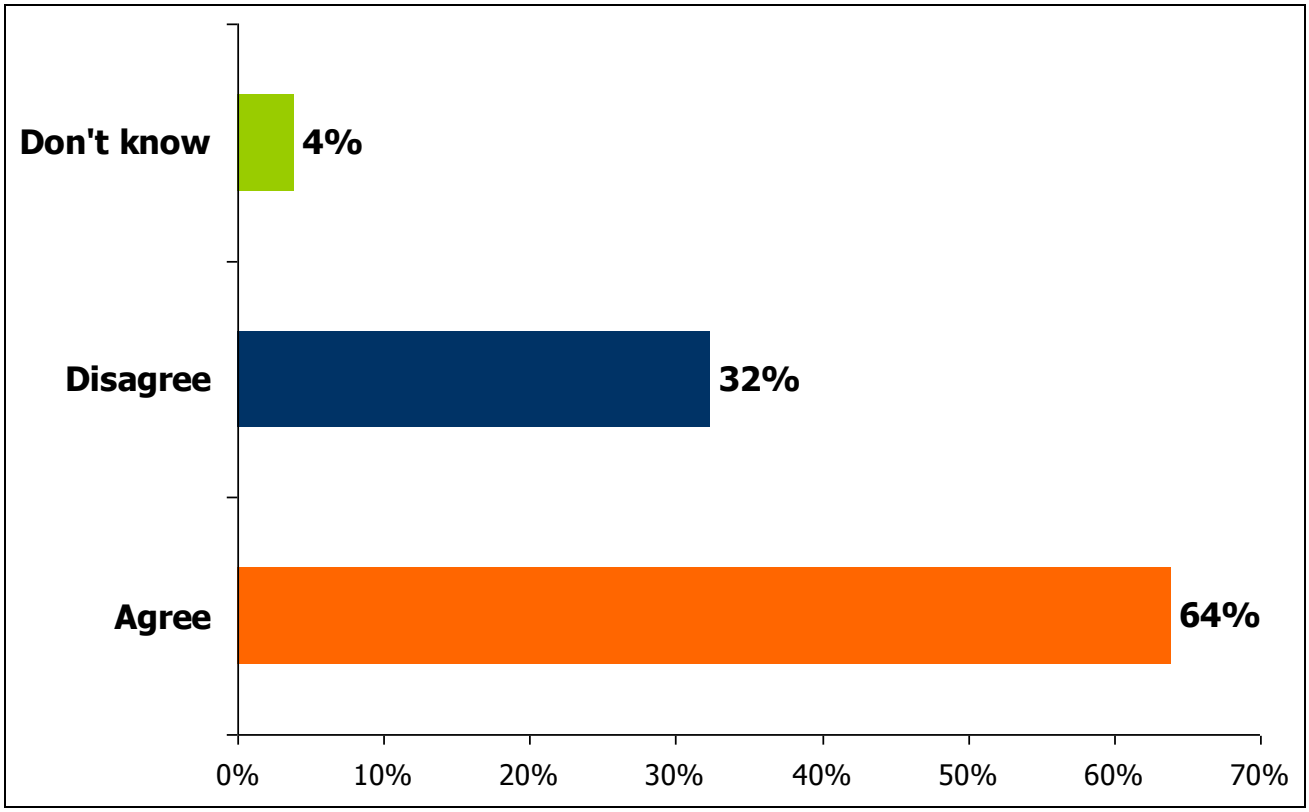
An EDCTP-specific research ethics committee, composed of African and European experts, may simplify and accelerate this process by performing the following tasks:

i) Revising clinical trial protocols before their submission for final approval;

ii) Providing clearance or suggesting modifications to these protocols according to accepted ethical standards;

iii) Communicating with participating countries' ethics committees to obtain their preliminary approvals;

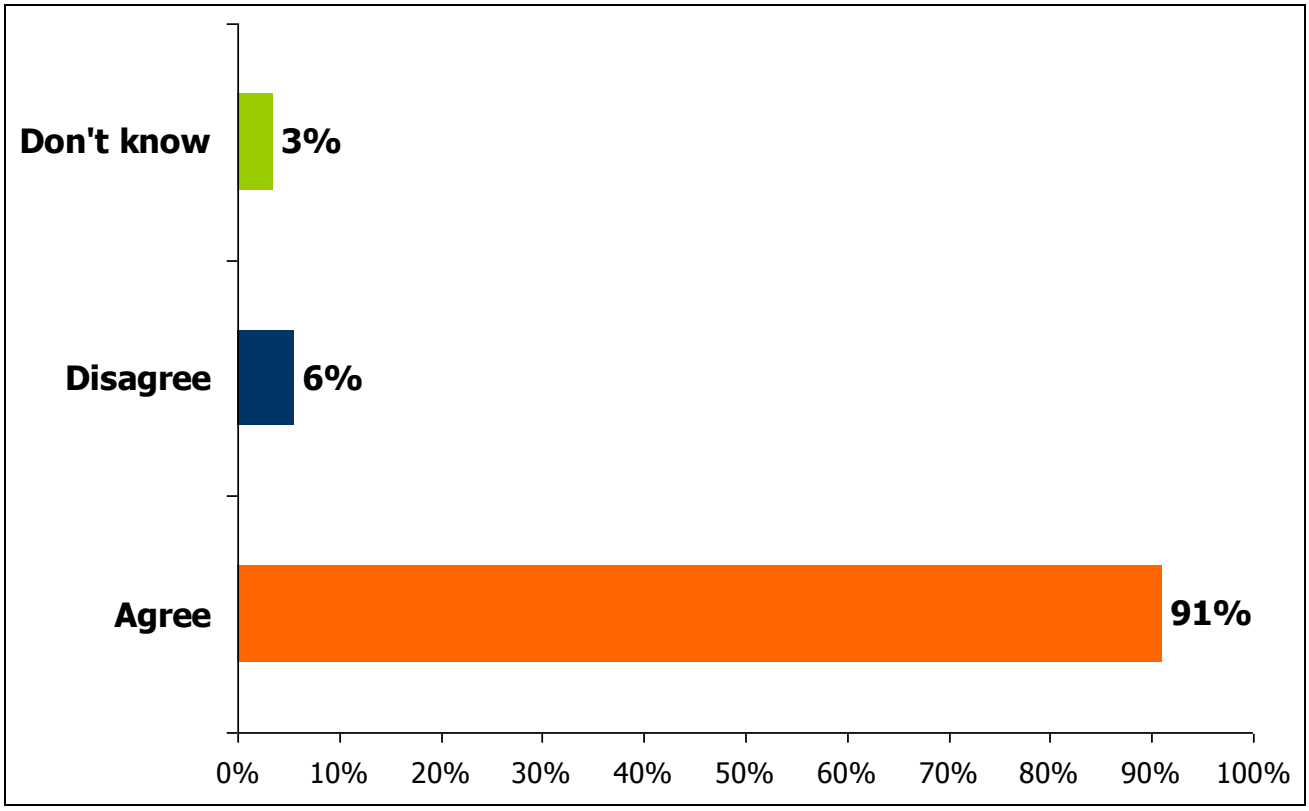
iv) Monitoring the application of ethical rules during the implementation of these clinical trials.



F2. Intellectual Property Rights

A balance must be struck to support the involvement of Industry in developing new and improved drugs and the condition of EDCTP funding that patients in developing countries should have affordable access to the resultant products. This is a complex matter and an overarching Intellectual Property Rights policy has been difficult to define.

A new EDCTP initiative should have a balanced, clear and comprehensive Intellectual Property Rights policy.

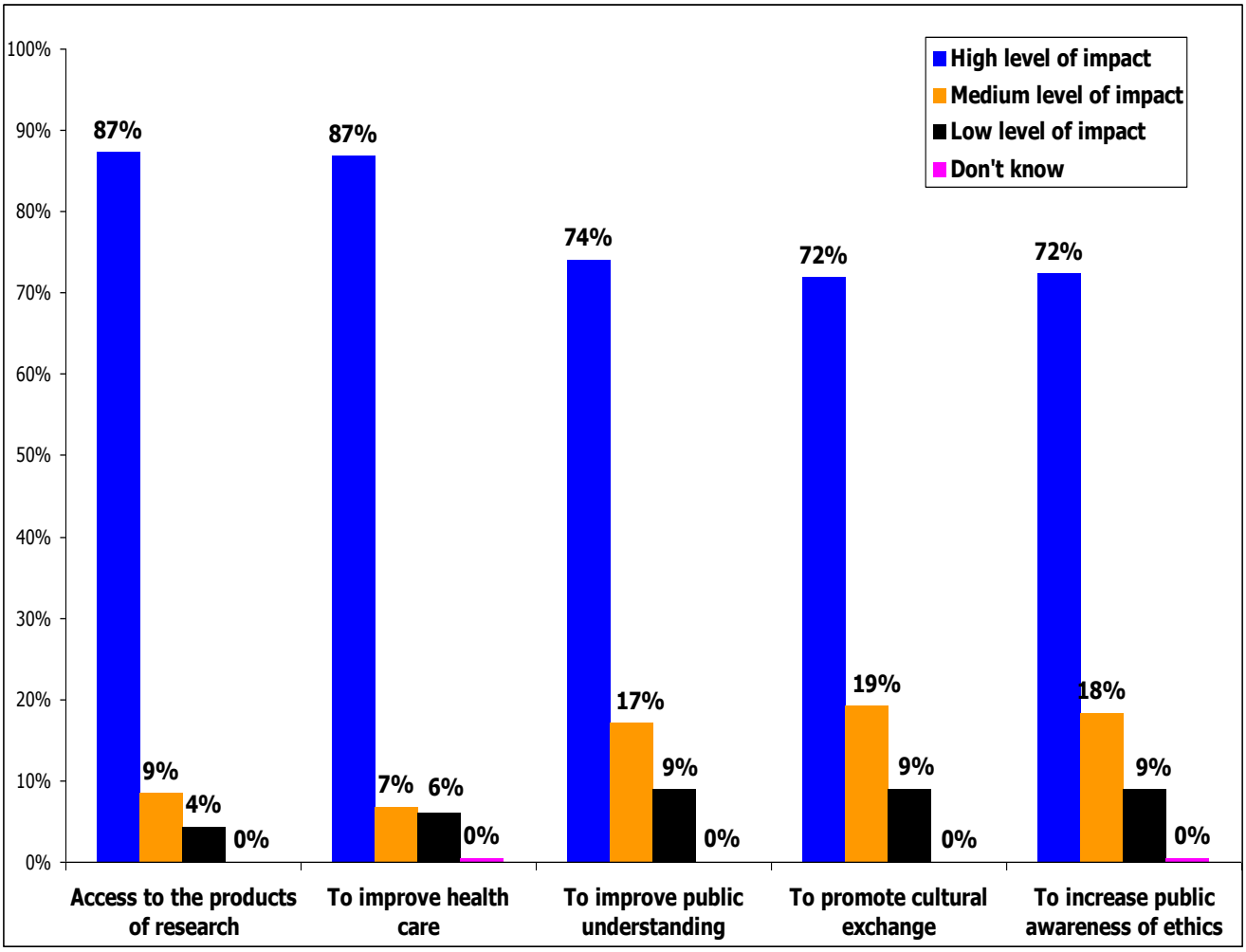


G. Social and Economic Impact

G1. Social impact

What level of impact should a new EDCTP have on the following social objectives?

- To help combat discrimination in all of its forms, including, but not limited to those based on racial or ethnic origin, religion or belief, disability or age
- To promote equality between men and women
- To ensure all enjoy access to the products of research findings
- To promote cultural exchange through research by supporting dialogue between African and European researchers
- To improve public understanding of clinical trials
- To increase public awareness of ethics in clinical trial research
- To improve health care benefits and equal treatments

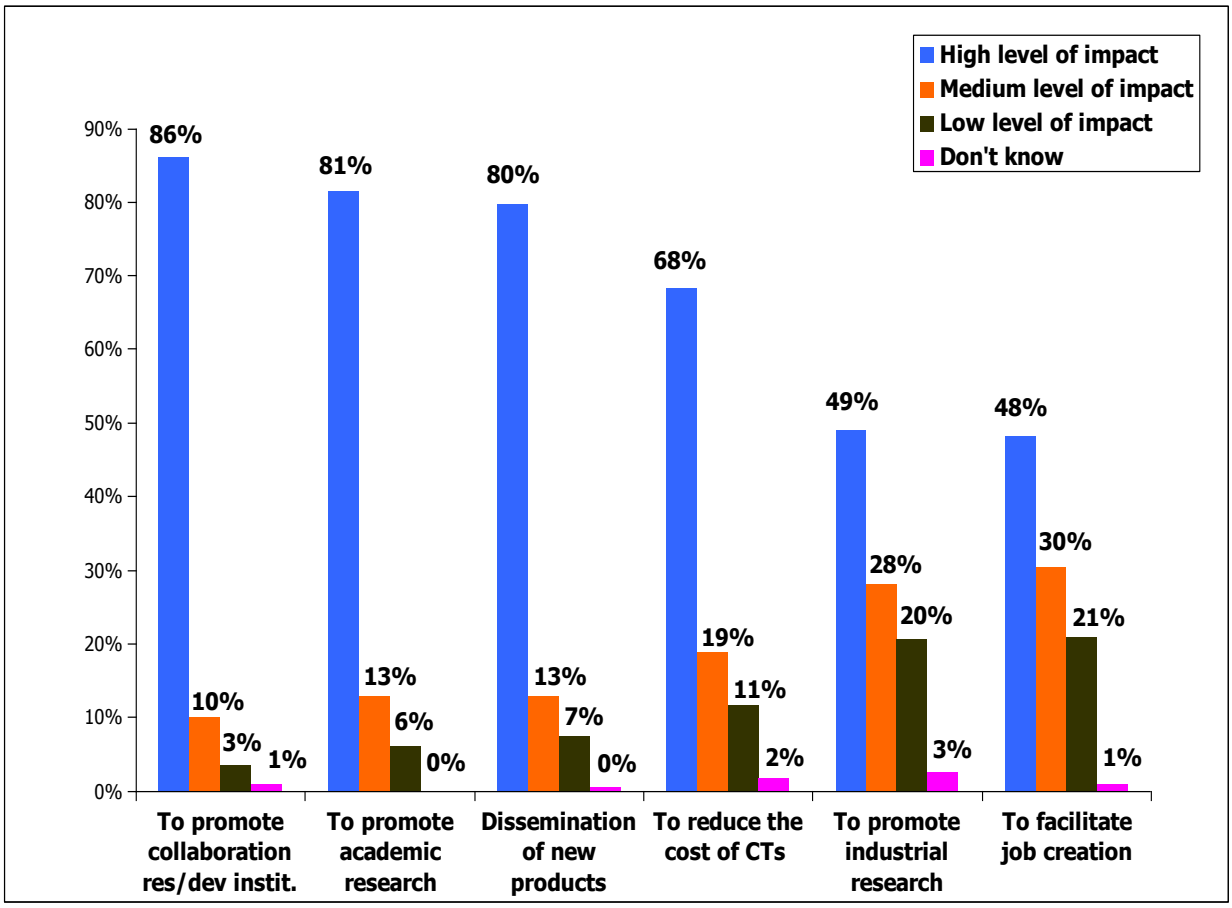


G2. Economic impact

What level of impact should a new EDCTP have on the following economic objectives?

- To reduce the cost of clinical trials
- To facilitate job creation
- To facilitate the introduction and dissemination of new products, technologies and production methods

- To promote industrial research
- To promote academic research
- To promote collaboration between research and development funding institutions



H. Governance Structure

H1. EDCTP governance

The governance of EDCTP is guaranteed by the European Economic Interest Group (EEIG), and external partnership structures.

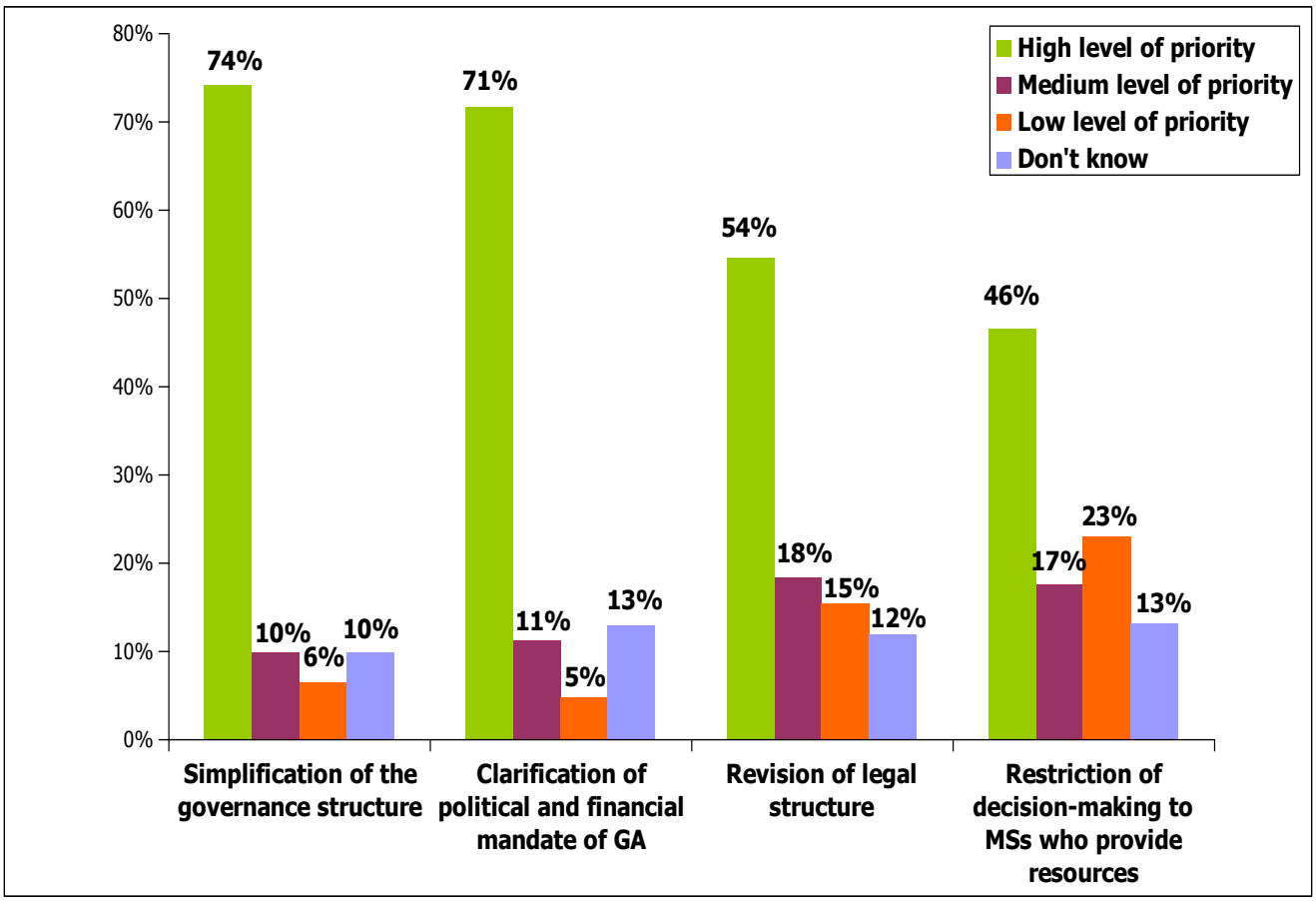
The EEIG is responsible for the programme and consists of: i) the General Assembly, a governing body, in which all participating European Member States are represented and ii) the Secretariat, which assures the day-to-day management.

The partnership structures external to the EEIG consist of: a) the Partnership Board, an independent panel of scientists; b) the Developing Countries Coordinating Committee, consisting of African scientists; c) the European Network of National Programmes, which includes representatives of the European national programmes.

In a new EDCTP initiative the following actions relating to governance should be addressed:

- Simplification of the governance structure
- Revision of the present legal structure to incorporate voting rights for African government representatives
- Clarification of the political and financial mandate of General Assembly members

- Restriction of decision-making to Member States who provide financial or other resources



4. RESULTS DIVIDED BY CATEGORY OF RESPONDENTS

As mentioned on page 5, of the 235 answers received, the majority (175, 75%) were personal opinions, 48 (20%) represented the view of an organisation/company and 12 (5%) were from public authorities. This section analyses the results of several questions from the Public Consultation by the following categories of respondents: private individuals, public authorities and organisations.

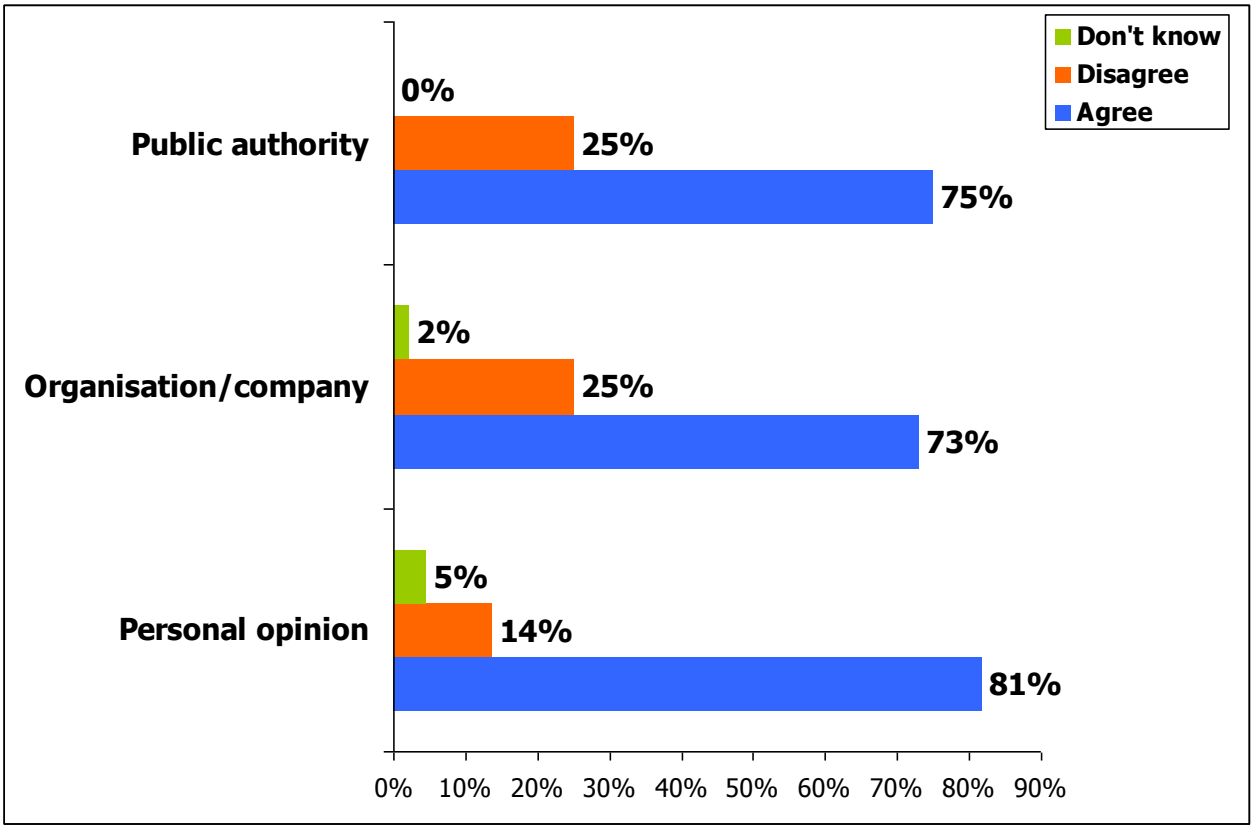
As described on page 10, the category of respondents by geographical location is the following: concerning personal opinion, 58% of the answers received were from Europe, 30% from Africa and 12% from other geographic areas; for organisation/company, 56% of the answers were from Europe, 23% from Africa and 21% from other geographic areas; for public authority, 75% of the answers received were from Europe, 17% from Africa and 8% from other geographic areas.

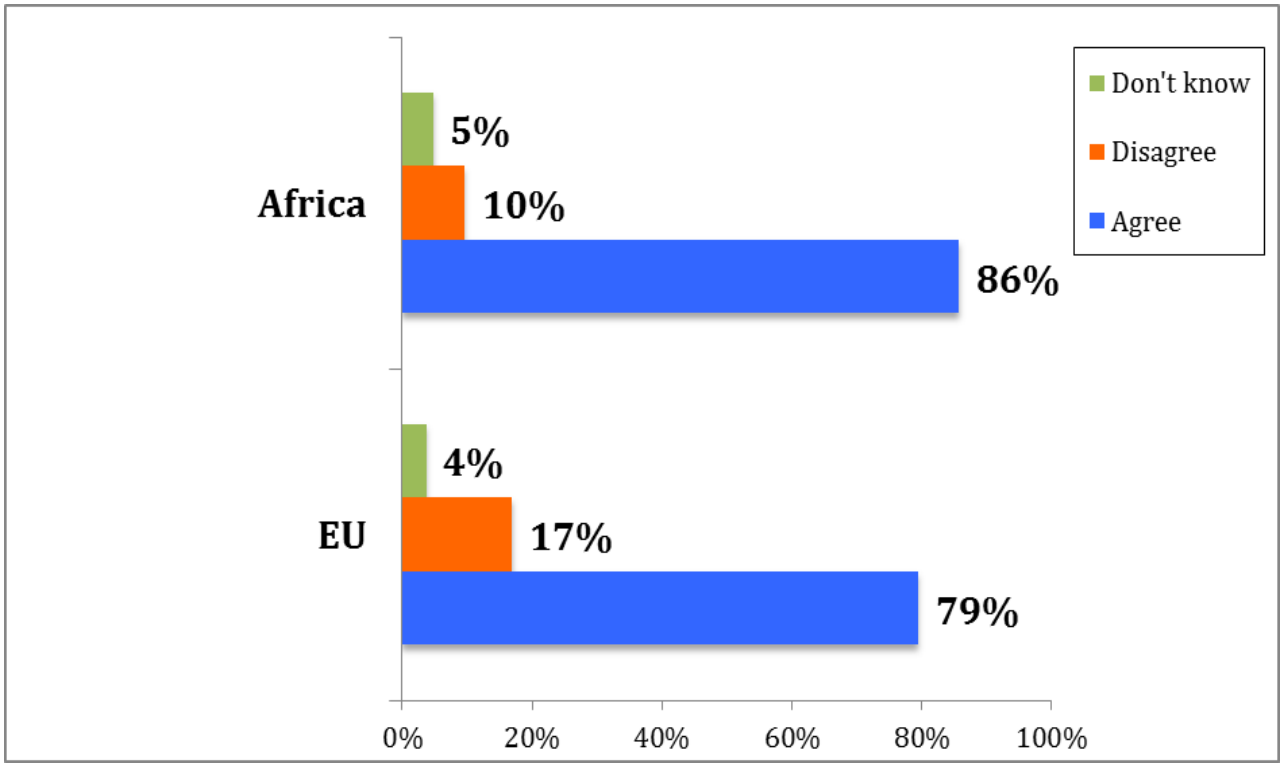
In order to ensure a balanced overview of the conclusions of the public consultation, the following section details the breakdown of the conclusions and main stakeholder inputs by socio-professional categories and place of origins.

B. Activities, Scientific Strategy and Management

B2. Phases of clinical trials

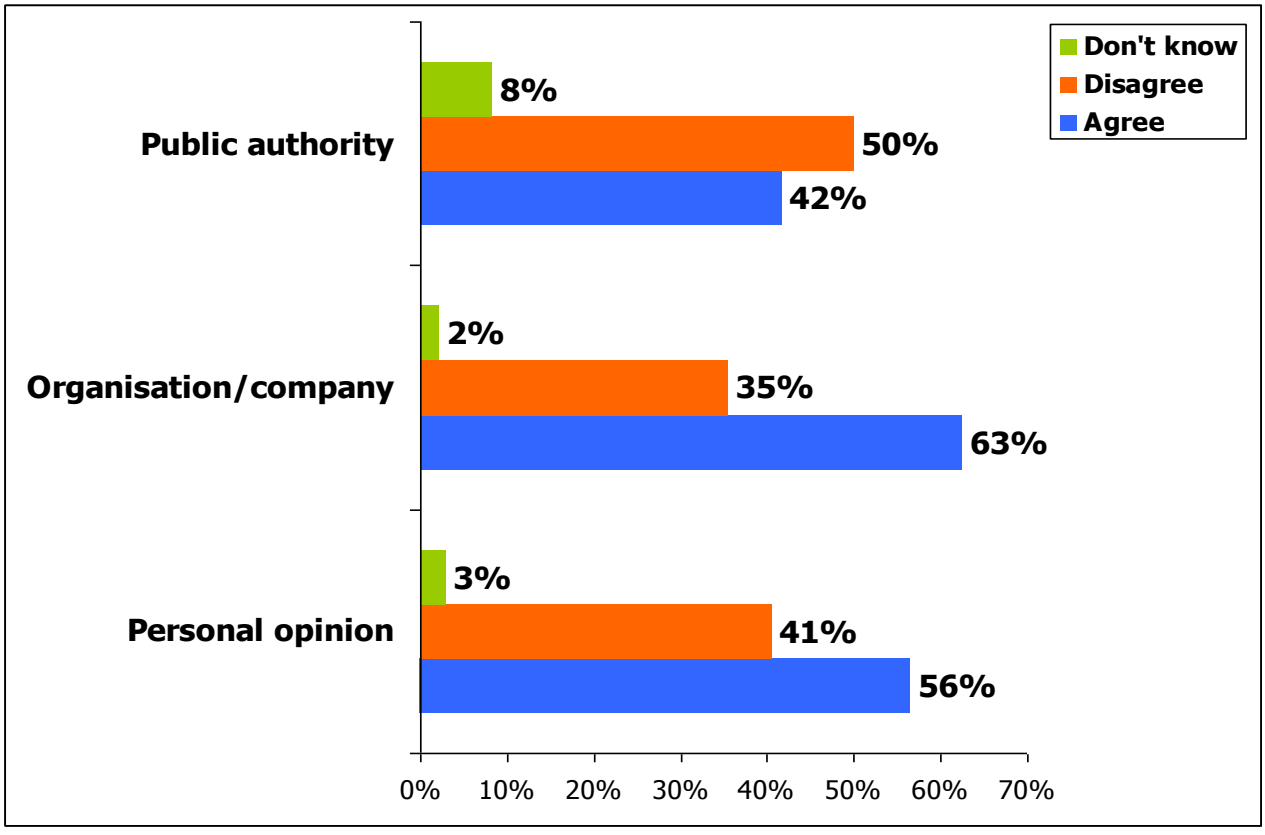
A new EDCTP initiative should be broadened to support clinical trials in Phase I and Phase IV.

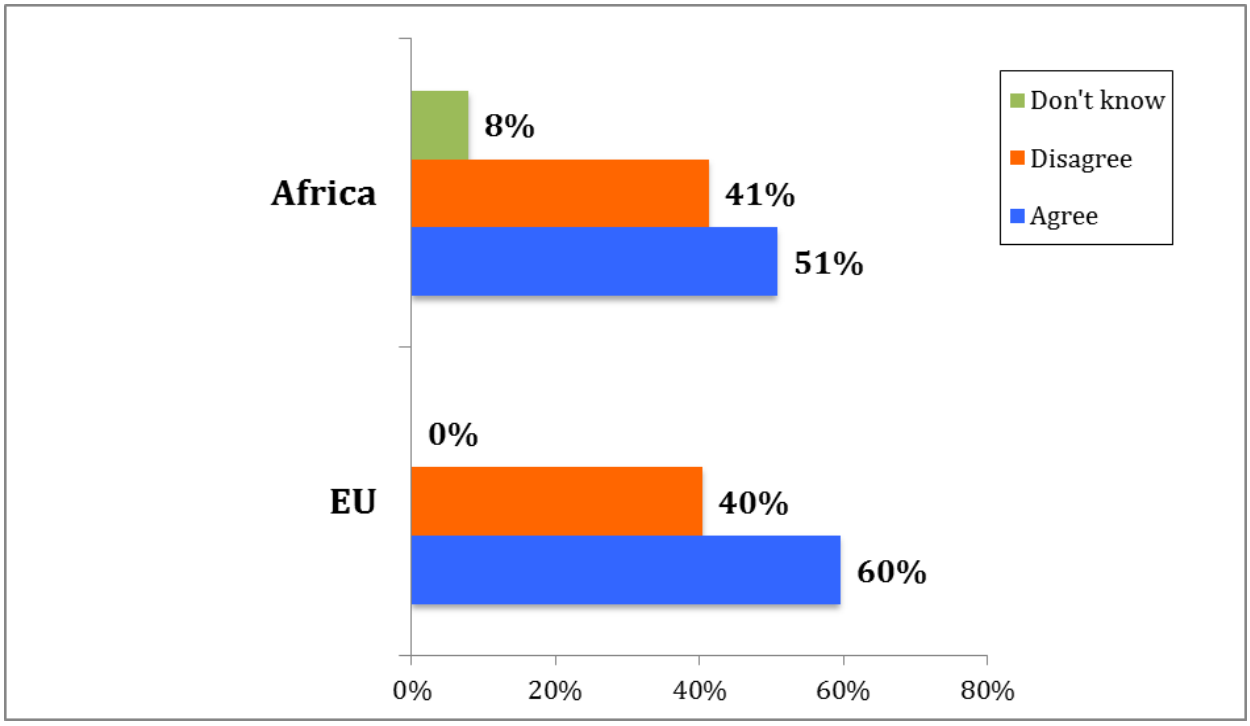




B3. Areas of geographical interest

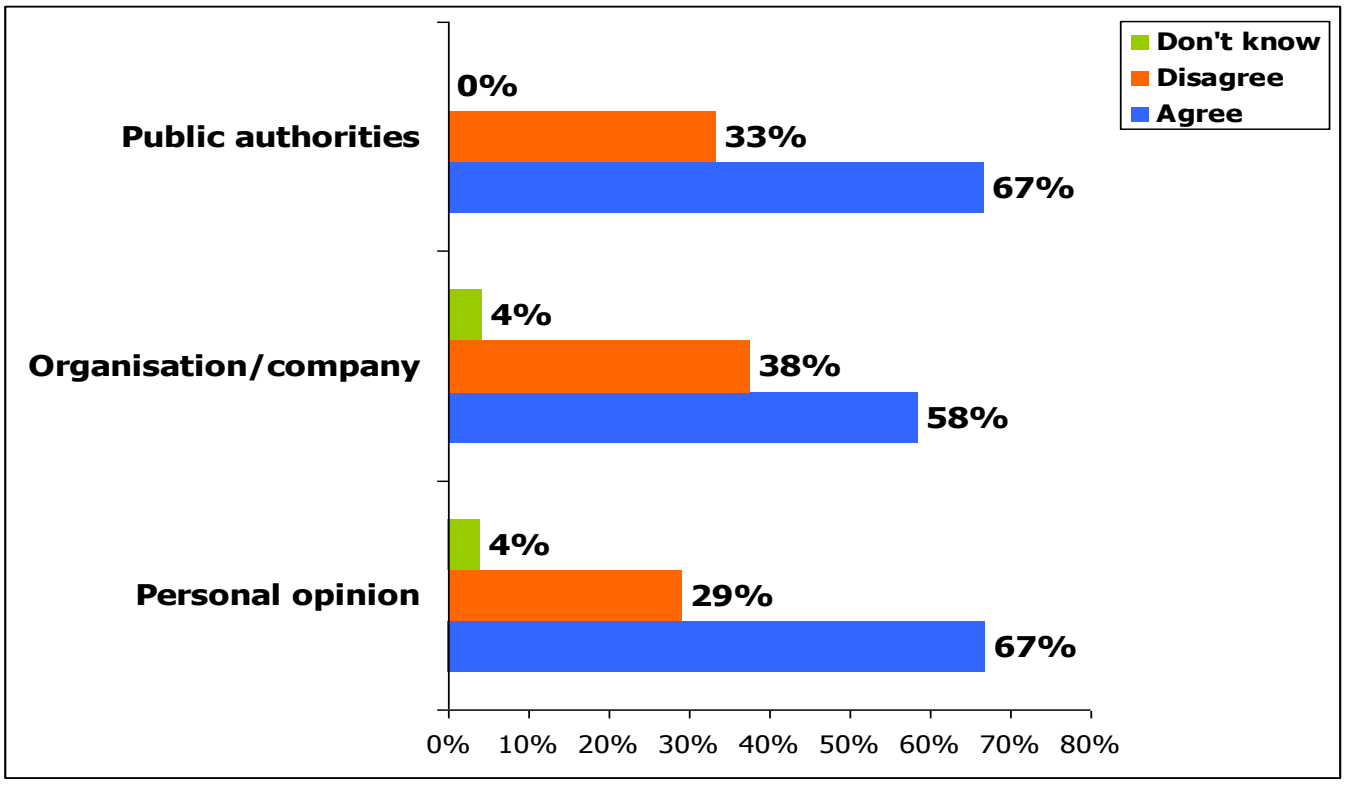
A new EDCTP initiative should expand to additional geographic areas.

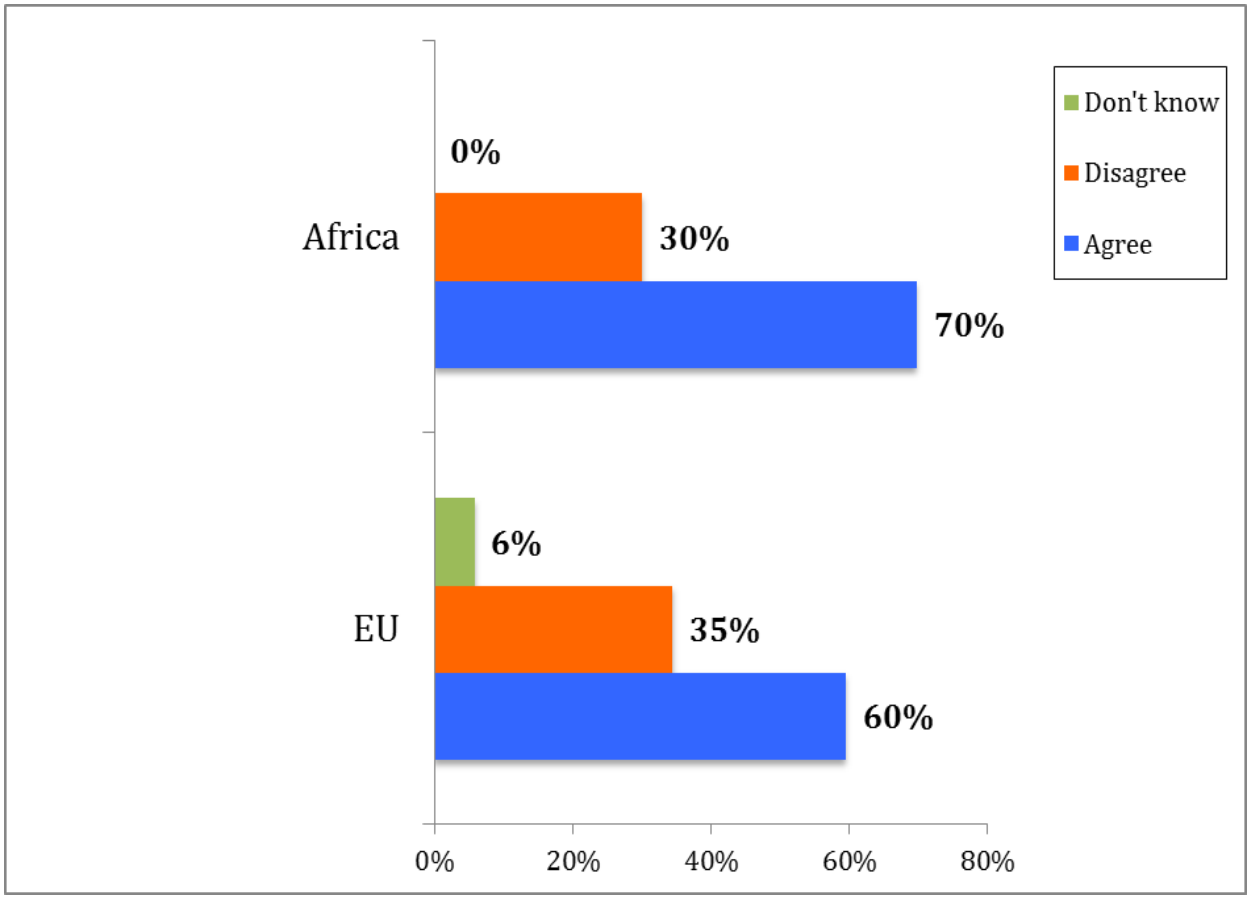




B4. Disease scope

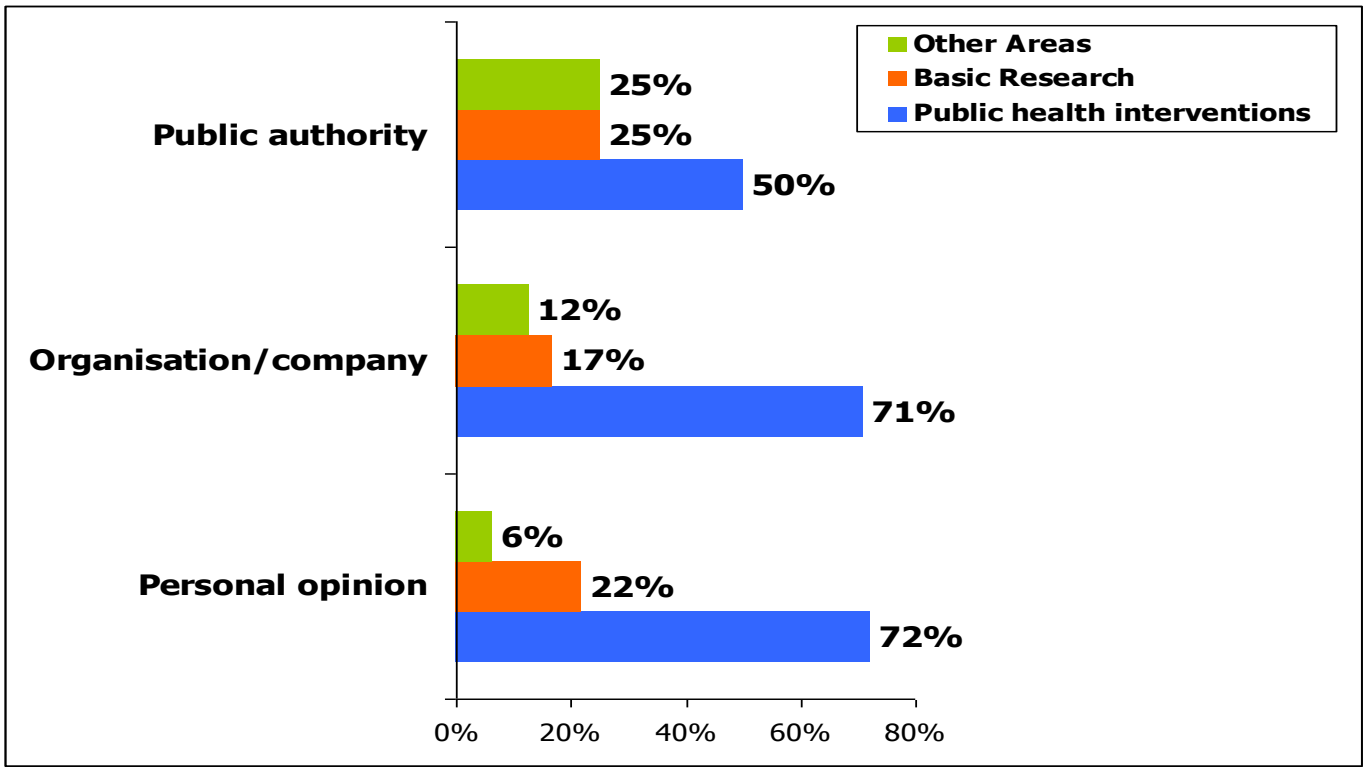
A new EDCTP should investigate other infectious diseases in addition to the three poverty-related diseases.

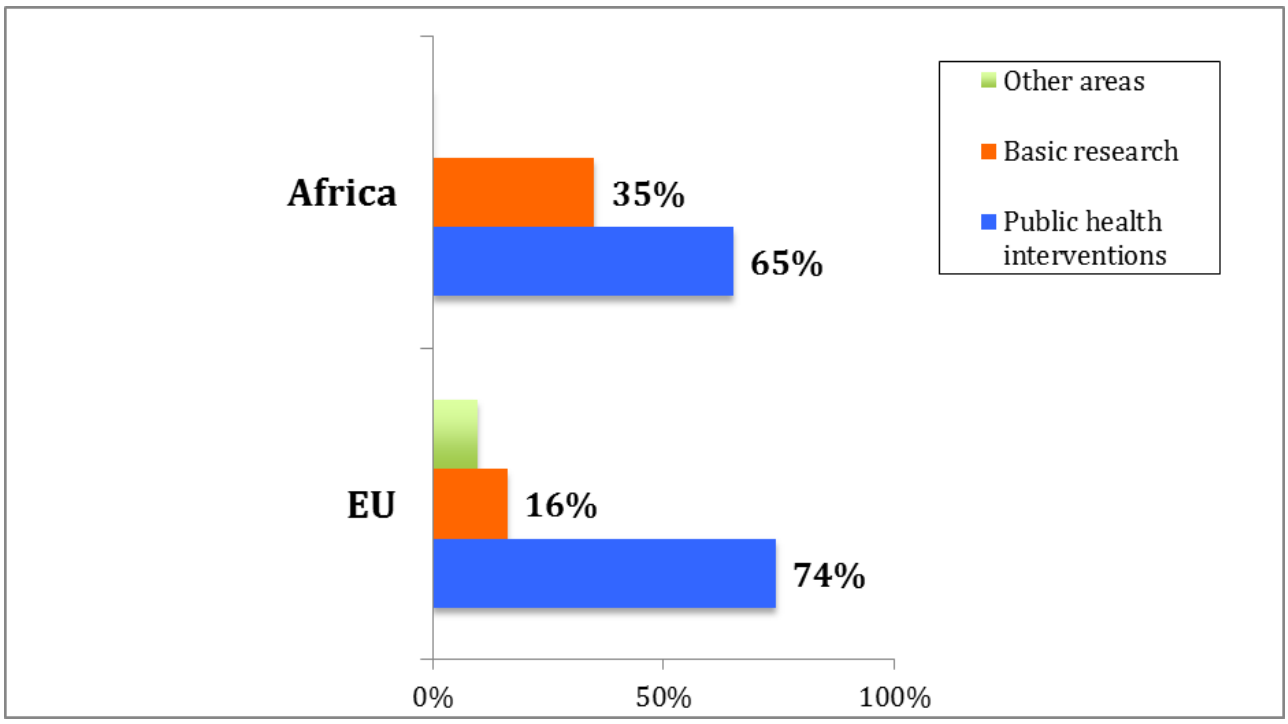




B5. Research priorities

If a new EDCTP initiative were to be extended to new areas of research which one of the following areas should be prioritised?

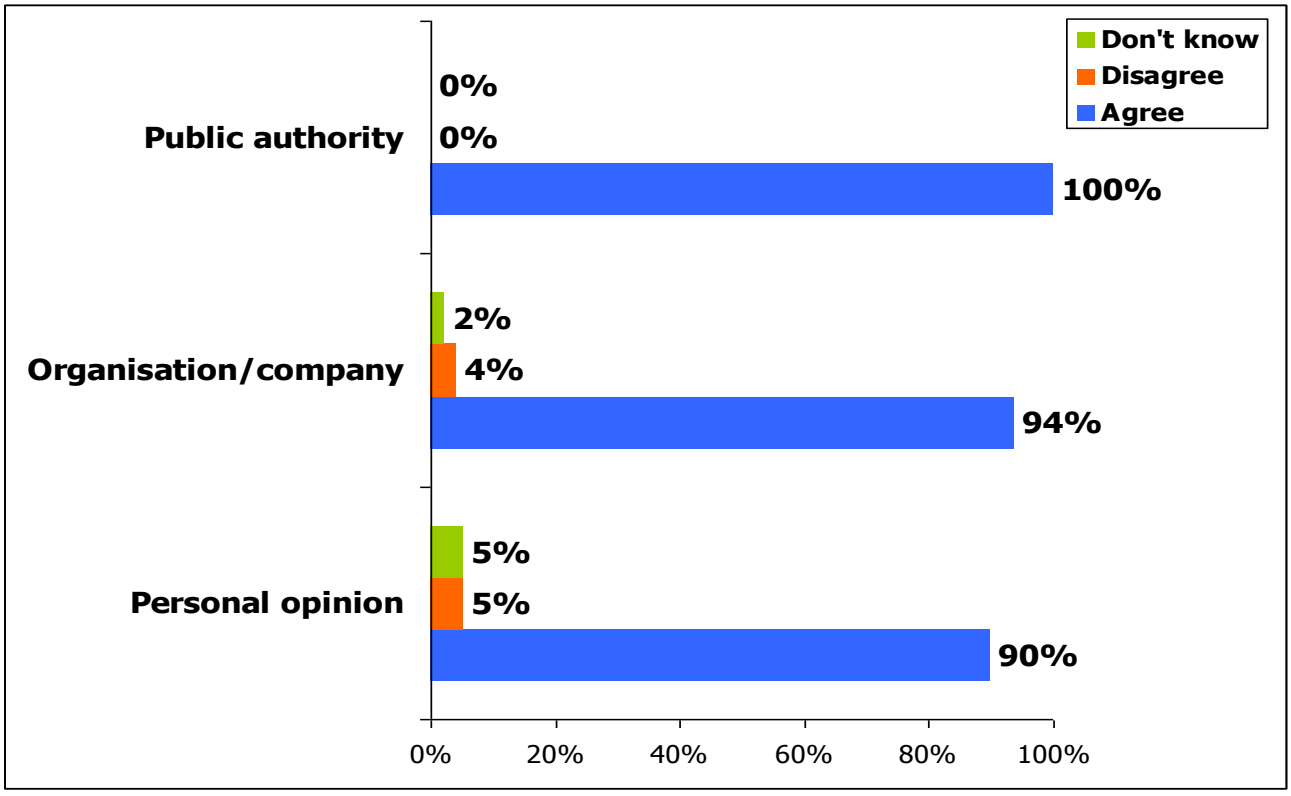


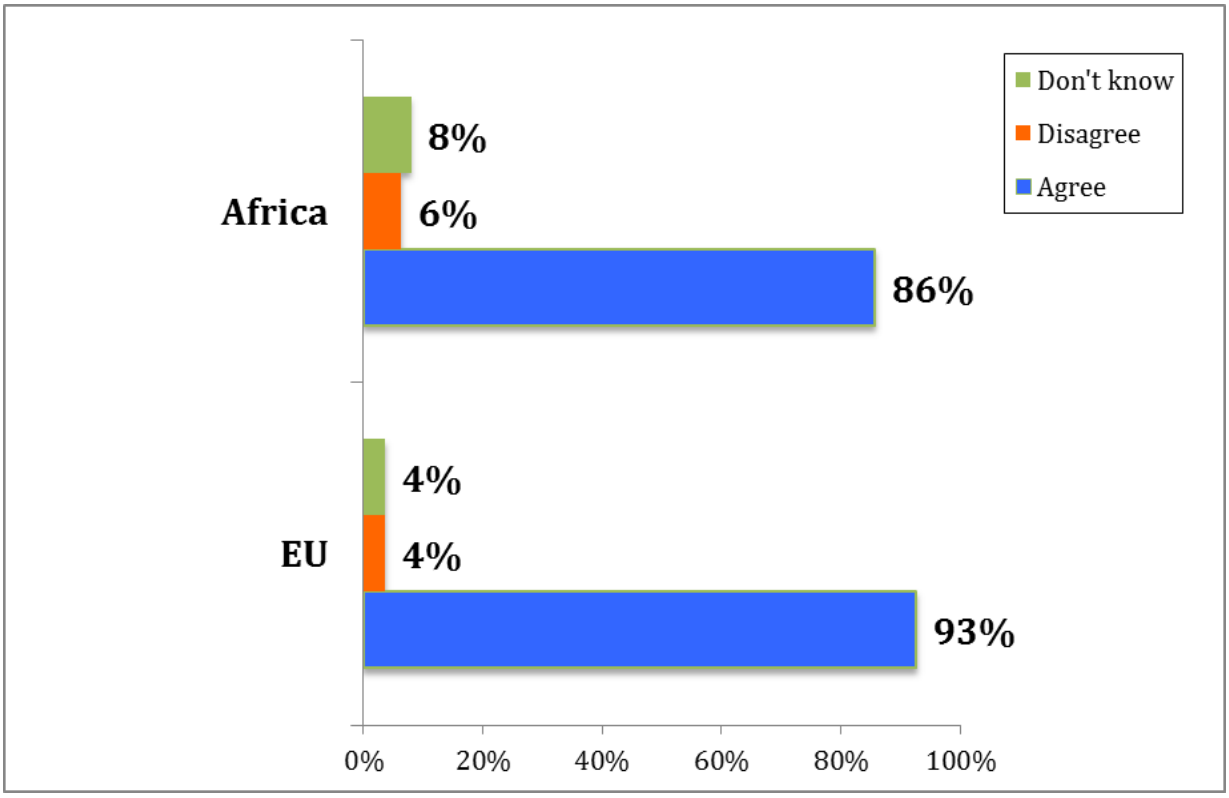


C. Funding

C1. Co-funding arrangements

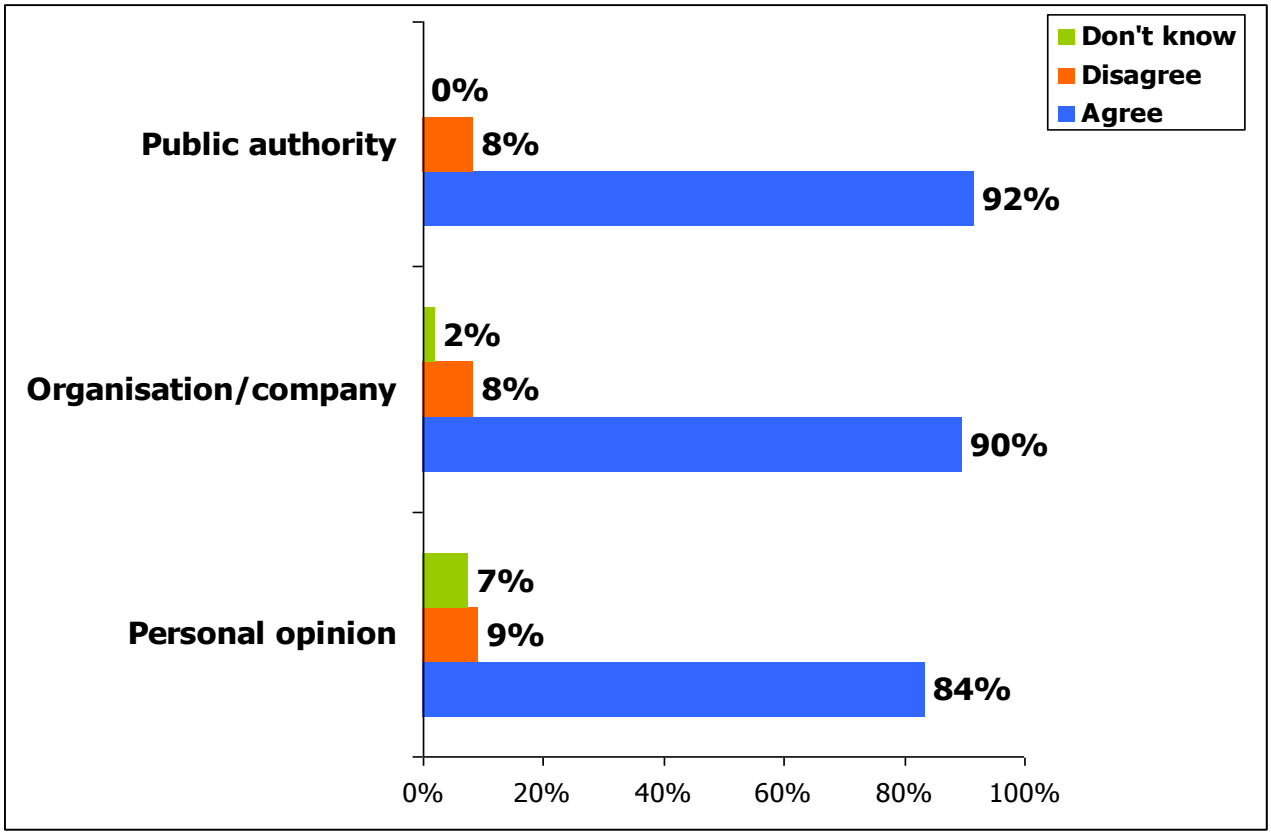
The successor to EDCTP should better define co-funding arrangements at the start of the programme.

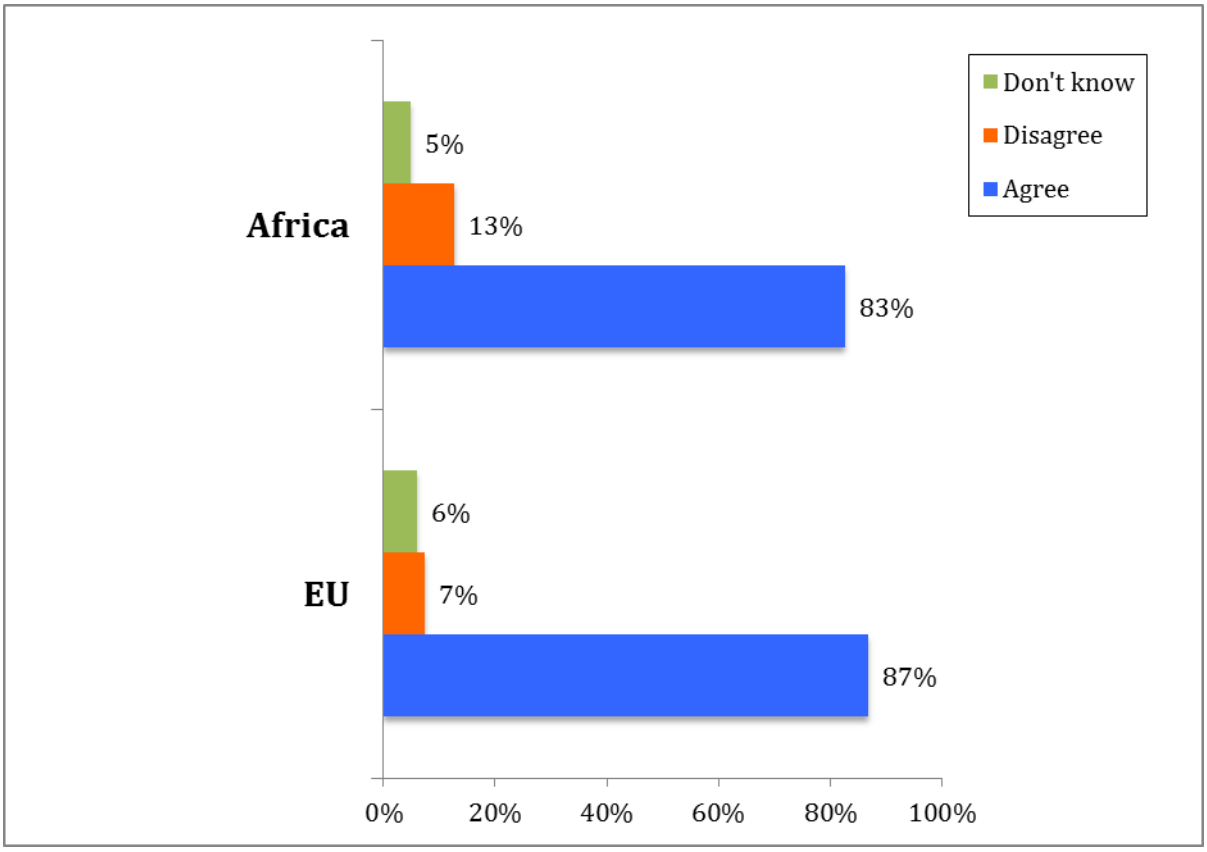




C2. Member State's commitments

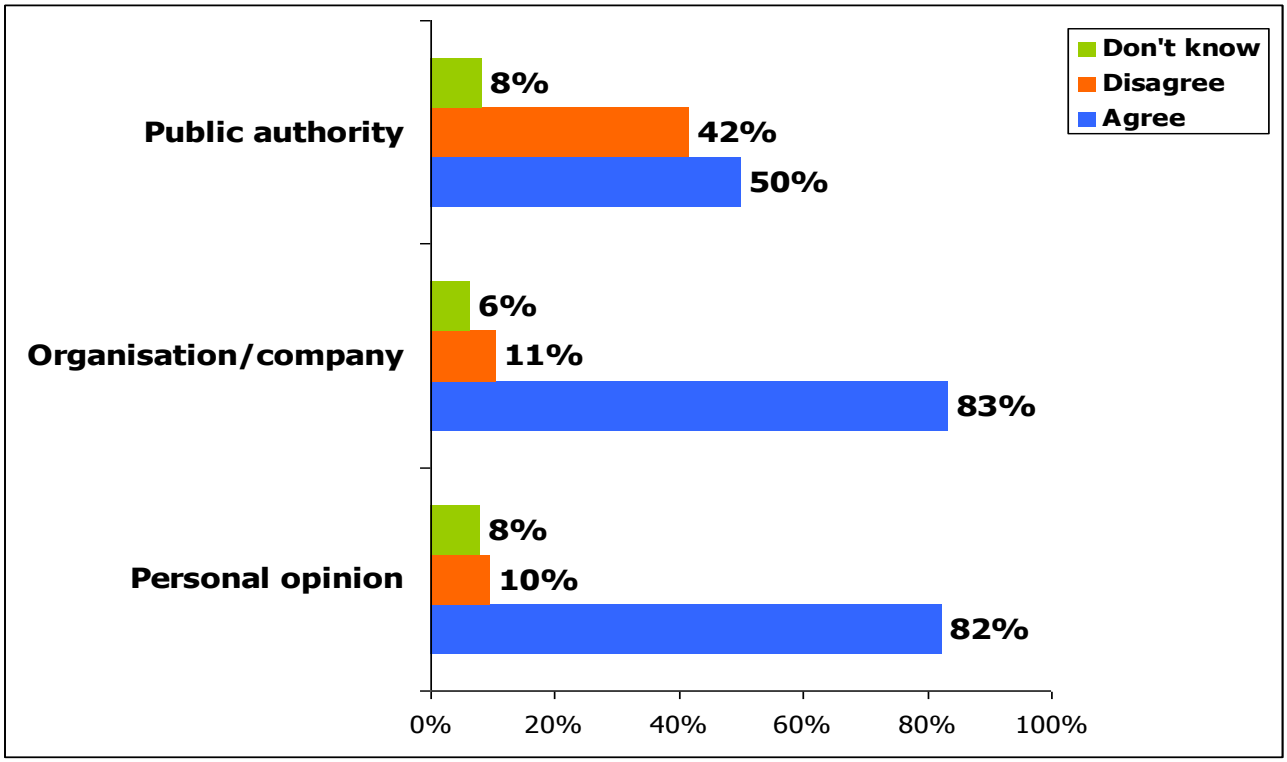
Each Member State should make a formal commitment for a minimum annual payment throughout the life of a new EDCTP initiative.

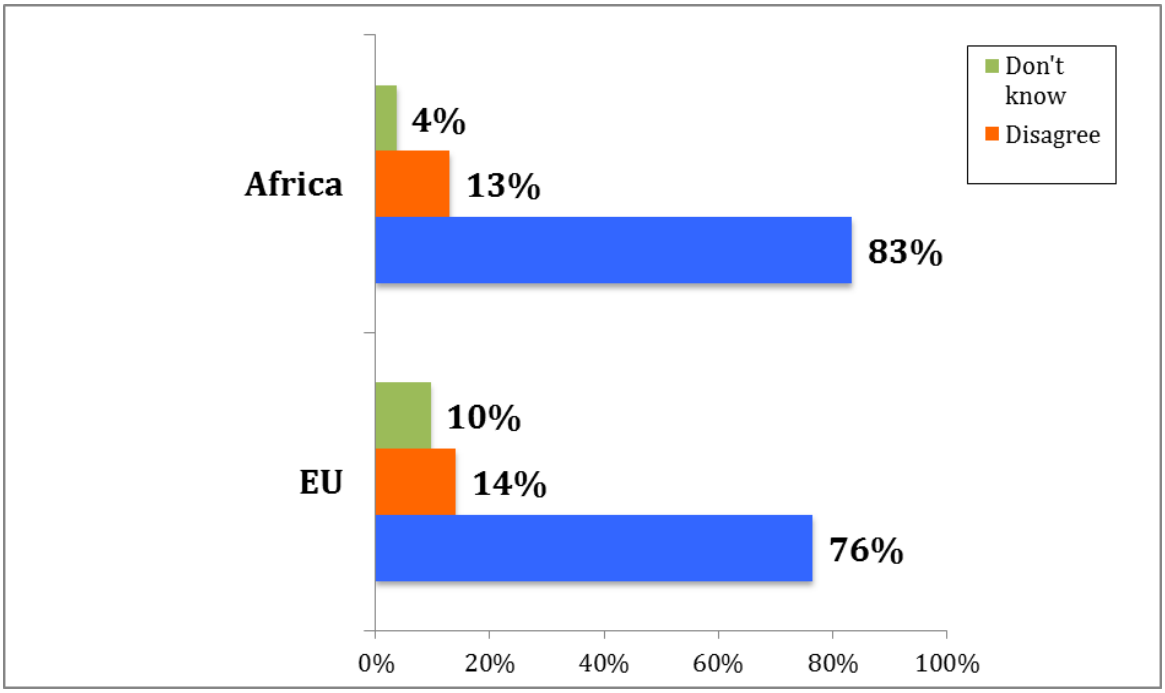




C3. A single fund

In order to reduce operational complexity, a new EDCTP initiative should simplify and streamline co-funding, by creating a single fund.





D. Policy Options

D1. EDCTP future options

Four options can be envisaged for the future of the EDCTP programme:

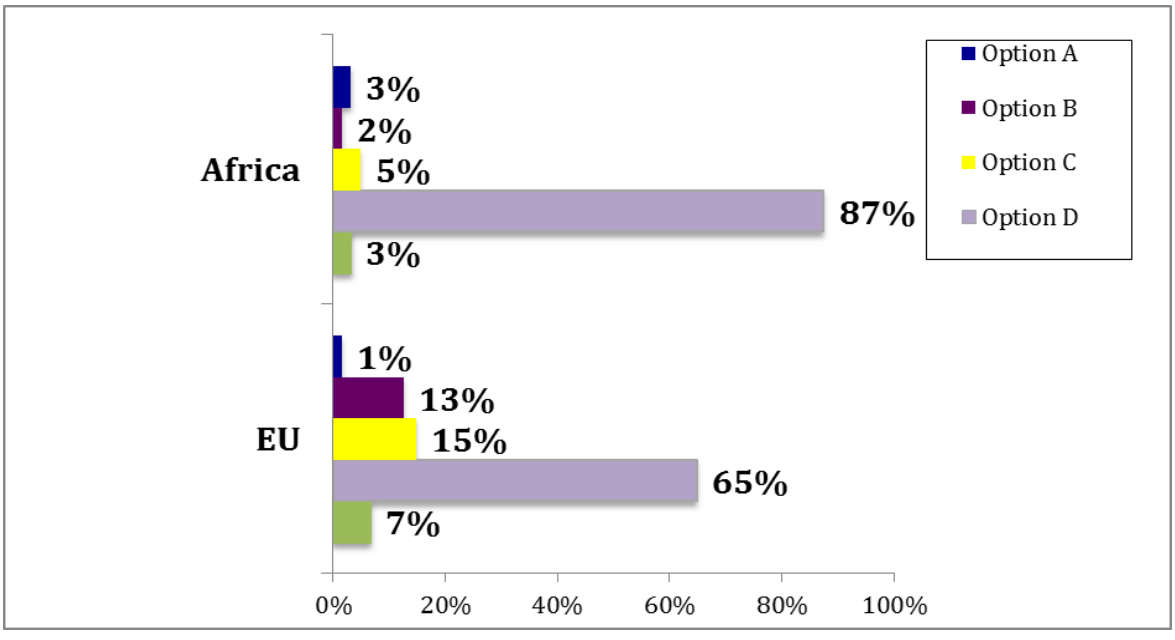
Option A: "No European Union policy"

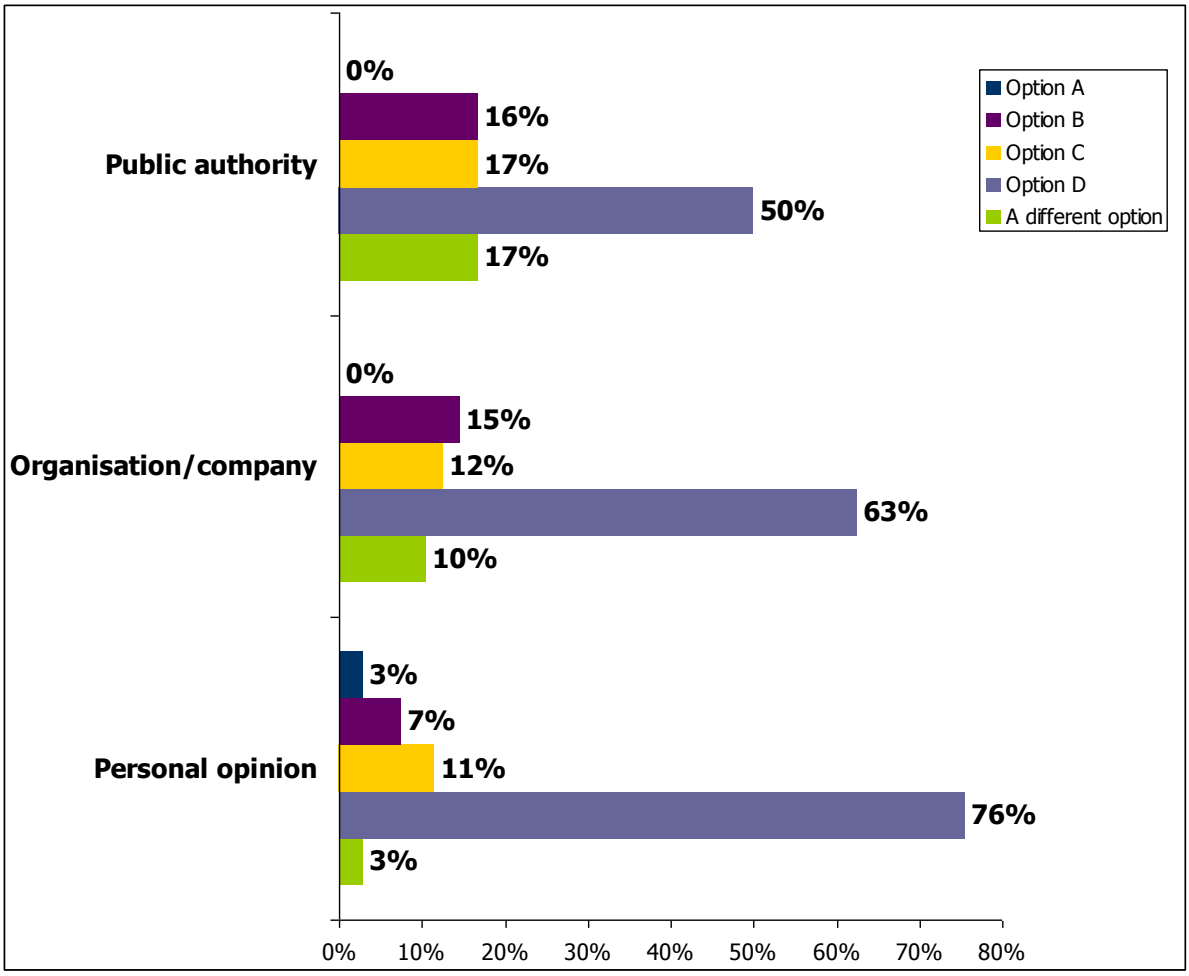
Option B: "Programme based"

Option C: "Business as usual"

Option D: "Expanded scope"

A different option.




Public authority
0%
16%
17%
50%
17%
Organisation/company
0%
15%
12%
63%
10%
Personal opinion
3%
7%
11%
76%
3%
Option A
Option B
Option C
Option D
A different option
0%
10%
20%
30%
40%
50%
60%
70%
80%

5. RESPONSES TO OPEN QUESTIONS

The final parts of questions B1, B5, D1, and all of E2, were open questions and responses received are presented below divided by category of respondents. Answers that did not directly address the question posed were included in the general comments. Answers which were offensive or directed at individuals were excluded.

Question B1. Programme activities

The main activities of the EDCTP are: i) research and training activities to support clinical trials; ii) capacity building in Africa; iii) networking and coordination; iv) ensuring visibility and sustainability of the EDCTP programme. Please describe any other potential areas of activity.

PERSONAL OPINIONS

Alasan Jobe

To provide more scholarships for needy especially the developing world. To scientifically proven interventions not research in order to support their implementation, monitoring and evaluation especially in developing world so as to reduce or even eliminate/eradicate HIV/AIDS, Malaria and TB.

Asfaw Yared Merid

If possible, supporting other research from Africa in addition to clinical trials.

Brian Greenwood

The area which has not received much attention in this questionnaire is research capacity development in Africa. EDCTP has been successful in this area, especially in recent years. It is very important that this component of the current EDCTP's activities is carried over into the new programme, linking the development of the research abilities of individuals and institutions to the conduct of new trials. It will also be important for the new EDCTP to sustain links with the developing country scientists whom it has helped to train.

Britta Wahren

Continued and strong effort to support PIs and researchers at senior level, to perform clinical trials and capacity building.

Charles Arama

Strengthen young researchers where these diseases are endemic.

Comaritan Costa

Sport, democratic living, a good activity.

Chemtai Kipkeu

Collaboration with publication houses to better support African scientist to publish more eg a special feature on an African publication etc.

Davina Ghersi

South-south should include facilitating networking and communication between African nations and the low and middle income countries, including Latin America.

Dorothee Kinde-Gazard

Advocacy to present EDCTP in countries level to both minister in charge of health and minister of education and research.

Erasto Vitus Mbugi

EDCTP should also think of formulating junior grants for starting researchers (researchers at their early stage of research); for example PhD graduates who have just completed their training. They have to be able to get some grants before they get lost into deep frustrations. Supervision may be provided by their seniors at various respective institutions in preparation for independent research.

Eric Sandström

Nodes of excellence junior and senior scholarships support for regulatory agencies in DCs.

Elly Katabira

Training for Masters and PhD levels of African researchers within African institutions either within countries or regions.

Friedrich von Massow

Projects should be given special consideration which rise opportunities to link clinical research with improving knowledge, attitude and practice of public health services' staff.

George Blaskó

Clinical trials.

Godwin W. Nchinda

I have been working on HIV vaccine research for last 12 years in Europe and USA. Now I am hoping to return to Africa to head an Immunology Laboratory in Cameroon. When I arrived home recently to visit the structure I was impressed with the size but we still need equipments and proper mentoring to make Africans participate more fully in research. Funding for African scientist and salaries are frustrating.

Johanna Spreeuwenberg

Strengthen African capacity to manage health research and innovation according to the development priorities of each particular country; strengthen regional collaboration in health innovation in Africa.

Jonathan Kayondo

Mentorship.

Michael Hoelscher

After a difficult start, EDCTP has really made a difference in CT funding in Africa. While all the Gates PPDs have abandoned the idea of capacity development (this has been expressed by high representatives of GTBA and AREAS, EDCTP is the only large organisation that supports Cap Dev.

Michael Ramharter

Career development of African researchers.

Millen Ringo

Involvement and empowerment of all cadres of health centre in conducting CTs.

Odor King

There is need for EU states to support and build the capacity of young African researchers for sustainability of development programme sake in Africa. Periodic training is suggested very necessary.

Roger Tatoud

EDCTP should adopt a holistic approach and strongly support initiatives that address more than one of the above diseases as one impact on the others. Trials with multiple outcomes should be encouraged.

Sam Mardell

Developing the capacity of African institutions to carry out their own research projects (beyond EDCTP funding) - knowing where to look for funds and how to manage them.

Stephen B. Kennedy

Major activities, as described in the survey, should be to support research and capacity building in Sub-Saharan Africa for HIV/AIDS, Malaria and TB, as well as strengthening of SSA research infrastructures.

Wendy Burgers

I think supporting small research projects from African researchers, even if basic research linked to CTs, would be really helpful for capacity development. Small fellowships for PhDs or postdoctoral researchers for study in other African countries (South-South networking) would be another excellent way to build CTs-related capacity.

Xavier Daura

I do not sense public awareness of the EDCTP programme and its activities. There should probably be some work done on this direction.

Anonymous

Supporting upcoming scientists through more increased Msc and PhD scholarships.

Anonymous

The EDCTP should be less disease area focussed (e.g. on HIV/AIDS, TB and Malaria). This leads to exclusion of many other areas of research which are as relevant e.g. trauma and violence. Focus should be on building capacity for conducting any CT of relevance to the local population and not only infectious diseases!!!!!

Anonymous

Interaction with communities studied for CTs purposes in the relevant developing countries and imparting to them of good and feasible sanitation and health practices.

Anonymous

Lay groundwork for and promote capacity for basic science research in Africa for relative field of study.

Anonymous

Kindly consider funding trainings and networking for community engagement in research more specifically HIV/AIDS clinical research.

Anonymus

Building laboratories to support the clinical work is critical. Training for local staff critical.

Anonymous

The questions ask about strengthening capacity. I agree with that, but the EDCTP seems to preferentially support the establishment of new sites and appears to not care at all about sites that are established, but need support to sustain themselves. This seems to be ridiculous. The questions do not make that obvious and answers could fail to reveal the real problem.

Anonymous

Support establishment and/or strengthening of research support (administrative) services in academic institutions.

THE VIEW OF ORGANISATIONS/COMPANIES

Aeras Global TB Vaccine Foundation (Private non-profit organisation)

EDCTP could play a major role in coordinating efforts between major funders of clinical research for neglected diseases in order to promote efficiency and minimise duplication.

Expergen Drug Development GmbH (Austria)

Training of performing clinical trial according international guidelines which can be used for submission to international regulatory bodies.

Heliox Films (Private for-profit organisation, France)

Communication toward the citizens to make them understand where the money goes...

International Centre for Reproductive Health (Private non-profit organisation, Kenya)

Setting and promoting public-sector standards for ethics and research (GCP / GCLP) to avoid the current private-sector domination of expensive training courses; improving transparency of national IRB procedures; improving guaranteed throughput of national ERC/IRB processes; stopping funding for groups that are competing rather than collaborating on a local level; initiative to foster hybrid-funded (US-EU, public-private trusts) projects or research platforms; etc.

Istituto di Management Sanitario (IMS) (Private for-profit organisation, Italy)

Exchange of technologies and innovative tools (low cost and great impact) in the health field.

MRC Clinical Trials Unit HIV Senior Scientists (Public organisation, UK)

High level support for the continuation of EDCTP funding of HIV/AIDS, malaria, and TB CTs. High level support for the continuation of EDCTP funding of strengthening of African capacity to undertake clinical trials. High level support for the continuation of EDCTP funding for North-South and South-South networking; North-North networking less important. High level support for fundraising by EDCTP, and for advocacy by groups in global South but little point trying to raise money in the global South.

Assuming Governance structure refers to regulatory and ethics, the former is best tackled by WHO, and ideally ethics and regulatory strengthening would be carried out together under a normative agency umbrella rather than a donor, so low level support.

What is meant by "communications"?

Stellenbosch University (Higher Education Establishment, South Africa)

Grant writing; Publishing.

Training and Resources in Research Ethics Evaluation (TRREE) (Switzerland)

Strengthening ethical review capacity in collaboration with the research ethics committees and the national regulatory authorities networking and coordination of training programs in research ethics and GCP.

University Cheikh Anta DIOP of Dakar (Higher education establishment, Senegal)

1. Strengthening Health Research systems; 2. Increasing building facilities, equipment of low equipped African research institutions; 3. Strengthening human capacities.

THE VIEW OF PUBLIC AUTHORITIES

Bundesministerium für Bildung und Forschung (Centralised authority, Germany)

Cooperation with similar international initiatives (PPPs, PDPs).

Harry van Schooten (Netherlands)

Linking with national health systems strengthening policies broadening the scope to include other neglected diseases.

Ministry of Foreign Affairs (Netherlands)

Strengthen collaboration with other initiatives that meet EDCTP objectives (ie PDPs, WHO capacity building etc). Research and training to support implementation of new products (registration and access).

Netherlands Vaccine Institute (Centralised Authority, Netherlands)

Develop strong liaisons with the other EU-EEIG on vaccines: EVI-EEIG (Heidelberg).

Question B5. Research priorities

The current EDCTP is focused on the three major poverty related diseases: HIV/AIDS, malaria and tuberculosis.

If a new EDCTP initiative were to be extended to new areas of research which one of the following areas should be prioritized: Basic research, Public health interventions, other areas (if so please specify).

PERSONAL OPINIONS

Adrian Llerena

Depression and other relevant chronic diseases.

Andreas Holtel

Baseline epidemiological studies to prepare clinical study sites; expand to other neglected diseases pertinent to Africa; expand to implementation research.

Bankole Marian

The area of brain science should also be looked into as it is fast becoming an important area of research that researchers have neglected. Neuroscience is actually supposed to be an integral part of all diseases, and so attention should be given for research in this field.

Bankole Munir Akinwale

1. Hepatitis B virus infection should be included, based on increasing rate of deaths associated with HBV infection. 2. Toxic adverse reaction study of drugs should also be included. 3. More research efforts in to clinically viable antimicrobial and antiviral herbs with low or without toxic impacts on the subjects should be encouraged. 4. EDCTP should encourage researches into anti-viral and antimicrobial herbs with very great prospects especially in Africa.

Bernard Mulligan

Possibly look at neglected infectious diseases.

Bernhards Ogutu Ragama

There should be some support for non-communicable diseases as well in Africa because they are also becoming a major cause of morbidity and mortality. Emphasis should be placed in training with Africa by supporting African training institution to increase s-s collaboration and limit s-n brain drain.

Brian Greenwood

A renewed EDCTP needs to consider whether to extend its CTs activities into areas beyond the three infections currently covered, for example into trials on treatment or prevention of pneumonia or diarrhoea, bigger killers than malaria. Such a move would have benefits and drawbacks. It could enhance support for the control of infectious diseases other than the big three which receive a lot of attention from others, but would have the danger of leading to a loss of focus.

David Hendrickx

I believe the EDCTP currently has an important opportunity to broaden the scope of its activities. Especially the inclusion of neglected infectious diseases would signify an important, and logical, step forward.

Derrick Elemu

I also feel that the EDCTP should focus more on the social aspects that would hinder and/or facilitate effectiveness in clinical trials. As a researcher with a social science background, I believe clinical trials cannot be efficiently and effectively conducted without taking into consideration the socio-economic and political contexts of the settings within which clinical trials are undertaken. Thus, elevating the role of social scientists in the EDCTP is very critical to successful clinical trials, especially in the developing world were cultural specificities are important.

Erasto Vitus Mbugi

More research on nutrition and malaria immunity.

Francine Matthys

Neglected diseases in general.

Janneke van de Wijgert

I agree that the new EDCTP initiative should investigate other infectious diseases in addition to HIV, malaria and TB but only when these diseases are a burden in Africa (or in the larger geographical areas of interest) It is difficult to find funding elsewhere to tackle these diseases or develop these public health products. This would include diseases/products in which the pharmaceutical industry does not sufficiently invest, and diseases/products that are less important to resource-rich governments (for example, because the threat posed by these diseases is much lower in their own populations than in Africa). For example, I would encourage EDCTP to invest in vaccine development for herpes simplex type 2 virus (little investment by industry and by resource-rich governments, but a very important enabler of the HIV pandemic in Africa) but I would not encourage EDCTP to invest in research related to Swine/Mexican flu (sufficient investment by industry and resource-rich governments).

Joyce Ikingura

Research and training activities to support ethical review and strengthening ethics review committees (institutional, national and private).

Julius Atashili

Research on opportunistic affections (including cancers). Preclinical research that could lead to drug/vaccine discovery. Increasing access particularly in terms of internet connectivity.

Lênia Ribeiro de Souza Vieira

Research priorities: HIV/AIDS, malaria, TB, dengue, influenza, and contamination diseases from heavy metals, hormones, floods, landfills and mining activities in the water, soil and air.

Environmental sanitation; environmental epidemiology; public health; environmental health and environmental biotechnology.

Pauline Mwinzi

To include support to neglected tropical diseases which are also diseases of poverty, affecting the most marginalized of populations in Africa.

Peter Heering

Non communicable diseases in changing societies.

Raffaella Ravinetto

Even if there is strong emphasis in the media on HIV, malaria and TB, the EDCTP should strive to address the unmet needs in the field of public health oriented clinical research for vulnerable populations. In this sense, the EDCTP should include in its portfolio also CTs aimed at finding new therapeutic strategies for neglected disease (e.g., leishmaniasis, African Human Trypanosomiasis, elminthiasis). If a geographical expansion is foreseen, based on the vulnerability of populations, than American human trypanosomiasis could also be included.

Robert Colebunders

Job is not done therefore continue to work on the 3 main diseases, however treatment of HIV co-infections (HBV and HCV infections), opportunistic infections, co-infections with neglected diseases and HIV related malignancies should be included.

Stafford N. Kibona

I think neglected tropical diseases should be considered.

Tirt Dorel Petru

Strengthening public health in Europe and Africa evaluating therapy for non communicable diseases in Europe.

Verhelst Rita

Research and training activities to support Helminth clinical trials.

Werner Christie

Orphan diseases; simple personal and medical measures related to early childhood mortality and development.

William Campbell

Specifically in cancer, more important than infectious diseases.

Willem Hanekom

About the current research focus, take cognisance of the fact that, world-wide, 5c is spent on TB research for each dollar spent on HIV research - so, it may not be equitable to assign the same amount of money to each of the big 3 diseases.

Anonymous

The support to clinical research capacity should be generic, and broaden up to diseases other than AIDS, TB, Malaria. In particular, neglected tropical diseases being a high burden in Africa, should be part of the scope of EDCTP. It doesn't make sense to address the need for CT capacity in isolation.

Anonymous

Why concentrate so rigidly on the three big diseases? There are many other important problems. And why focus only on disease-targeted interventions? Other more general interventions may increase resistance towards the diseases (nutrition, unrelated vaccines and other immuno-modulating interventions).

Anonymous

Focus more on research methodologies so that irrespective of disease areas, trials can be conducted to address any relevant local problem.

Anonymous

Epidemiology.

Anonymous

Strong emphasis on integration of social science research into clinical trials urgently needed.

Anonymous

The focus for the EDCTP should be on moving products to efficacy trials. The smallest efficacy trials possible are most important. Post license this infrastructure is not as critical as it is early in the program and we have no viable candidates, so phase IV is not a good investment. Also getting new viable candidates tested is important but only with true guidelines and no-go parameters in place based on immune endpoints. More geographical regions should be considered based on positively helping with this task. To add sites at the expense of other sites would not be prudent. The EDCTP should not duplicate the work of other networks. Other diseases can be considered but HIV, Malaria and TB are a huge mouthful.

THE VIEW OF ORGANISATIONS/COMPANIES

AIDS Vaccine Advocacy Coalition (Private non-profit organisation)

Implementation or operations research to improve delivery of validated interventions to prevent or treat.

Drugs for Neglected Diseases initiative (Private non-profit organisation)

Expand the activities of the EDCTP to include other neglected diseases as well as other phases of clinical development (Phase I, Phase IV). Expansion of geographical scope i.e. Latin America for Chagas disease.

EDCTP constituency

Health service research.

Faculty of Pharmaceutical Medicine (Private non-profit organisation, UK)

The EDCTP should focus on key issues such as public health interventions rather than basic research. Greater focus on prioritised objectives is required to ensure crucial success factors are met. A broad spending approach may prevent clear progress across a range of projects.

Institut Pasteur (Private non-profit organisation, France)

Preclinical development.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

If EDCTP feels able to expand then there is some logic to expanding into the area of public health interventions but not bench to clinic research.

Novartis International AG (Private for-profit organisation)

General health education to combat local cultural misconceptions. HC infrastructure; logistics.

Oxfam (Private non-profit organisation, UK)

Expand to other diseases especially those prevalent in Africa i.e. sleeping sickness.

Special Programme for Research and Training in Tropical Diseases (TDR) (Public organisation)

Operational/implementation research.

THE VIEW OF PUBLIC AUTHORITIES

Department of International Development (Centralised Authority, UK)

Research priority: Social science should be included in all trials and EDCTP needs to find its own niche to add value and avoid duplication of other work funded by a range of different funding bodies/governments. For instance it may want to include health systems research relevant to the clinical trial areas - not starting up in other areas.

Public health interventions, implementation research, health systems research.

Netherlands Vaccine Institute (Centralised Authority, Netherlands)

Research priorities: new interventional methods and technologies are needed.

Pharmacy Department, Ministry of Health and Social Welfare (Centralised Authority, Zanzibar)

Research and training to support research on traditional medicine especially on HIV/AIDS.

Question D1. EDCTP future options

Four options can be envisaged for the future of the EDCTP programme:

Option A: "No European Union policy"

Option B: "Programme based"

Option C: "Business as usual"

Option D: "Expanded scope"

A different option: please specify in more detail.

PERSONAL OPINIONS

Andreas Holtel

Renew using art 185 but the EC needs to better and more intelligently design gradual progress towards co-funding by Member States' national programmes, not by a common pot (not realistic at this stage). Nor co-funding at project level (putting the burden to the applicants to get co-funding), but intelligent ways to first identify pertinent national programmes, then to make them converge to an EDCTP "template" programme, grant "EDCTP accreditation" of these EDCTP-pertinent national programmes etc, developing a gradual stepwise convergence of national programmes in this area towards the EDCTP Joint Programme. Not easy but a real task for the EC.

Irmgard Nippert

Option D without extension to other geographical areas.

Janneke van de Wijgert

My preferred option is option D "Expanded scope". (As in Option C, a new European Union decision establishes a successor programme to the EDCTP under the same terms. The successor takes account of the recommendations provided in the 2007 and 2009 evaluation reports. The scope of the programme is expanded to include some or all of the following (i) other diseases, ii) other stages of clinical trials, iii) other geographical areas.) I think that the EDCTP programme should continue, but that the co-funding requirements should be carefully reviewed and revised, and that expansion into Phase IV trials and other diseases should be considered (as explained above in more detail).

Anonymous

In my view, EDCTP programme needs firstly to consolidate before adopting any of the given options here. Option C seems to be the more realistic choice; however, with a strong emphasis in improving EDCTP management and the internal procedures so that the Secretariat can provide the highest performance for the future programme.

Anonymous

Direct involvement of the beneficiary members on a 50% basis of the composition of the EDCTP programme.

THE VIEW OF ORGANISATIONS/COMPANIES

Institut Pasteur (Private non-profit organisation, France)

We consider that it would be relevant to think of a different option than article 169/185 (e.g: incorporate EDCTP into FP8 regular programme).

Mbale Regional Referral Hospital Institutional Review Committee (Public organisation)

I strongly feel that the design of the programs and policies should involve consultations especially if these consultations could be in a consultative conference setting where each country in the sub Saharan Africa is represented by at least 3 representative categories: i) scientist (high level scientist, mid level career scientist and starting scientist); ii) politician and iii) academic. These categories should be matched with the same scope of categories from the EU zone.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

We have not checked the Article 185 terms. With this in mind, we believe our preference is for a different option. If the only way to ensure member state funding is for EDCTP to be linked to the EU, then we cannot vote for option A or B. However option C and D are not ideal (same terms), and we advocate strongly for the governance of EDCTP to be independent of EU bureaucracy, particularly with respect to the management of the awards. Phase IIb/III by definition encompasses product development which is subject to delays outside the scientists' control, and which require a flexible adaptive approach. Furthermore, the setting is African countries where the national laws are not driven by EU directives, and the infrastructure for approval of protocols and import of products lacks capacity and leads to delays that are also outside the control of researchers.

Resist-TB

EDCTP has proved a unique mechanism for improved coordination and effectiveness of, and capacity building for, clinical trials on HIV/AIDS, malaria and TB. It should definitely be continued. The expanded scope will allow the necessary inclusion of related types of research and geographical areas.

Special Programme for Research and Training in Tropical Diseases (TDR) (Public organisation)

Expanded scope. On Phase I, support only to capacity building.

The Pan African Clinical Trials Registry based at the South African Cochrane Centre, located at the South African Medical Research Council (Public Organisation, South Africa)

The second stage of EDCTP funding should be a consolidation phase of current projects and goals. At the end of the next phase, the expansion of the scope to other regions where resources are constrained should be considered.

The University of Oxford (Higher Education Establishment, UK)

EDCTP stands to now be a very effective organisation if some of the hurdles can be removed. The main limiting factors are the linking of capacity development to specific trials. In practice this means only experienced sites are applying for grants and these are those who are already well supported by the HIV, TB and malaria product development organisations. It is the sites that have no experience but a need and want to do research who cannot access training and skill development. There is also a great need for disease management studies, to explore better interventions to reduce maternal and neonate mortality for example. These types of studies are woefully under represented as sites do not have the skills to design and operate them. Running externally sponsored trials do not leave sites with the full skills they require – they merely learn how to run that specific study, this is very different. At the moment sites are ask to complete a capacity development section within each grant application and here sites enter activities such as distance learning MSc's, exchange visits and in-house GCP courses. All well and good but these will not fundamentally change capacity and so this need to be de-linked from specific studies.

THE VIEW OF PUBLIC AUTHORITIES

Bundesministerium für Bildung und Forschung (Centralised Authority, Germany)

Expanded scope but only in terms of other stages of clinical trials. Absolutely no other geographical area. Better no other diseases.

Department of International Development (Centralised Authority, UK)

A future EDCTP needs to have clearly defined boundaries in terms of geography, diseases covered, types of research and stages of clinical trials. It should aim to provide coverage where there are gaps - and not to duplicate the work of others. If necessary it should develop partnerships with other initiatives to make the best use of existing structures in developing countries to maximise investments and to provide better research career pathways in country.

EC to clarify the specific commitments, expectations and reporting requirements under A185/189.

Harry van Schooten (Netherlands)

An African owned and driven partnership with strong support from EU without too many bureaucratic procedures.

Medical Research Council (Non-Departmental Government Body, responsible to the government Department for Business, Innovation and Skills, UK)

The EC needs to clarify the specific commitments, expectations and reporting requirements under A185/189.

Netherlands Vaccine Institute (Public Authority, Netherlands)

Policy options: 1) Focus on Phase 1 support. 2) Include other vaccine preventable diseases with pandemic potentials, such as influenza 3) Expand to global geographic covering (all developing countries).

Norwegian Directorate of Health (Centralised authority, Norway)

Even though we ideally would like to widen the scope, (ref. our answer to B2 and B4) we believe that it is crucial to build a widening on a more solid structure than we see now. This is the reason why we have answered "Option C Business as usual" in D1.

Question E2. Collaboration with third parties

How should a new EDCTP initiative collaborate with third parties?

PERSONAL OPINIONS

Abraham S. Alabi

Through Memorandum of Understanding clearly stating the type of relationship in a mutually beneficial, and possibly complementary manner.

Alasan Jobe

Complementing EDCTP programmes, funding gaps and sharing relevant information. Strengthen partnership at all levels.

Andreas Holtel

With SMEs at project level - with large pharma at larger scope projects eg phase 4 studies or long term capacity building to prepare sites for trials in Africa undertaken by large pharma - global stakeholders like WHO, Gates etc, develop Memorandums of Understanding with concrete activities and definitions of cooperation (e.g.

mutual participation in external advisory boards, recruitment of experts from the respective together sides for evaluations, etc).

Aude Galli

EDCTP should closely work with development organisations too. There is a crucial and urgent need to strengthen the collaboration between development and research organizations, in order to identify research needs to scale-up malaria control and eradication, but also to speed up the delivery process. With the new WHO guidelines for malaria, EDCTP should also invest in research for rapid diagnostics test (RDT). Currently available RDT have some limitations. A second generation of RDTs, able to estimate also the parasite density, is needed for a more accurate diagnosis and treatment. Finally, EDCTP should not only improve coordination and networking between the European research organisations or with the south, but also with the US initiatives, or other non-EU based organisations to avoid duplication and ensure complementarity. For instance, EDCTP should work closely in the field of malaria with the Malaria Vaccine Initiative (MVI), but also with MMV, etc...

Bankole Munir Akinwale

1. To develop new drugs with great potential in tackling current disease burdens. 2. To seek support that will enhance research and discovery of new and active drugs. 3. To collaborate in the creation of adequate awareness on clinical trial issues in Africa. 4. To collaborate in the area of patenting a final approved drug(s).

Bernard Mulligan

Always according to real need rather than for "political" considerations (e.g. no rules such as "15% for SME").

Bernhards Ogutu Ragama

How this should be on a specific project depends on some leverage of resources they bring to the table.

Brian Greenwood

Collaborations with either large pharmaceuticals or other major funding bodies need to be set up in such a way that the EDCTP maintains its identity and has a strong voice in the direction of collaborative programmes.

Chemtai Kipkeu

Co-funding capacity development activities. Provide internships for developing scientists within these large companies given the value of industry experience.

David Hendrickx

Industry collaboration should be organised through mutually beneficial PPP-models. Collaboration with major funders is of importance, also to avoid fragmentation of available resources.

Davina Ghersi

The EDCTP should be about empowering individuals in low and middle income countries to do investigator-initiated clinical trials addressing locally relevant research questions. This is core to capacity building for clinical trials in African countries. Expanding to phase I and IV trials and working with large pharma is not going to achieve this as the sponsors will simply impose pre-designed studies on African investigators and will not contribute anything to capacity building in trial design or conduct.

Derrick Elemu

Of course, the EDCTP cannot function without sufficient funding. Thus, one line of collaboration would be in terms of funding from these third part collaborators. So, the third parties could be a huge source of funding for future EDCTP activities.

Dorothee Kinde-Gazard

Co-payment, coordination mechanism at country level.

Eftyhia Vardas

It shouldn't. By remaining independent and not associated with pharma/other funding bodies, decisions regarding funding allocation can be free of any potential biases, in particular with funding streams being allocated to the same recipients repeatedly.

Erasto Vitus Mbugi

Joint support for research in developing countries and evaluation of research outcomes from trials.

Eric Sandström

1. Participate in stakeholders meetings and other fora to formulate calls and co-fund of EDCTP calls relevant to their interest. 2. Use the EDCTP system to launch competitive calls for sites in EDCTP prioritized areas of their own research trials.

Feiko ter Kuile

In order to leverage additional funding.

Fisseha Haile Meskal

Involve relevant and interested sectors in other countries, - involve relevant UN organisations, - national governments should contribute to some extent.

Friedrich von Massow

To pave the way for successful collaboration with the support of other funding bodies; groups supporting the fight again the 3 pandemics; SMEs with strong R&D activities. Related with pandemics EDCTP should organize annual special seminars to improve EDCTP's contacts with such entities and to support establishment of R&D related links among these groups. This should take special account of reflecting experiences and expectations of people working in the field and help to improve the more bottom approach in R&D on pandemics.

George Blaskó

Many networks exist in Europe. Some of them are very suitable for this collaboration.

George Miiro

Representatives of pharmaceutical companies & international funding bodies should be included in the revised EDCTP structures and to be engaged in its communication, advocacy and fundraising initiatives. Because of mutual interests they should be engaged in joint programme planning around all phases of clinical trials. EDCTP may increase access to various potential well characterised cohorts whilst the third parties increase access to co-funding and to potential products or registered products in support of clinical trials. They should also be engaged in the development of acceptable intellectual property rights. They should be engaged in improving access to products by vulnerable communities in resource-limited settings. EDCTP can support

pharmaceutical companies in monitoring compliance to ethical standards for trials conducted by these companies whilst funds saved from use of costly CROs may be offered to EDCTP to conduct more CTs and training or other capacity building activities.

Godwin W. Nchinda

EDCTP should not fund projects already being funded by international bodies within specific areas. Right now most of the funded projects are concentrated with specific areas of Africa. There is need to fully utilized the potentials of every region within Africa.

Janneke van de Wijgert

I encourage collaboration between EDCTP and SMEs, large pharmaceutical/biotech companies, and international funding bodies. However, I think that these types of collaborations should not be mandated, and that the desired extent of collaboration should be reviewed for each type of project and subsequently announced in the request for proposals. While collaboration is important, networks with too many partners, or highly diverse partners (e.g. for profit and not for profit), can also be administratively and politically cumbersome. Furthermore, large pharmaceutical companies, PDPs, or funding bodies may dominate partnerships because they have the biggest budgets. Therefore, projects that are focused on building new research sites, strengthening existing research sites, or academic/leadership capacity-building of individual African investigators benefit most from very close interactions with just one or a limited number of (academic) partners (or in the case of leadership building – one-on-one mentoring). On the other hand, Phase III trials of experimental products would benefit from involvement of pharmaceutical industry and multiple financial donors; EDCTP funding alone would not be sufficient.

Jan A Verschoor

At least in South Africa, there exists separate national initiatives for Malaria, TB and HIV research. These are called Centres of Excellence or Centres of Competence. They represent the top research activities that happen in the country and may be collaborated with to get the best inputs for managing effective EDCTP research programmes.

Johanna Spreeuwenberg

Look at different models of Product Development Partnerships. What can be learned from them? What elements are relevant for EDCTP? The added value of third parties should be made explicit at the start and should be the subject of evaluations.

John R. Williams

Invite third parties to contribute to EDCTP.

Lênia Ribeiro de Souza Vieira

In developing countries by fostering international collaboration: scholarship research programs (calls, announcements, direct invitation via Curriculum, scientific collaboration) involving doctoral and postdoctoral students, senior and junior scientists in partnership with SMEs and universities, foundations, research centres (north-south networking).

Maria Sliwowska

Funding - cooperation in clinical trials conduct and advocating better clinical trials policies.

Maria Teresa Bejarano

Engaging medium enterprises so that they become interested in the diseases of low income countries and the bottlenecks that conducting research and clinical trials represent. With large biotech companies engaging in similar way and stimulating the cooperation for support and research on trials and diseases of the poor. The support does not need to be in funds but can be in kind and providing ways to scale up production of compounds found to be of interest. International funding bodies, strong advocacy for that one part of the funding goes to research activities. Harmonization with other global and international initiatives supporting research and clinical trials.

Martin Grobusch

This depends on the nature of individual calls. There is no 'one size fits all' solution to this.

Michael Hoelscher

Yes definitely. However EDCTP should try to make sure that it gets enough recognition and public awareness in those partnerships.

Mirabel Otuonye Ngozi

Individuals interested in grant application in relation to the products they want to research on should contact these third parties with support of EDCTP.

Mireille Tshiteya

New EDCTP initiative collaborates with the local clinical research organizations.

Muhammad Ali Dhansay

With clear terms of reference at the outset (e.g. what are the primary objectives?) Not profit for certain.

Nicholas White

EDCTP collaborations have often been considered a) highly political b) a bureaucratic nightmare c) forced by some a priori idea that they would be a good thing I think collaborations should not be imposed but should arise organically and be facilitated if scientifically justified.

Nosten

EDCTP should collaborate with third parties to establish priorities (based on science) and co-funding of projects.

Odor King

Very necessary to EDCTP programme activities especially in Africa.

Pablo Rojo

I think that the collaboration with international funding bodies should be very close and a high priority.

Paul Janiaud

SME is easy to introduce since some of them provide already new approaches, but SME should not be translated as CRO. Big pharmas could provide in kinds either work forces or products to be tested in the EDCTP areas and guarantee the furniture international agencies could make agreements to avoid wild concurrence, interfering clinical trials by changes of the biological background of the patients. There are

examples of providing vitamins or oligo-elements unknown by the EDCTP consortia members which could change effects of tested molecules.

Raffaella Ravinetto

To ensure sustainable funding for addressing all the unmet needs in poverty-related diseases is crucial. The EDCTP initiative should then try to ensure that each third party contribute to it, according to its own skills and specificities. The same applies to support to African research site, for structural upgrade (beyond the specific study budgets).

Renzo Pace Asciak

Here you need good governance so that SMEs and large pharma companies do not take over the leadership. The new programme should have a steering committee and also a 'third party' forum wherein the third party members have a say on how they can contribute towards the common good. However the steering committee should maintain leadership at all times.

Roger Tatoud

Large pharmaceutical/biotech/industrial companies and SMEs to provide new product and management expertise. International funding bodies to coordinate funding with EDCTP and financially support EDCTP programmes.

Rosemary M Musonda

This will depend on specific calls for certain trials that needs the involvement or support by the product developer or new technology or needs extra funding for trials that may be of interest for both parties. The international collaborator may pay for certain activities in accordance with their comparative advantage or pay for gaps in funding or provide technical support where needed etc, or sponsor a product for testing in multi centre trials or training depending on different circumstances and initiatives of teams and consortia for specific research studies or clinical trials.

Sam Mardell

Support for drugs use in the studies. Private sector support in increasing capacity to manage and operate clinical trials within African institutions.

Sarah Arbe-Barnes

Sharing of skills/expertise/experience between projects of same, and different areas of interest ie process improvement to ensure non-reinvention of "wheel" each time a different project comes along. Interaction with WHO to implement/advise on project implementation. Interact positively with industry to ensure industry-standards (GxP) are employed in all activities. Provide a positive forum for industry to become involved in trials in developing world.

Provide a framework for collaboration and interaction of PDPs, funding bodies, industry and other skills-based interested parties. Currently this is a seen as a "closed-shop" yet may advances and efficiencies could be made by broadening the scope of involvement from multiple skills, including IT, project management etc.

Stephen B. Kennedy

I strongly think that EDCTP should work independently of the international funding bodies, large pharmaceutical/biotech companies and small-medium enterprises. However, results should be shared to minimize duplications and funding of the same researchers from the same countries for similar work.

Wendy Burgers

Establish a link with bodies such as Gates Foundation and incorporate some of the "Grand Challenges" in EDCTP research activities.

Werner Christie

Public Private Partnership Models like StopTB, Gavi, Iavi etc, seems to fit this field fairly well, but can still be improved. Intellectual property issues needs to be solved in new ways with new mechanisms.

William Campbell

Individual contacts with physicians in the third world.

Anonymous

It is important at least to profile the funding opportunities made available by other major funders (e.g. US NIH and UK Welcome Trust) to avoid duplication of effort and identify key gaps in their funding opportunities for developing countries and design funding opportunities accordingly. EU Pharmaceutical entities could contribute to EDCTP funds as they will benefit from research and infrastructural capacity that is built in developing countries. This also creates EDCTP as a neutral conduit for those seeking research or capacity development funding who do not wish to be directly linked to pharmaceutical entities because of the perceived conflict of interest. EDCTP could thus collect member state contributions and pharma contributions. This would be a unique funding model.

Anonymous

All of current funding to develop capacity and R&D programs have no long term vision. Projects developed shut down once funding runs out. Getting governments to become partners who can add in advance funding which can sustain what is developed over a longer period e.g. 10 or 15 years is required to develop capacity. […] These investments have to be accounted for. Collaborations with industry or charity partners […] has resulted in slow progress with no deliverables in 4 years. […].

Anonymous

Agreements should ensure transparency of procedures protection of IPR and non-bias towards funding body especially commercialization of established products or procedures.

Anonymous

Avoid duplication and seek synergy, but also avoid dependency.

Anonymous

Involve third parties in policy and structure. Ensure third party structures and policies are in line with EDTCP systems.

Anonymous

To make sure there are no duplications and work is done more efficiently.

Anonymous

Without question. Especially to streamline its work and to prevent duplication. Also EDCTP should not set up a competitive situation with other organizations. Working together is important for conservation of resources. Also its mission should be to help advance products to efficacy if they meet rigid benchmarks.

Anonymous

For good interaction with third parties clear views and guidelines on how to deal with the IP rights are strongly required.

Anonymous

Focus should be on excellence of proposal. Forcing groups into artificial partnerships is very unhelpful.

Anonymous

On a case by case basis, depending on the protocol, disease etc.

Anonymous

To cooperate with other organisations and foundations (of similar characteristics).

THE VIEW OF ORGANISATIONS/COMPANIES

Aeras Global TB Vaccine Foundation (Private non-profit organisation)

EDCTP should seek out and build relationships with third parties across the globe, which have similar aims and objectives. EDCTP should work with these parties to ensure that important research and development initiatives are adequately funded.

Centre for Health Policy and Innovation (Public organisation)

Randomised controlled trials are registered at their inception (at the time of ethical approval and/or funding approval); Registered information should be potentially accessible to all interested parties; Registration should be with a register that complies with an appropriate minimum standard of practice; Prospective registration of trials should be part of ethical guidelines for clinical trials; Government agencies should ensure that adequate mechanisms and infrastructure are provided so that all randomised controlled trials can be registered prospectively; Government agencies should explore legislative and other strategies to mandate prospective registration as a condition of, for example, funding, ethics or regulatory approval.

Drugs for Neglected Diseases initiative (Private non-profit organisation)

To support clinical trials significant funding is needed and thus multiple sources of funds will be required. EDCTP should work with other donors to ensure cooperation and a division of labour for development and implementation of new products for neglected diseases.

EDCTP Constituency

By exploring areas of synergy and avoid duplication and competition.

Expergen Drug Development GmbH (Austria)

Giving SMEs a real chance to become a partner in projects.

Global Alliance for TB Drug Development (Private non-profit organisation)

Collaboration with a range of research entities will be needed to ensure a robust pipeline of candidates and a vibrant poverty-related disease product development sector. An efficient way for the EDCTP to partner with small and large research groups (public, private, and academic) as well as international funding bodies is through collaboration with Product Development Partnerships (PDPs). PDPs work with a range of public, private and not-for-profit research groups, matching capacity and expertise with coordination and funding, to manage the development of a portfolio of candidates. PDPs pursue only products that are suitable for developing country settings and negotiate agreements to ensure access to and affordability of the resulting technologies. Furthermore PDPs bring to bear the contributions of other public and philanthropic funders, as well as in-kind and cash contributions by the private sector, thereby leveraging the EDCTP's investment with other resources.

Faculty of Pharmaceutical Medicine (Private non-profit organisation, UK)

The EDCTP should proactively engage with external stakeholders such as the pharmaceutical industry to deliver maximum chance of successful outcomes. This is seen as critical if significant outcomes are to be realised.

Heliox Films (Private for profit organisation, France)

Think global but act local through SME's.

i-LSE GmbH Institute for Life Sciences and Development (Private for-profit organisation, Germany)

1. For preparing robust continuous contacts (a) to other funding bodies, (b) to pandemics oriented groups, and (c) to encouraging participation of pharma SME, an annual programme of regular seminars/meetings for and with members of such groups should be established and offered jointly by EDCTP and the respective group. Such joint activities of EDCTP and the above described a/b/c group (at least 1 event per group per year) will help e.g. to give practical support/advice or to continuously reflect support needs to new diseases/disease patterns as e.g. skin cancer.

2. It should be reflected to also include special cancer R&D, in particular skin, as skin cancer is expected to affect about 50% of mankind after 20-30 years from now.

3. The restricted geographical area Africa should be extended to SE-Asian states (particularly ASEAN members). This is to give way (like an open door) to establish special South-South R&D partnerships between African and SE Asian institutions/organisations. This will also help to create medium- or long-term development partnerships e.g. between more developed pharma SMEs of SE-Asian countries and clinical R&D partners from African countries, or things alike. However, the qualified involvement of or link up with an African partner should be a must. But no co-funding of proposals from SE-Asian bodies without support to the Africa-SE Asia partnership approach.

Instituto de Salud Carlos III (EDCTP Constituency, Spain)

To explore EDCTP participation in other international bodies' constituencies, while opening a new EDCTP Advisory Board to these bodies.

International Centre for Reproductive Health (Non-profit organisation, Kenya)

1. Joint programming with other international funding bodies to avoid overlaps and gaps in funding

2. Allow for any type of organizational setup of research networks as they actually exist; have full and transparent insight into these setups; apply funding where most useful.

3. Do not force scientific teams to form 'unnatural' networks in order to get approval and/or to qualify for funding. (in particular, do away with the notorious Euro-by-Euro matching requirement of the co-funding).

Istituto di Management Sanitario (IMS) (Private for profit organisation, Italy)

Collaboration should be based on technology transfer, i.e. third parties agree to transfer and share their technology in the South countries. Large pharmaceutical/biotech/industrial companies should co-finance projects without being financed, while SMEs should be financed in order to promote their participation.

Kilimanjaro Clinical Research Institute (Kcri) Kilimanjaro Christian Medical Center (Kcmc) Tumaini University (Private non-profit organisation, Tanzania)

EDCTP collaborate with third parties in find raising, scientific and technical issues, but without the third parties influencing on policy issues.

KNCV Tuberculosis Foundation (Private non-profit organisation, Netherlands)

Memorandums of Understanding, common goals, co-funding agreements, pre-marketing agreements.

Mbale Regional Referral Hospital Institutional Review Committee (Public organisation)

Bring them on board as sponsors with non-operational voting rights so that their economic contribution should not influence the running of EDCTP. Secondly they can decide on which programme/research theme they want their money to go to but should not decide which recipient or country. Again, this is to protect the integrity and autonomy of the EDCTP.

Medical Foundation Pneuma (Private non-profit organisation)

The third parties could be organisations promoting social policies related to fighting against HIV, TB, malaria. These diseases are also "social diseases", so combating them needs combating the social determinants, too (e.g. TB and smoking are "poverty diseases" with high prevalence in Africa and some MS of EU). A complex approach could be done by collaboration between WHO - FCTC - Bloomberg Initiative and EDCTP.

MRC Clinical Trials Unit HIV Senior Scientists (Public authority, UK)

We can’t envisage how a collaboration between EDCTP and SMEs or large pharmaceutical/biotech companies would work or be useful and recommend that efforts in this direction are driven and limited to the science i.e. after awards are made. Low level for both. We strongly recommend a high level of direct collaboration with other funding bodies to ensure that EDCTP adds value.

Novartis International AG (Private for-profit organisation)

More transparent coordination of programs and more opportunities for funding.

Oxfam UK (Private non-profit organisation, UK)

We propose tiers of engagement with other parties. Some possible engagement should include: (a) other governments to pool resources for clinical trials (e.g. US and other developing countries, consider a G20 initiative); (b) WHO and the IGWG process; (c) PDPs – especially if there is an expanded disease scope.

Resist-TB

It will be highly important for EDCTP to work closely with international funding bodies, as these are increasingly aware of the need for development and evaluation of new products and interventions for the three major poverty-related diseases. Their financial contributions could considerably increase EDCTP’s potential to

fund the larger and more expensive trials that will be needed, while EDCTP's mechanism for issuing calls and selecting applications can guarantee effective use of these contributions. In addition, EDCTP should work closely with the existing global disease control partnerships, such as the Stop TB Partnership. This can help better aligning EDCTP's programme priorities with the disease control and research priorities identified by these partnerships, and will furthermore help forging collaborations with international funding bodies. Close collaboration with pharmaceutical and biotech companies will be important since EDCTP can provide the funding for phase 2/3 trials of new drugs and diagnostics for diseases of poverty that would otherwise not be evaluated due to limited commercial potential. Potentially this could be relevant with regard to SME's as well.

Special Programme for Research and Training in Tropical Diseases (TDR) (Public organisation)

Clear memorandum of understanding between EDCTP and partners on project by project basis, guided by a set of mutually agreed guidelines.

Stellenbosch University (Higher Education Establishment, South Africa)

Co-funding of research.

Stop TB Partnership

It is extremely important for EDCTP to liaise with international funding bodies that are increasingly involved in the development and evaluation of new products and interventions against the three major poverty-related diseases. Since clinical trials for drugs and vaccines are increasingly based on multiple sites and their costs are increasing, it becomes more and more difficult for institutions to carry the burden of support of single large trials alone. Assembling with other institutional funding bodies would allow partnering to support major multicentre trials that are needed. In addition it is essential that EDCTP aligns with disease control and research priorities as being identified and developed by international institutions, so as to allow better harmonisation and avoiding funding gaps.

The Wellcome Trust (Private non-profit organisation, UK)

We consider 'international funding bodies' to mean the major global health non-governmental organisations, such as the Global Alliance for Vaccines and Immunisation (GAVI), and suggest that it is particularly important that EDCTP engages closely with these organisations. If the new EDCTP initiative is to collaborate with third parties, then more flexibility would be required than the present system, which has complex specific requirements for partners and funding. These current requirements can be difficult for third parties to work with. An informal network of funders with similar goals may be a more practical way to increase synergies and reduce duplication.

University Cheikh Anta DIOP of Dakar (Higher Education Establishment, Senegal)

Agreement based on programme from the start.

University of KwaZulu-Natal (Higher Education Establishment, South Africa)

Could check with other large funders (e.g. NIH, Wellcome) that funding calls do not overlap and that each offers unique opportunities.

THE VIEW OF PUBLIC AUTHORITIES

Bundesministerium für Bildung und Forschung (Centralised Authority, Germany)

By expanding or creating appropriate structures in the secretariat.

Department of International Development (Centralised Authority, UK)

Will depend on the individual circumstances - so under a broad strategic framework but with flexibility built in to the approach. The aim should be always to maximise the impact on reducing poverty.

Harry van Schooten (Netherlands)

Actively engaging with initiatives which are able to keep the pipeline filled on the one hand and with private sector partners to prepare actively for market uptake on the other hand.

Medical Research Council (Non-Departmental Government Body, responsible to the government Department for Business, Innovation and Skills, UK)

Strategically.

Ministry of Foreign Affairs, (Centralised Authority, Netherlands)

Collaboration with large pharma is necessary to ensure rapid upscaling of new inventions into clinical trials stage 3. This can be done by contracting those companies in an early stage, by ensuring that contracts respect the TRIPS agreement and all its flexibilities. PDPs have a lot of experience with this matter, EDCTP should learn from them. International funding bodies could perhaps be interested in co-funding part of research, particularly public health research (access issues). Moreover, organisations like the Global Fund could perhaps allow that part of the country funds are used for research purposes (as they do nowadays for health system strengthening and evaluations).

National Authority for Scientific Research (Centralised Authority, Romania)

Inviting third parties to participate and bring their contribution on their own expenses.

Netherlands Vaccine Institute (Public Authority, Netherlands)

Consider close collaboration with EEIG-EVI. Consider liaison with emerging vaccine manufacturers DCVMN as new third party.

Norwegian Directorate of Health (Centralised Authority, Norway)

Strengthen the secretariat with the needed skills to collaborate.

Uganda Virus Research Institute (UVRI) (Centralised Authority, Uganda)

1. Engage pharmaceutical companies to sponsor clinical trials by accessing their products/candidates. 2. These parties can fund trials through involvement in EDCTP governance structures and participation in fundraising initiatives of EDCTP. 3. These parties can sponsor capacity building initiatives through training of human resource, provision of laboratory or ICT equipment and other supplies. 4. Pharmaceutical companies can help guarantee availability/accessibility of efficacious products from EDCTP-site conducted trials.

6. GENERAL REMARKS AND WRITTEN SUBMISSIONS

The final section of the questionnaire (Section I: General Remarks) allowed the addition of general remarks.

Question I1. General remarks – Other suggestions/remarks

PERSONAL OPINION

Scientific Strategy

Bankole Munir Akinwale

1. EDCTP funding should be increased and its activities extended to include other African countries. 2. CTs should include other geographical regions especially Asia that have similar burdens with Africa. 3. Decision making on CTs should not be the exclusive rights of the funding countries or organisations, but to include extensive contributions of the region(s) where trials are held. 4. Issues concerning adverse reactions on trial subjects must be given serious priority.

David Hendrickx

Geographic scale up to include Latin America and Asia in the short term would be preferable, but only if it doesn't undermine the EDCTP's activities and its governance. Geographic expansion should in any case be an ambition.

Eric Sandström

The investment in EDCTP is just now starting to pay off, it is breaking new ground. Its activities in Africa have been very successful and it is now starting to be recognized as a major player. A continued support for the same structure is warranted. In addition, since sustainability is so vital for development the reputation of the EC is at stake as a committed partner if a continuation of EDCTP is not granted. In a future EDCTP it should be specified how and when decisions to continue that activity should be taken. The hiatus between the present EDCTP and a new one is damaging. Funds are grossly inadequate for phase III, registration, trials. The expansion of the scope should be limited. Since so much is invested in a specific set of individuals and institutions it is important to solidify that before moving into other geographic regions, while other diseases and stages in clinical trials can be considered.

Feiko ter Kuile

Research should be expanded to include Phase I and Phase IV trials, feasibility studies of interventions shown to be promising in Phase III trials, and to other geographical areas.

Friedrich von Massow

The restriction on the geographical area Africa should be extended and include SE-Asian, in particular ASEAN countries (but not India and China) to create a fruitful climate of South-South cooperation of these countries having similar problems but different strategies for problem solving. This approach should open the road for projects with special focus on SE-Asia but obligatory linked with an African partner showing similar regional conditions (and health problems). However, there should be no opportunity given for "only SE-Asian projects".

George Miiro

Whilst the expanded scope of EDCTP2 is so much desired, it is dependent (on) securing more financial commitment from EU member states and, other international funding bodies. Still major concerns about

expansion of the geographical scope in the context of limited funding and this could be considered later after securing adequate funds. Implementation and operational research are critical areas for expanding research priorities of EDCTP in order to improve utility of research findings; secure engagement of policy makers and development agencies.

Janneke van de Wijgert

I agree that the EDCTP initiative should be broadened to include Phase IV trials (to ensure that products that were shown to be efficacious are rolled out in public health programs and any obstacles can be removed), but I disagree that it should include Phase I trials, unless funding for those Phase I trials cannot be found from other sources. I think this for two reasons: 1) Funding for Phase II, III, and IV trials (of the types of interventions/products that EDCTP supports) is very difficult to get from other sources whereas funding for preclinical studies and Phase I trials can be obtained from the European Commission Framework programs, national governments and other sources. 2) EDCTP does not have the required expertise to properly review preclinical (basic science) studies and Phase I trials. This type of research requires a completely different skills set than the type of research that EDCTP has funded thus far. I personally think that it would be better to further strengthen EDCTP's capacity to review and monitor multi-country Phase II, III, and IV trials in the next five years, and to leave the basic science and Phase I trials to other funding organisations that already have this expertise.

Areas of geographical interest. I disagree that the new EDCTP initiative should expand to additional geographic areas, unless the total amount of resources available is significantly increased. Research sites that have already been established in Africa during the first five years of EDCTP need continued investment to survive. It would not make sense to build new sites in other parts of the world and reduce funding for the existing sites in Africa at the same time. Also, most of the countries with the highest burden of HIV and TB are in Africa.

Marceline Djuidje Ngounoue

The future proposal for a new EDCTP is well done. It will be really appreciable if other infectious diseases are targeted, phases I and II studies included as well, and of course, other geographic areas.

Nicholas White

Why is EDCTP confined to Africa? It only makes sense politically. There is no moral or scientific reason. Why is South Africa more in need of help that Laos or Myanmar? There is an implicit assumption that trials will lead to health benefits, but a bad trial is worse than useless. For example what is the point in conducting trials with drugs at the wrong doses? EDCTP should reconsider what it is trying to do and why it is trying to do it.

Nzokire Ivan Bushaija

EDCTP should try to raise funds to support the IT field in health sectors by proving IT scholarships like Bioinformatics, Health system study for people to improve on the IT knowledge.

Pablo Rojo

I believe that EDCTP is a great idea and it should keep its work. I believe that EDCTP should focus on Africa and on Malaria, HIV and TB.

Philippe Clevenbergh

Please open EDCTP programme to Asian countries where a large burden of the three diseases is also present.

Veronique Nintchom Penlap

Expansion to phases I and IV.

Willem Hanekom

The EDCTP has stimulated fantastic research. Congratulations! I think translational clinical research should remain the primary focus - and not social, basic science, or other research. This is because other major funding agencies often focus on other aspects of research - I think EDCTP has created a unique niche. Although I feel that other poverty-related diseases, and other geographic areas are important, realism is of utmost importance for success. Therefore, EDCTP should think very carefully before "diluting" into other research areas or geographic locations. I feel very strongly that terms such as "Centers of Excellence" should be avoided. The reason is that "excellence" is primarily a resource issue, and therefore within the relatively resource-poor African context very quickly becomes a term reflecting judgement: I think we wish to facilitate and enhance efforts, rather!

William Campbell

Latin America should participate in clinical trials mainly in cancer disease.

Management

Brian Greenwood

Anything that could be done to simplify the application and reporting procedures of the EDCTP would be a bonus. The complexity and detail currently required is a deterrent to application to the EDCTP by well qualified researchers who have other potential sources of funding. For many in this group, an EDCTP application is not the first choice for an interesting new proposal for these reasons.

Davina Ghersi

EDCTP governance must be a collaboration between the donor countries and the countries who could potentially benefit from the donation. It may not be the easy option but it is important that governance is a transparent collaboration. Clinical trials are expensive regardless of where they are conducted. EDCTP should not be trying to reduce the cost of trials, but should be working with countries to make sure trials are conducted with efficiency and in compliance with international standards.

George Miiro

EDCTP needs to simplify and minimise delays in reviewing and approving proposals and progress reports. Progress reports should also be requested from EDCTP projects annually rather than bi-annually. EDCTP also needs to offer more regular support supervision and guidance/nurturing to its projects such as the NoEs in order to proactively facilitate their progress and advice accordingly where challenges/obstacles may be encountered by projects. EDCTP needs to improve its information management through the website and a dedicated information management officer who can facilitate alerts on new information by contacting key contact persons of the different EDCTP projects.

Jan A Verschoor

Official rating of research outputs in respect of initial aims and expectations to be done and published in EDCTP Newsletter. This will sharpen the focus of what is expected of a research programme and how to proceed from published and final reports.

Roger Tatoud

Coordinated funding and lack therefore are serious issues. Complexity of the funding and in particular co-funding in kind is clearly not working. Current administrative micro-management of EDCTP grant is the main obstacle to relevant and productive clinical research.

Anonymous

Firstly, and as member of the 'Calls and Grants' team at EDCTP, I would like comment on question B.6 (Submission and Evaluation of Proposals) and to note that I 'partially' agree in the way the question has been worded. In general, the handling and evaluation of proposals as well as the monitoring of successful applications is very thorough. I however sympathise with the fact that the organisation adds in many occasions administrative bureaucracy to the evaluation process. Secondly, another aspect I would like to comment on it is the role of EDCTP Secretariat, which in my view, needs to be well defined and established in the new EDCTP initiative. EDCTP management team must highly improve in the future EDCTP initiative; must be solving-problem oriented; must promote a tight coordination within the teams as well as among the different departments; management must be operational and have a sound scientific experience in the research areas of interest for the organisation; it must perform with professionalism both internally and externally. And lastly, and to ensure the employees' rights the new EDCTP initiative must implement a true and independent Human Resources Department, where employees can consult and discuss personnel matters with freedom.

Anonymous

If all CTs to be performed in Africa on TB, HIV/AIDS and malaria are properly registered in a general accessible database before the start of the project, researchers of the EU MS and other African countries will be aware of other initiatives. Collaborations can and will be established on scientific level. Coordination of national programmes on this topic appeared to be very difficult.

Anonymous

There are several academics from Africa who have excelled in R&D and cap dev programs over the past 30 years and have been excluded from any EDCTP processes. These should be brought in to EDCTP committees enhance EDCTP activities. […] The EDCTP has funded inexperienced PIs in clinical trails […] on TB and thus the slow progress and no deliverables. The main flaw in the EDCTP is monitoring of financial investments and management, delivery of outputs (scientific and advocacy) and value impact of the investments. Many structures created by rushed funding will not deliver basically because of poor review processes and audit practices.

Anonymous

The major problems associated with the current EDCTP procedure and governance are: 1. Poor audit of funded activity. No visible outputs in terms of manuscripts or trial results have been seen since the EDCTP was founded in 2003. 250 million Euros invested and not one PhD or high impact factor journal paper produced. Are the monies being wasted by non-committed grant holders or is there a basic problem with selection and background check of academics who apply or is there a basic flaw in the review process with political criteria being applied rather than awarding the grants to the best qualified candidates? An independent audit will reveal all. 2. Too many cooks involve in the processes and the quality of peer review is extremely poor. 3. EDCTP admin are a nightmare. 4. Most PIs of grants have little experience of conducting multi-country research and are failing to manage multiple sites. […] Serious audits of currently funded activities will reveal irregularities and a proper accountability procedure must be in place.

Anonymous

I would like to comment that being EDCTP Secretariat an essential element of the EDCTP governance structure, it is crucial to invest more resources in order to ensure the implementation of a functional, competent and committed/dedicated EDCTP management body.

Anonymous

Developing capacity at administration and financial accountability, honesty and efficiency Most of the Africa programs have not yet been audited for their accounts and investment value in terms of deliverables. The academic outputs and training outputs of the EDCTP considering the 250 million euro spend are simply pathetic and unacceptable.

Anonymous

Proposals with the highest score do not get funded because of political reasons. Partnership Board members do not have much experience of doing the actual research and may have bias towards their own geographical area and ethnic proposals. Funding should be based on merit, not origin. Proposal application and review processes are basically flawed and reviews are very poor, contradicting each other.

Anonymous

Guidelines should be published on-line. Procedures should be fair and transparent ensuring equal opportunity for participation.

Anonymous

Quality assessment and quality control of implemented activities.

Anonymous

The EDCTP Secretariat needs to be sensitive to the needs and environments in developing country institutions.

Anonymous

Too many agendas and many sleeping EU partners. […] Main problem with current bureaucracy is that grants are awarded to those with no track record of experience in that area and much monies are wasted […] All investments must be monitored for deliverables. Budgetary audits should be mandatory and investment value of funds be monitored. 255million EUR invested by the EDCTP in 6 years and no visible academic or political relevant outputs seen. What a waste.

Funding

Abraham S. Alabi

I strongly think funding should be improved greatly above the current level; and may be in addition to increased funding by the EU, able African countries could be approached to also provide financial support. The current co-funding arrangement tends to promote historical/existing North-South partners (e.g. Sweden-Ethiopia or UK-Uganda) and given very limited chance to new entrants. Things should be better if co-funding is in a central pot with no strings attached. EDCTP in the next phase should also be more interested in product development.

Chiotan Domnica Ioana

Co-funding should not be limited to government money, only. Other donors should be involved in accepting projects performance-based.

Janneke van de Wijgert

Member State's commitments: I agree that each member state should make a formal commitment for a minimum annual payment throughout the life of the new EDCTP initiative. (This would be an ideal situation

but I am not sure if it is feasible, especially given the current economic situation in many European member states).

A single fund: I agree that a single fund for co-funding should be created to simplify and streamline co-funding. (Again, this would be an ideal situation, but it is unclear whether this is feasible). The current co-funding requirements need to be reviewed and revised because they are unrealistic, unfair, and cumbersome. It is unrealistic to think that individual investigators can mobilize large sums of funding within their own countries; investigators are almost always perceived as having conflicts of interest because they mostly lobby for their own areas of research. The current co-funding system is unfair because each member state has handled the EDCTP co-funding requirements differently, and individual investigators have no or very little influence in these processes. Some member states have pledged funding but have not followed through on their promises, others have never provided any co-funding, and yet others have given more than their fair share but via different mechanisms (direct funding to investigators, direct donations to EDCTP, etc.). Within networks of European and African investigators, those with the best access to co-funding often have more power within the network than those with poor access (which includes almost all of the African investigators). Finally, the system is cumbersome, as many EDCTP-funded investigators have indicated in the past.

Paul Janiaud

If possible common pot funding, guarantee for providing meds, vaccines on a sustainable option.

Rosemary M Musonda

There is a need for the European Member States to have a basket funding yearly for grants and we should do away with co-Funding that has been a problem.

Willem Hanekom

I strongly feel that the approach that investigators should look for co-funding from EU member states is entirely the wrong approach! Why not facilitate that investigators do what they do best - investigate, which includes writing the scientific part of the grant - that is already a mammoth task!! Do not put such additional burden on them - rather involve the right advocates or other specialists to deal with the money issues. This means - when you call for a grant application - state how much you will fund and that is that, without a requirement for co-funding.

Anonymous

Pooling with other funders to create funding which will sustain projects for longer periods.

Ethics and Intellectual Property Rights Policy

Davina Ghersi

Building capacity includes building capacity for ethical oversight, and I fail to see how a centralised EDCTP research ethics committee would help in this regard. It may help trial investigators but it won't help countries improve their oversight systems. If ethical review is a problem then I would suggest that EDCTP work with WHO, COHRED (and others) and the relevant ministries in countries to try to solve the problem.

Jan A Verschoor

On Intellectual Property Rights: once in a while there is an original idea coming from a developing country. If EDCTP could be very flexible in the definition of its IP property stance, then the particular developing country may benefit from its own invention. Often, however, the developing country does not know how to exploit its patent and can often not even afford to have it manifested beyond the nationalization stage. If IP rights are

rigorously allocated to the country where the research work/ invention was done, but with EDCTP given the first right of refusal to assist in its exploitation in return for its funding role, then I think justice is done, without dampening the innovation spirit of the researchers involved. I had no objections, however, to the way IP was handled before by EDCTP.

Janneke van de Wijgert

Ethics. I disagree that EDCTP should establish its own research ethics committee. EDCTP is to be commended for funding capacity strengthening of African ethics committees, and should continue this work. However, I think that each country should review its own research, and an EDCTP review can therefore not replace in-country reviews. Adding additional layers of review and approval would only make multi-country research more complex than it already is (it currently takes 6-12 months to get a multi-country study approved by all relevant ethics committees and, if applicable, national regulatory agencies). Finally, at the moment, EDCTP does not have the required capacity to provide the services that are proposed.

Raffaella Ravinetto

Ethical review of medical research cannot be taken away from the country responsible authority. Even if an IRB was created at the EDCTP, it should never lead to skipping the submission to the Ethics Committee and Competent Authorities in the host country.

Governance

Andreas Holtel

Evaluation should generally be overseen by Commission; if the same clients are in too many proposals, it's not a problem of guidelines but the way of phasing the calls which should encourage new applicants; phrasing the call texts should be more strongly overseen by EDCTP's and EU's governance bodies, as it's been misused by interested parties.

David Hendrickx

A strong governance structure which allows a broad input for researchers and policy makers from the South is important and should be consolidated in the 'new' EDCTP.

Janneke van de Wijgert

H. Governance structure H1. EDCTP governance, I think that European taxpayer money donated to EDCTP should be governed by European governments (as is the case in the EEIG), and that all grant-making decisions within EDCTP should be based on public health importance and scientific merit and not political motivations. The grant-making governance structure within EDCTP could be simplified by combining the Partnership Board with the DCCC, and ensuring that sufficient numbers of European and African scientists with the desired scientific/public health expertise are included in this revised structure. Simplification of the governance structure: high level of priority (5) Revision of the present legal structure to incorporate voting rights for African governments: low level of priority (1) Clarification of the political and financial mandate of General Assembly members: don't know; it is unclear to me what the current mandate of the GA members is. Restriction of decision-making to member states who provide financial or other resources: don't know; depends on which decision-making.

Lênia Ribeiro de Souza Vieira

The developing countries coordinating committee should have Latin America scientists. Revision of the present legal structure to incorporate voting rights for other developing countries government representatives such as Latin America (above suggestion).

Peter Heering

Transparency is a must.

Renzo Pace Asciak

Governance is extremely important. I must confess that I do not know exactly how decisions are taken. On one hand it is important for the Africans and other third world countries to be part of the decision making process as they certainly know what they need. However a correcting mechanism must be in place such that if funds are intended to be spent on other conditions/solutions that do not fall under the clearly defined objectives, then the Plenary Assembly can over-ride and correct the situation. Amongst all it should be legally fair and transparent, not too dominated by the EU and Member States but procedures are in place for over-riding actions should the situation be necessary.

Stephen B. Kennedy

Non-funding Member States could have voting rights. In such situations, they may be encouraged to provide future support after monitoring the EDCTP activities in Sub-Saharan Africa.

Anonymous

The secretariat needs to expand in order to be able to cope with the current and future workload. Any future EDCTP must have improved planning and strategy-making so that it is more proactive than reactive. The management team should also be strengthened.

Other suggestions/remarks

Abraham S. Alabi

As someone associated in one way or the other with the EDCTP from its inception, I will say it has achieved a lot of successes with the relatively short time and resources at its disposal - particularly in the areas of capacity building in sub-Saharan Africa, North-South and South-South collaborations. EDCTP has also been reviewed internally as well as externally, and I believe there are recommendations from these reviewers that EDCTP need to consider and apply in its next phase.

Alex Hakuzimana

I would suggest promoting research, run by freelance and individuals even not affiliated to any institution. This will ease the reach of remote areas and villages that might not have benefited of the bureaucracy and slow process.

Andreas Holtel

For new EDCTP - keep focus on Africa - expand to implementation research (how to best implement new interventions), include vector control trials (vector-borne diseases) - include epidemiological baseline studies of African sites (first step to prepare more sites for future clinical trials according to GMP/GLP), also contribution to capacity building - improve governance by more Commission involvement at all levels as long as most funds come from EU - DEV from Commission side an intelligent concept to stepwise come to joint programming: identify concrete MS programmes, develop EDCTP template programme, accredit MS programmes by EDCTP, have first only small amounts of regular MS payments to EDCTP, develop "light" co-funding mechanisms (eg MS investments under their EDCTP-"accredited" programmes are counted as co-funding etc). Stop co-funding at project level to be organised by applicants!

Asfaw Yared Merid

Generally, I highly appreciate the efforts made by EDCTP in the prevention and control of infectious disease. This has to be acknowledged by its partners and collaborators. Every effort has to be exerted to make EDCTP more efficient so as to play its role.

Bernard Mulligan

Nice questionnaire. A bit difficult to give a simple answer to some questions (e.g. the last ones on governance structure) without some detailed knowledge of how EDCTP works (e.g. do/will African counties put in cash or other contributions? Is there a level of contribution that gives voting rights now?).

Bernhards Ogutu Ragama

The expansion to other regions should be strategic on staggered. The leadership of EDCTP should remain neutral of the EU member states nationals to counteract perceived bias. More grants should not be linked to EU member states institutions.

Britta Wahren

A multitude of relations have been obtained both between European countries and African countries and a large number of projects have been started. The education and fellowship programs have been successful. Several clinical trials have been initiated and are successfully ongoing. This has created the beginning of an intercontinental collaboration that is unheard of for the world. After many years of upstart, the organisation can now effectively interlink projects, persons and countries It would be a waste of all the present links and work to change everything. Instead, continue to build on the capacity building efforts supporting clinical trials of the three major diseases. The diseases are still around!

Chemtai Kipkeu

Engagement with CRA organisations may be of benefit to provide training and support to African research. These services are only tasted by African researchers who are usually carrying out large regulated industry trials. Mandatory involvement of African scientists in DSMBs in EDCTP supported trials to further develop them.

Comaritan Costa

Its very interesting your proposal but not completely too understanding. Thanks.

Daniele Dionisio

Ideally, a future proposal for a new EDCTP should be equipped to tackle the evolutionary directions from emerging markets, while bringing opportunities to all concerned parties. Aside from support to domestic employment, market increase and effective response to resistance mutations of pathogens in the low-income countries, it should boost and improve: For-equity dynamics in trading policies facing brand and generic drug manufacturers. This model should allow the brand name pharmaceutical companies to keep R&D standards and marketing power, while taking advantage of new partnerships. In the perspective of the generic pharmaceutical industry, instead, this model should streamline innovation, South-South and North-South ventures as a premise to enhanced competitiveness beyond the under-served markets. Manufacturers' incentives to supply appropriate streams of reliable drugs. R&D and international level high-tech plans. Opportunities for researchers working in the developing countries. Strengthened capacity to generate, manage and use technology to address domestic health needs in the developing countries. Setting of high-level, country-owned plants for TB, malaria and HIV medicines in Sub-Saharan Africa. In a word, this model should be up to promoting a free and equitably driven world market, while helping scale up long-term access to appropriate and affordable medicine formulations, with no discrimination between end-users in wealthy and resource-limited countries.

Derrick Elemu

I just want to appreciate the work of the EDCTP. I have participated in the last two EDCTP Forums in Ouagadogou and Arusha. The knowledge and experience sharing that goes with these Fora is just irreplaceable. It is from this background that I feel the work of the EDCTP must continue and even enhanced through increased funding. All the best as you finalise these activities.

Dorothee Kinde-Gazard

The African researcher cannot produce good proposal for funding. It is important to develop training for young researchers and to establish ethic committee in some countries.

Feiko ter Kuile

After a 'false' start EDCTP has been able to make an excellent contribution to malaria, TB and HIV research. More flexibility between funding categories within programme grants, and more funding for capacity building including MSc and PhD training fellowships is needed.

Janiaud Paul

Time was lost because of lack of clarity, lack of engagement of governments, the epidemics are running , it is urgent to start with new binding rules for co-funding, for inclusion of other sources of funds. It is also urgent to act on capacity building for organising clinical trials, with avoiding double standards, by facilitating adaptation for ex of ethical rules (consent with somebody neutral to testify in case of chief of village consenting for the village). The inclusion of African representatives in the ethical board of EDCTP may be a good step. A better connection for incorporation of fundamental research results by better communication of the objectives, bottlenecks of EDCTP in direction of the scientific communities is an important step to provide.

If all the targeted objectives are fulfilled this would be a gigantic achievement.

Jean-René Kiechel

An expanded EDCTP would be very valuable. The European community as an entity needs to participate to the health improvement efforts of other states in the world. This can only be of benefit for both the countries needing development and the ones more advanced in their health system and research. Europe should also assure its active participation.

Johanna Spreeuwenberg

The European Commission should be much more active in championing the EDCTP and take more initiative.

Jonathan Kayondo

EDCTP has the potential to become a truly successful and model partnership. It is willing to consider interests of developing countries as articulated from their point of views, and this is remarkable and should be encouraged.

John R. Williams

In my experience EDCTP has supported some very good projects. It is essential that the program be continued in some form, and even expanded. As is evident in the evaluation, capacity-building in ethics is a very important objective and must be incorporated in future initiatives.

George Blaskó

I think that an instrumentation network is necessary to set-up in Africa on regional basis. This network should facilitate the initiation and setting-up clinical programmes in the 3 area being investigated. I would like to suggest to overview the mission statement of ECRIN (European Clinical Research Instrumentation Network) and an African analogue should be initiated.

Marceline Djuidje Ngounoue

Thank you for that very good job. May the new EDCTP be the real success, tremendous, capacity building, networking, the best research policy and funding.

Marcel Reyners

Thanks for the opportunity to participate in this evaluation. During two years I was closely involved in several research projects sponsored by the EDCTP (microbicides capacity building; biomarkers study) and highly appreciate what the program was contributing to contain the AIDS pandemic. I also want to mention the flexibility EDCTP managers (in Amsterdam) showed to adjust activities in the course of the project. Well done!!

Millen Ringo

Nurses make a great contribution in EDCTP but don't get the recognition and empowerment to take greater roles and activities. This should be reviewed.

Mirabel Otuonye Ngozi

So far you have done well and have archived a lot in terms of health research particularly admitting younger people on board. However, with few adjustments here and there, we will be looking forward to an improvement in more research options and conditions.

Muhammad Ali Dhansay

I wish to commend the EDCTP for having had evaluations in 2007 and 2009. The programme is relatively 'young', but has gone a long way. The current public consultation is also to be commended. I trust that the response from all players, especially in the developing countries, will be overwhelming. Looking forward to the extension of EDCTP1 to 2013, and to EDCTP2. I'm glad the question of ethics and affordability of the resultant products from the trials (IPR -related) have been flagged. These are critical issues in the context of Africa.

Nicholas White

EDCTP needs to change. It should be needs-directed, equitable, non-discriminating, flexible, pragmatic and as independent of the vested interests of European Institutions as possible.

Philippe Eugène Ngaunji

I really appreciate the commitment of EU in fighting alongside African countries against poverty by focusing on endemic diseases as Malaria, tuberculosis and AIDS. I strongly encourage European researchers to cooperate directly with African scientist during the whole process of research not only collecting data to transfer in Europe for computation. If there are not good software in Africa and skills personnel to correctly handle the statistic, there is a strong benefit to build their capacity by acquainting them with this exercise. Subjects to be studied could be proposed by both partners since the diseases are in Africa and the scientific knowledge is from the north.

Raffaella Ravinetto

Most clinical research sites in Africa are able to provide clinical sites, clinical investigators and study subjects, but they cannot yet assume sponsorship of CTs, because they lack structural resources (e.g. regulatory affairs, pharmaco-vigilance, data management and statistics unit, possibility to make a no fault liability insurance in the country etc.). If the EDCTP wishes to transfer the capacity not only to carry out, but also to lead clinical research, the possibility to fund structural costs for some research sites overseas should be considered.

Rosemary M Musonda

The EDCTP has generally performed very well and has really raised the bar high in capacity building and visibility of African scientists to conducts trials and training for new fellow at PhD and Master Degree level. It is hoped that the programme should continue with an improved European support and more African countries to participate.

Vasee Moorthy

Facilitate information sharing between African HIV, malaria and TB clinical trial activities to maximise synergies and reduce inefficiencies.

Veronique Nintchom Penlap

Stronger support for ERC and EC; Fixed national financial contribution.

Werner Christie

None specific.

Anonymous

EDCTP to date has provided a very valuable suite of funding opportunities for health researchers and academics in Africa that fill some of the gaps left by other major funders (US NIH and UK Wellcome Trust) and should continue to do so. It is sincerely hoped that this initiative will continue to exist and expand its mandate in consultation with stakeholder groups.

Anonymous

Current structure is much too complicated and discourages applications from potentially strong proposals. The primary consideration should be excellent science and potential for impact on public health. Forcing partnerships simply for the sake of an application is unhelpful. EDCTP has gained a very poor reputation for these and other reasons.

Anonymous

EDCTP is one of the best funding organisations in African Research. Please do not make unnecessary changes that will make it a restrictive bogus organisation like others on the continent who just want to get samples from African volunteers; and then take back to developed countries for further advanced work. Thank you so much for all that you have done these past three years. Let's pray we all keep on track. Imagine a world without HIV/ TB/Malaria.

Anonymous

This is a very 'factual' consultation.

Anonymous

The data gathered should be given priority in decision making if the new EDCTP initiative is to reflect participatory planning and implementation of programmes research activities especially in the developing world Africa inclusive.

Anonymous

The EDCTP should not have mixed goals. The number one goal is to set up a network and two move products through the network that are worthy of testing in the area of HIV, Malaria and TB; other goals should be way second. There should be little to no discussion of how expensive a final vaccine product would be if it is successful as history has taught us if you make it then we (the world) find a way to distribute it. Do not confuse the baby with the bathwater. Get a product that works first and then work to provide complete access.

Anonymous

EDCTP is a failure. It has not resulted in any significant progress in the field of malaria or TB. It is discriminatory because it only spends funds in Africa neglecting the majority of the world population, and it is responsible for the terrible inflation in the cost of trials. It should be driven by science and not by politics as it is now; at present it is a waste of public money.

THE VIEW OF ORGANISATIONS/COMPANIES

Scientific Strategy

Academy of Medical Sciences (Private non-profit organisation, UK)

Of particular importance will be downstream research such as public health interventions, phase IV trials, operational studies and investigations into the better use of existing treatments. While recognising the need to maintain focus, a new EDCTP should consider broadening its remit to cover more of the diseases that disproportionally affect the world's poorest people (such as pneumonia and diarrhoea) and geographical areas that experience significant poverty-related disease (such as Bangladesh, Cambodia or Laos) in addition to Sub-Saharan Africa.

Aeras Global TB Vaccine Foundation (Private non-profit organisation)

Regarding the questions related to expansion of scope and program activities, it is difficult to address these questions without knowing if funding levels are expected to be maintained at current levels or increased. For the purpose of this survey, those questions have been answered based on current and previous funding levels. Existing funding levels are not sufficient to expand the scope of activities. However, should there be a substantial increase in funding, we would support such an expansion.

Drugs for Neglected Diseases initiative (Private non-profit organisation)

Expand the activities of the EDCTP to include other neglected diseases such as Chagas disease, leishmaniasis, human African trypanosomiasis, helminths... Expansion of the scope of diseases will require expansion of geographic areas in some cases, ie Chagas disease to Latin America Expand the activities to other phases of clinical development (Phase I, Phase IV) with the priority to phase I trials. Strengthening sustainable research capacity in disease endemic regions through networking and collaborative projects Strengthen regulatory bodies in disease endemic countries, i.e. fund centres of regulatory excellence in each Africa main sub-regions.

Global Alliance for TB Drug Development (TB Alliance) (Private non-profit organisation)

The new EDCTP mechanism should not expand its priorities beyond CTs and capacity building. Expanded focus would dilute EDCTP resources in an area where funding is critically needed. Many products are in or approaching CTs and late-stage clinical research is not adequately addressed by existing funding sources. EDCTP involvement in CTs is critically needed to ensure that investments in product development made to date yield products that can be accessed by people in developing countries.

Global Alliance for TB Drug Development (TB Alliance) (Public non-profit organisation)

The scope of EDCTP's successor should be expanded to include new geographic areas. Large-scale registration-standard CTs will require considerable capacity, which at present, cannot be entirely met within the geographic boundaries of Africa. Additionally, for registration and uptake, many countries require trials in their own populations, necessitating an approach to clinical testing that includes patients from a range of geographies. Other epidemiologically important regions are excluded from the current scope of the EDCTP mechanism, for example, Asia. In this region, India and China comprise approximately 50% of the burden of tuberculosis and require testing in domestic populations as a condition for domestic registration of new TB drugs. The EDCTP's current focus on Africa alone limits its ability to be relevant to the global TB epidemic and the trials that are necessary to ensure registration and use of new products in developing countries most affected by the epidemic. Support outside of Africa will also accelerate the pace of research, hastening registration and adoption in Africa.

Instituto de Salud Carlos III (EDCTP Constituency, Spain)

We strongly agree with EDCTP performing phase IV trails but not phase I.

MRC Clinical Trials Unit HIV Senior Scientists (Public organisation, UK)

Phases of clinical trials. We disagree about expansion to Phase I as EDCTP is not well placed

to review Phase I trials of new products as expertise in biology, toxicology immunology etc is

required. Phase I pharmaco-kinetics could complement the current programme. Furthermore,

there are several sources of funding for Phase I.

We did not agree on a common definition of Phase IV. If Phase IV is implementation and health systems strengthening we would be cautious about recommending an expansion into this area. However, if Phase IV includes strategic trials of licensed drugs to assess individual benefit, and pre-licensed trials of new technologies to determine how they should be introduced, we agree would be a natural expansion for EDCTP and ensure that products shown to be effective in Phase IIb/III were rolled out. Late development trials are more costly and there are less sources of funding to call on, so EDCTP's role is critical in this area.

Areas of geographical interest. We disagree that EDCTP should expand the regional focus beyond Africa as this is where the gap between the burden of disease from HIV, TB and malaria and the capacity to deal with it is greatest. In addition, it is important that the infrastructure and reputation that EDCTP has already built in this region is sustained. We can assume in the current economic climate that there are no plans for a substantial increase in investment in the EDCTP management structure and so expanding to other regions would considerably dilute the ability of EDCTP to maintain their presence in Africa.

Disease scope. For similar reasons we disagree about an expansion to other disease areas. However, some diseases such as sepsis in children are strongly linked to HIV and it makes sense to accommodate these especially where the main pathology for the presentation cannot be clearly identified. Another justification for inclusion is when the disease in question is of little interest to the pharmaceutical companies/donors in the global north and a burden in Africa.

Novartis International AG (Private for-profit organisation)

Many pharma companies run development programs for neglected diseases through not for profit institutes. EDCTP should work on cooperating effectively with these institutions.

Expansions in either geography or disease are a focus should not result in dilution of ongoing focus. Can only be undertaken when funds are increased or selected activities are de- prioritized.

Resist-TB

CTs in phase I and phase IV. Yes, but this should not take away resources from the current focus.

Additional geographic areas. Increasingly clinical trials are needed, for example for MDR- and XDR-TB, that cover various epidemiological settings and require multiple sites.

Other infectious diseases in addition to the three PRDs. Broadening the disease scope runs the risk of diluting already scarce resources needed to address the three major poverty related diseases.

Solvo Biotechnology (Private for-profit organisation)

Decrease the support for HIV/AIDS and TB to level 3 (because there are HIV and TB patients in the developed countries as well), but extend the focus on the neglected diseases.

Stellenbosch University (Higher Education Establishment, South Africa)

Extend mandate to include all poverty-related diseases.

Stop TB Partnership

As a major institution supporting the conduct of Phase II and III clinical trials, EDCTP could extend its activities to support Phase IV trials and impact evaluation studies.

There has been a wide development in new drugs, vaccines and diagnostics for TB over the last ten years, and there is now an increasing demand on potential CT sites to test the new control tools, that relate to the specific aspects of drug-susceptible (DS) TB, drug-resistant (DR) TB and HIV associated TB. Due to methodological issues, most of the trials for treatment or prevention of DS and DR-TB have to be conducted in multiple sites, that respond to GCP and GLP international standards. In this, the work carried out by EDCTP over its first mandate is of prior importance and should be pursued and reinforced. It should also be harmonised with other efforts being carried out by international or national funding institutions that support site capacity development and/or support clinical trials. There is an increasing need for harmonisation and rationalisation on the demands on trial sites so as to assemble efforts and avoid duplication, and ensure best operationalisation. In this, collaboration with international funding bodies and major stakeholders involved in the control of TB worldwide (such as the Stop TB Partnership), is highly suitable.

MDR-TB treatment. Treatment of MDR-TB is very difficult due to the association of costly and highly toxic drugs given for a long duration (18 to 24 months). Conducting treatment trials to define optimal and simplified regimens to treat MDR-TB, including or not newly developed drugs, is a high priority. Such trials are difficult to conduct and request contribution of highly capable clinical trials sites with excellent laboratory capacity. EDCTP is extremely well placed to encourage capacity development of sites to conduct MDR-TB trials and issue calls for testing new shortened MDR-TB treatment trials, in association with other international funding bodies.

Joint treatment of TB and HIV. TB/HIV co-infection is a major challenge for TB control as HIV infection significantly increases the risk of developing active TB and combined treatment is hampered by severe drug-

drug interaction and risk of serious adverse events. In addition, under-resourced health systems are ill-equipped to provide the complex individualized care required for co-infected TB/HIV patients. Trials must be conducted to investigate the possibility to improve treatment of HIV infected TB patients efficiently including the use of newly developed TB drugs.

Treatment of paediatric TB infection. Children comprise up to 20% of TB incident cases in high-burden settings and have a higher risk of severe and rapidly progressive forms of TB such as disseminated disease and meningitis. However, evaluating anti-tuberculosis treatment in children is difficult. There is inadequate evidence to support dosing recommendations, but studies suggest that internationally recommended doses of first-line drugs result in suboptimal drug exposure. There is even less information to guide usage of second-line agents. Uncertainties about the safety of ethambutol and fluoroquinolones in children also limit their use. It is essential that paediatric drug formulations are developed to suit high-burden settings and specific studies are conducted to investigate the right dose in children.

Treatment of latent TB infection. About one-third of the world's population is infected by M. tuberculosis, which serves as a reservoir for active TB. The spread of HIV infection in many parts of the world is fuelling the TB epidemic. The objective of latent TB infection treatment is to prevent the development of TB disease in high-risk populations, such as contacts of infectious TB cases or HIV-positive patients. Isoniazid monotherapy can reduce the risk for the development of TB in contacts of infectious TB cases when taken for 6 to 9 months but there is limited information on its long-term impact. Shorter, simpler, and safe therapies against latent TB infection are needed to allow for an efficient control of TB transmission in addition to vaccination.

The University of Oxford (Higher Education Establishment, UK)

The EDCTP should focus on strengthening capacity for CTs and not be diluted to support basic research or public health/implementation research. EDCTP now has strong leadership and experienced staff and it should focus on the task of developing skills for researchers based in resource poor setting to enable them to design and manage their own trial programmes.

The Wellcome Trust (Private non-profit organisation, UK)

We are pleased to have the opportunity to respond to this consultation on the EDCTP, having contributed funding as a third party under the current scheme. We would be happy to discuss any of these points in further detail. We suggest that it is particularly important that any new EDCTP initiative engages closely with major global health non-governmental organisations, such as GAVI. We would envisage any additional costs of expansion of the geographical and disease scope of EDCTP being met through closer partnerships with these organisations.

Management

Drugs for Neglected Diseases initiative (Private non-profit organisation)

Publish revised procedural guidelines to ensure clarity of regulations.

Faculty of Pharmaceutical Medicine (Private non-profit organisation, UK)

Greater transparency on spending outcomes and measureable objectives are required to enable project progression. A review of funding outcomes from the previous five years should be performed in-order to assess the objectives and inform the EDCTP moving forward.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

We strongly agree that the new EDCTP initiative should review the way it handles proposals and publish the revised procedural guidelines on its website. The independent scientific reviews have improved over the course

of EDCTP, but it's not always clear that the subsequent layers of review pay attention to the independent reviews or offer a truly independent opinion, and at times the final review reflects a lack of knowledge of international standards for conducting clinical trials.

We suspect that the reason there are researchers involved in multiple projects is two-fold. Firstly there are a limited number of individuals working in these disease areas, and secondly the ones that survive with infrastructure intact in between the large clinical trials can only do so because they are involved in multiple projects. The best route for institutions and new researchers in the global south to get involved in research is to partner with institutions that have an established track record.

Resist-TB

Reviewing application procedures after the first 7 years seems sensible. However, broad consultation would be required.

The Wellcome Trust (Private non-profit organisation, UK)

Please note that we are unable to comment on the handling of proposals to EDCTP because we are not familiar with the submission or evaluation process.

University Cheikh Anta DIOP, Dakar (Higher Education Establishment, Senegal)

Strengthening Africa Office by recruiting more projects officers. Delocalising the gestion of projects to the Africa Office.

University of KwaZulu-Natal (Higher Education Establishment, South Africa)

EDCTP provides excellent opportunities. Grant governance structures are relatively inflexible and could be loosened up a bit - e.g. allow some % deviation in budget line items at discretion of PI because reality always differences from proposed budgets. EDCTP office staff and management seem to be friendly and considerate of PIs - appreciated, but decisions seem inflexible/legalistic at times instead of allowing variation provided that the variation requested is aligned with the overall purpose of the grant.

Funding

Aeras Global TB Vaccine Foundation (Private non-profit organisation)

Thank you for the opportunity to participate in the public consultation regarding a future proposal for a new EDCTP. We recognize and appreciate the important role of the EDCTP in supporting and promoting research collaborations between African and European institutions and building research capacity in African nations which bear the highest burdens of disease. We would like to take this opportunity to clarify and expand on some of our responses to this questionnaire. In reviewing the co-funding aspect of the program, please consider a revision such that African applicants do not have the onerous responsibility of seeking out European partners. It is accepted that North-North, South-South and North-South collaboration are beneficial, but it should not be a prerequisite for funding. EDCTP should make funding available to African researchers for relevant projects and proposals should be judged specifically on their scientific merit. Furthermore, the current co-funding requirements limit the ability of international Product Development Partnerships, which operate globally but may not have a legal presence in Europe, to participate in the EDCTP program. PDPs work in partnership with research institutions in Europe, Africa and other regions of the world and are involved in many of the CTs for new tools to prevent, diagnose and treat TB, HIV/AIDS and malaria. PDPs often work in partnership with EDCTP to advance common objectives, but have no mechanism to receive funding through the EDCTP nor are the financial contributions of many PDPs to CTs considered eligible for co-funding by EDCTP. As products advance to larger scale CTs, funding needs will become particularly acute. Allowing for a funding mechanism

for PDPs to receive funds and to have their financial contributions be eligible for co-funding would both advance the objectives and add value to the work of EDCTP.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

Co-funding arrangements: This is one of the most difficult, most confusing, and most time-consuming requirements of the current EDCTP. Whilst the idea makes sense as it helps to integrate the national programmes with EDCTP, in practice it could only work if member states honoured their commitment and were willing to give up direct control. At the outset the requirement helped to ensure that EDCTP shared responsibility for projects which in theory facilitates sustainability, but now there are viable networks established largely through EDCTP, that have no source of funding other than EDCTP, which are endangered by the co-funding requirements. We strongly agree that co-funding arrangements should be better defined at the start of the new EDCTP initiative.

Member State's commitments: We strongly agree that each member state should make a formal commitment for a minimum annual payment throughout the life of the new EDCTP initiative. (This would be an ideal situation but I am not sure if it is feasible, especially given the current economic situation in many European member states).

A single fund: We strongly agree that a single fund for co-funding should be created to simplify and streamline co-funding.

Resist-TB

Co-funding arrangements: Indeed the current co-funding arrangements are counterproductive, e.g. by promoting inclusion of weak northern partners, use of less suitable study sites, and inflation of costs. This problem should definitely be addressed. Better defining these co-funding arrangements would be a first and necessary (though not sufficient) step.

MSs commitments: making such commitments is likely to improve the effectiveness of the EDCTP programme, although it will not be sufficient to solve the problems.

A single found: this would in our view be the single most effective way of dealing with the co-funding problem, because it will avoid the situation that individual Member State contribution determines by whom and where the research is done.

Ethics and Intellectual Property Rights Policy

Aeras Global TB Vaccine Foundation (Private non-profit organisation)

Regarding the proposed Ethics Review Committee, we appreciate and agree with the emphasis that EDCTP places on the need for ethical review in a timely manner. We are not certain that the proposed process will achieve the goal of an accelerated review and forming a new body may lead to unintended delays. However, we welcome the opportunity to participate in further discussions about simplifying and accelerating ethical review of protocols.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

Ethics: We strongly disagree that EDCTP should establish its own research ethics committee. EDCTP is to be commended for funding capacity strengthening of African ethics committee, and should continue this work. However, it's critical that the research is reviewed within the country it is being conducted, and the best way to build this capacity is to encourage south-south exchange. If EDCTP were to establish an ethics committee this would send out all the wrong messages implying lack of confidence in the African ethics committees.

Intellectual property rights: We are aware of issues with unrealistic requirements for IPR in the overarching agreements with EDCTP. EDCTP should seek advice with this as it is important to accommodate commercial motivation for participating in public-private initiatives, as well as obliging the public health goal of access.

Resist-TB

The current need for multi-country ethical review is a major impediment to timely and effective implementation of EDCTP-funded trials. The proposed committee would strongly improve this situation.

The Pan African Clinical Trials Registry based at the South African Cochrane Centre, located at the South African Medical Research Council (Public organisation, South Africa)

Local efforts to monitor trial work should be supported by the EDCTP, not undermined by decisions made by persons not in the area in question.

Training and Resources in Research Ethics Evaluation (TRREE) (Switzerland)

EDCTP lacks an Ethical Body that should have an overview in the fact that it is actually respecting the basic requirements in terms of research ethics and conflicts of interest. The ethics calls were not sufficiently coordinated and the beneficiaries were not enough encourage to bring their efforts together. The overall impact of this call has not met the objectives that one could have hoped. More attention should be paid to that issue from the beginning in making sure that the funds are allocated to researchers having the proper training and experience in research ethics, that the ethical review mechanisms are respected and that there is a proper follow-up. It would certainly be useful to offer bigger grants in this field in order to encourage networking at the regional level.

Governance

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

Simplification would be welcomed as would clarification of the political and financial mandate of the General Assembly members as it's key that decisions are made on scientific and public health merit. We don't know how to comment on the revision to include African government and restriction to member states that provide finances.

EEIG is the appropriate overarching body. Simplification could be achieved by combining the external committees into one and creating an executive from the members for review of ongoing awards. Members could rotate through the executive on an annual or bi-annual basis and this group would convene more frequently and report to the overall external committee.

Other suggestions/remarks

Academy of Medical Sciences (Private non-profit organisation, UK)

We welcome the opportunity to respond to the consultation and believe that the European Commission should establish a new EDCTP with expanded scope. The EDCTP is in a stronger position now than when it first began and has helped to build much needed research capacity. The EDCTP partners must work even more closely together in the future to achieve their shared goals. To ensure medical research swiftly benefits the world's poorest people a new EDCTP should ensure its governance and application processes are as simple as possible without compromising their rigor. Complex governance and application processes slow the translation of research into healthcare and deter excellent researchers from seeking funding for valuable studies. A central aim of a new EDCTP should be to swiftly improve the health of the world's poorest people.

Agence nationale de recherche sur le sida et les hépatites virales (ANRS) (Public organisation, France)

A partnership between EDCTP and the institution(s) that act as sponsor in the clinical trials should be defined and implemented.

Centre for Health Policy and Innovation (Public organisation)

Sponsoring or conducting research in developing countries often poses special challenges arising from the combined effects of distinctive histories, cultures, politics, judicial systems, and economic situations. In addition, in countries in which extreme poverty afflicts so many, primary health care services generally are inadequate, and a majority of the population is unable to gain access to the most basic and essential health products and services. A result of these difficult conditions is that the people in these countries are often more vulnerable in situations (such as clinical trials) in which the promise of better health seems to be within reach. Whether the research sponsor is the U.S. government or a private sector organization, some justification is needed for conducting research abroad other than a less stringent or troublesome set of regulatory or ethical requirements. Moreover, when the United States (or any developed country) proposes to sponsor or conduct research in another country when the same research could not be conducted ethically in the sponsoring country, the ethical concerns are more profound, and the research accordingly requires a more rigorous justification. To meet the ethical principle of beneficence, the risks involved in any research with human beings must be reasonable in relation to the potential benefits. Plainly, the central focus of any assessment of risk is the potential harm to research participants themselves (in terms of probability and magnitude), although risks to others also are relevant. The potential benefits that are weighed against such risks may include those that will flow to the fund of human knowledge as well as to those now and in the future whose lives may be improved because of the research. In addition, some of the benefits must also accrue to the group from which the research participants are selected. NBAC understands the principle of justice to require that a population, especially a vulnerable one, should not be the focus of research unless some of the potential benefits of the research will accrue to that group after the trial. Thus, in the context of international research - and particularly when the population of a developing country has been sought as a source of research participants - U.S. and international research ethics require not merely that research risks are reasonable in relation to potential benefits, but also that they respond to the health needs of the population being studied. This is because, according to the principles of beneficence and justice, only research that is responsive to these needs can offer relevant benefits to the population.

Expergen Drug Development GmbH (Austria)

Giving unknown researchers equal chance and platform to express their opinion even may be not the same as of those of the opinion leader.

Global Health Research Initiative (Canada)

The Global Health Research Initiative, the Canadian global health research funding platform of 5 departments/agencies of the Government of Canada, is interested in potential research collaborations with EDCTP. Opportunities for partnership are most likely vis à vis GHRI's HIV/AIDS Clinical Trials Capacity Development Grants, just launched in June 2010.

i-LSE GmbH Institute for Life Sciences and Development (Private for-profit organisation, Germany)

The new designed EDCTP should be furnished with options to allow for special support to such proposals (maybe by guiding to assisting in establishing special links to other international active funding agencies/groups) which directly or indirectly include further development of well known APIs therapies. This support activity shall be directed to give more room to move to R&D approaches which are more oriented to improve access to affordable drugs than to the common trend of blockbusters. Thus, improving well experienced therapeutic strategies (with effect of decreasing cost) would have a similar effect as in the past decades the parallel engineering of Indian pharma companies. Giving priority to such proposals will create

more independence from present monopolizing R&D trends. However, options for such special support should have, in particular in the initial phase, character and effect of an "add-on".

Background reflection: In general, but also in the area of medicaments for treatment of pandemics, R&D policy and product marketing is dominated by profit oriented strategies, at present. The result e.g.: In countries of the North prices of medicaments and treatment costs go up continuously while progress in therapy is second line argument. A good example can be taken from oncology, where significant improvement of survival time (even if the significance is only some days or weeks – which is a more or less symbolic effect) is officially accepted valuing procedure when arguing for rising prices of final products before marketing. This has a very significant effect on health costs and on setting priorities in R&D policy. Therefore, usually you will hardly find R&D activities which result in improved therapeutic impact of well known products, e.g. OTC drugs; going for the "next line/generation" is what drives the market/s (and improves the profit). This is a well known fact; resulting from the common habit of international pharma companies to implement internal profitability guidelines. As a rule the level is: expected profit should reach 25% (for each company section!); sections which do not keep up with this guideline have to expect closing – if not this year, then next one. More details concerning the effects of suchlike R&D policy principles have been published. Suggestion: Therefore, in the new EDCTP design options room shall be given for 1) South-South cooperation; 2) policy support to pharma SMEs; 3) cooperative funding (in particular to give more stress on R&D improving well introduced therapies instead of supporting "new generations lines of medicaments").

Instituto de Salud Carlos III (EDCTP Constituency, Spain)

We recommend exploring a Joint Programming Initiative as a way of engaging Foreign Affairs and Cooperation for Development, both at national and European level (Commission) along with Research. We do not think it is feasible presently to substitute National Ethics committees by an EDCTP committee, but we would agree if otherwise. Voting rights for African governments should be linked to some form of proportional liability.

International Partnership for Microbicides (IPM)

As a product development partnership (PDP) aiming to accelerate the development and availability of microbicides, IPM is driven by the objective—common to EDCTP—of accelerating the development of appropriate and affordable new biomedical tools to prevent HIV infection in developing countries. We recognize and appreciate the important role EDCTP has played in promoting international research collaboration among African and European scientists and building the clinical trial capacity of African researchers and regulators.

It is our hope that a new EDCTP could do more to deliver on its stated aims, for instance by streamlining co-funding mechanisms, supporting larger, integrated product development efforts, and engaging further with international product development pipelines and priorities. This would enable EDCTP to contribute to substantive product outputs as well as ensure that new medical technologies to combat HIV/AIDS, malaria and tuberculosis are delivered as quickly as possible to the most vulnerable populations who need them the most.

PDPs such as IPM are non-profit enterprises created to develop new drugs and tools to fight HIV/AIDS, tuberculosis, malaria and other poverty-related diseases. PDPs work with pharmaceutical companies that do not have the economic incentive to pursue these products on their own. Typically, PDPs manage resources and partnerships from across public, private and philanthropic sectors to drive the development of new products that could save and improve millions of lives in developing countries. Over the past decade, the achievements of PDPs have validated the premise of the model: PDPs have become increasingly successful at advancing new products through the development pipeline towards registration, product introduction and use. Overall, some key achievements of PDPs have been: Establishing international partnerships across the public and private sector; Establishing and executing non-profit drug development programmes; Expanding candidate pipelines;

Strengthening clinical trial infrastructure for neglected disease research; Coordinating and conducting preclinical and clinical research; Launching products, and Becoming leading contributors to their fields.

Product development requires significant funds and PDPs rely on public and private donors to take forward their work and produce results. The European Commission and Member States have been important donors to IPM. However, the EC AIDCO budget line for "poverty diseases", which funded IPM in the past, no longer exists and was never intended to fund core PDP research activities such as research and development and clinical trials. IPM and others have also seen a trend in contributions from a number of Member States in 2009 declining by significant percentages from their 2008 commitments. Without continuous contributions from a broad range of donors, PDPs will struggle to fulfill their missions to accelerate the development of essential drugs for developing countries.

Given the many overlapping objectives of PDPs and EDCTP, it seems clear that EDCTP could be a natural partner to PDPs. Thus far, PDPs have collaborated with EDCTP as co-funders and technical partners. Most PDPs coordinate their work with, rather than receive direct funding from EDCTP. For instance, IPM has worked with EDCTP projects on joint training events for African research institutions and has provided bridge funding for a Microbicide Development Project (MDP) programme in Mozambique. EDCTP has also partially funded a protocol amendment to an HIV incidence study originally funded by IPM and conducted by Projet Ubuzima, in Kigali, Rwanda.

IPM has valued this collaboration with EDCTP and the dialogue, networking, and coordination opportunities it has provided. However, we believe that the development of a new EDCTP provides the European Commission and Member States with an opportunity to mitigate the current PDP funding gap, and leverage and complement the existing contributions of selected Member States to PDP efforts. In this way, the EDCTP could directly contribute to the product development efforts to date of PDPs such as IPM.

We would like to point out some of the challenging aspects of the administrative and co-funding requirements under the current EDCTP, which in themselves can be prohibitive to global PDPs:

1. Co-funding requirements/mechanisms: Current mechanisms present genuine obstacles and are overly restrictive to PDPs and their African partners wishing to access EDCTP funds. As a general rule, Member States require co-funding applicants to be national institutions or to have close links with national institutions, limiting the scope for global PDPs to access Member State co-funding resources, even though their work is done in and for developing countries. 2. Need for larger, more flexible grants for clinical trials/product development: EDCTP grants can currently support small, specific projects but cannot easily accommodate large PDP development programmes. PDPs require flexible funding, which can be allocated to R&D activities and programmes as required. Research conducted under the PDP model could be better supported by EDCTP if management processes take into account the specific nature of clinical trials. 3. Nationality requirements: Current requirements are also potential obstacles to global PDPs in accessing EDCTP funds. For instance, while IPM is a global organization and has a European-registered office, structurally, a significant amount of clinical work is managed through its South Africa office, which is legally a branch of its US headquarters. IPM does not have many technical staff based in Europe, though it has a considerable number of European collaborations.

We propose that a new EDCTP should:

1. Fund larger-scale clinical trials and open calls for proposals to global PDPs. This would require EDCTP raising more funds and loosening the nationality requirements to allow for global initiatives to take part, adding value to EDCTP programmes. 2. Create a common funding pot for Member State co-funding, to ensure more equitable access to co-funding. 3. Broaden EDCTP to support product development cycles—including Phase I-IV Clinical trials. 4. Ensure that research for HIV/AIDS and HIV/AIDS prevention in particular continues to be prioritized and is sufficiently funded under any new EDCTP programme. 5. Maintain a focus on Africa.

Kilimanjaro Clinical Research Institute (KCRI) Kilimanjaro Christian Medical Center (KCMC) Tumaini University (Private non-profit organisation, Tanzania)

EDCTP has been one of the only few international institutions that have been able to build research capacity (in terms of human resource and infrastructure) in sub-Saharan Africa. This is very commendable and appreciated. Though many research institutions in sub-Saharan Africa have been established, they still need to be supported in order to become sustainable. We recommend that EDCTP continues into another phase, by so doing many established research institutions will be stronger and sustainable.

Mbale Regional Referral Hospital Institutional Review Committee (Public organisation)

1. Create a special fund for first time researchers to access sponsorship in the sub Saharan Africa 2. Create centralized laboratories equipped to handle and promote clinical trials in sub Saharan Africa. The currently funded laboratories are not accessible to scientists easily. 3. create country coordination offices in each sub Saharan countries so that they coordinate research efforts, they sensitize the research community, they receive and process applications for grants, training and conferences. Such offices may be housed in already existing EDCTP funded programmes but the mandate of such offices should be centrally coordinated by the EDCTP head quarters. One suggestion is the use of national ethics coordination offices for these purposes.

MRC Clinical Trials Unit HIV Senior Scientists (Public Organisation, UK)

General observation: the EDCTP strategy of awarding the coordinator role and contract to a developing country organisation may meet the principles EDCTP works to but in practice, the organisation may not have the experience, skills and resources to undertake the financial and contractual obligations. We have been involved with a number of projects where it has fallen to MRC to put in place the consortium agreement, agreements with pharma companies and others but essentially we do not have the authority to negotiate these other than as 'delegated' from the coordinator. This delegation is by default rather than explicit. This assistance could be described as capacity building in that the skills are then passed on but in practice, we play an integral role. Similar things happen with financial reporting. Also, EDCTP insists on working only through the individual marked as coordinator – so complex admin and financial matters are being filtered through a scientist who may or may not be fully aware of importance of some of the issues.

Social impact: EDCTP needs to be realistic about which of these it can have an impact on. High score for access, cultural exchange, public understanding and public awareness of ethics; high score for equality between men and women as this can be achieved through the research staff but is only a small contribution to equality overall. Low score for discrimination in all forms as this is unrealistic and similarly, low score for health care benefits and equal treatments as this is beyond the scope of an agency funding research.

Economic impact: Using the same principles: low score for reducing the cost of trials, facilitating job creation, promoting industrial and academic research; high score for new products, collaboration between research and development funding and effective EC mechanisms.

National Institute of Infectious Disease (Public organisation, Romania)

Looking forward to a long-term fruitful cooperation.

Novartis International AG (Private for-profit organisation)

New technologies like social networking sites and smart phones are changing the healthcare landscape, transforming the way patients make their treatment decisions. More and more patients are using digital tools as health resources, so it's important we test and experiment with ways that leverage this growing trend. We will always help patients most with our innovative medicines, preventive vaccines, lower cost generics and self pay consumer health products, but we can use technology to help improve positive outcomes.

Our first iPhone application is a great example of how we're changing the way we serve patients to help them manage their care. It all started when one Vaccines & Diagnostics team member wanted a better way to track

his child's immunization boosters. Recognizing this common patient need, the team developed VaxTrak, which stores a family's medical records and reminds parents when their children are due for vaccinations.

We're also developing another iPhone app that will allow patients with wet age-related macular degeneration (AMD) to monitor their disease from home. With this app, a patient will be able to take a customized visual function test right on their iPhone, which will then automatically transmit their results to their doctor. The app could help the patient with compliance.

Oxfam (Private non-profit organisation, UK)

On IP Drugs/vaccines developed with public funding should not have IP in Developing Countries. Alternatively they should not have IP in LICs but in MICs, products have automatic licenses with low royalty rates. To avoid conflict of interest, the governance structure should not include drug companies.

Resist-TB

While social and economical objectives are all laudable goals we think EDCTP should primarily aim for impact in its core area, i.e. improved (access to) health interventions through research.

The Pan African Clinical Trials Registry based at the South African Cochrane Centre, located at the South African Medical Research Council (Public organisation, South Africa)

We would like to suggest the continuation of EDCTP with our full support. We would like the EU to consider how to facilitate more input from African nations, specifically on research objectives.

The University of Oxford (Higher Education Establishment, UK)

We would like to summarise our comments and recommendations for the EDCTP.

1. There is a vast gap in capacity to run trials between the developed and developing world. Currently over 90% of trials conducting in these regions are sponsored by northern partners. In practice this means that most of the scientific input and thinking being conducted by the sponsor and the trial sites merely operate the study. Sites are not left with skills to run their own programmes. Often capacity building in attached to these studies as window dressing.

2. We need product development and disease management trials. For the latter we need to build true capacity in sites and this requires de-linking this from specific and product development studies.

3. All regions, not just Africa should be included.

4. Any disease of poverty – including non communicable disease (such as mental health and malnutrition) should be within the remit of the EDCTP.

5. The need for a northern partner is counter-productive to developing capacity in these regions - it is very helpful and important on occasions but should not be a requirement when a good local network or collaboration is proposed and a northern partner then sought simply to meet the requirement.

THE VIEW OF PUBLIC AUTHORITIES

Scientific Strategy

Department of International Development (Centralised Authority, UK)

Phases of clinical trials: DFID would agree to inclusion of phase 4 trials, but not phase 1.

Areas of geographic interest: Care must be taken to ensure that the programme is not spread too thinly - what added value is there in extending the geographic range?

Disease scope: A clear justification for including other diseases must be presented - it should not be a fund for any research without clear indications of the impact on poverty reduction.

Medical Research Council (Non-Departmental Government Body, responsible to the government Department for Business, Innovation and Skills, UK)

Phases of clinical trials: the MRC would 'agree' to the inclusion of phase IV, but 'strongly disagree' on the inclusion of phase I.

Netherlands Vaccine Institute (Public Authority, Netherlands)

1) Extensions to other global disease areas recommended (e.g. Flu); 2) Extensions to other geographic areas (Latin America and Asia) recommended; 3) Extensions to other phases recommended (in particular phase 1 trials).

Management

Department of International Development (Centralised Authority, UK)

Handling of proposals needs to be done in a transparent way which has the confidence of researchers and national research organisations. There should be analysis of the spread of grants to ensure that the best research is funded

Funding

Department of International Development (Centralised Authority, UK)

Each member state should make a formal commitment for a minimum overall payment, not necessarily on an annual basis.

Medical Research Council (Non-Departmental Government Body, responsible to the government Department for Business, Innovation and Skills, UK)

Each Member State should make a formal commitment for a minimum overall payment, not necessarily on an annual basis.

Ethics and Intellectual Property Rights Policy

Department of International Development (Centralised Authority, UK)

The ethics committees must provide sufficient support for any challenges in Member states and African countries. Any EDCTP ethics committee should add value but not duplicate work or increase the need for paperwork from researchers.

For intellectual property rights a new EDCTP can set out principles but there needs to be flexibility to allow partners involved in the trial to work out the details within current legal frameworks.

Medical Research Council (Non-Departmental Government Body, responsible to the government Department for Business, Innovation and Skills, UK)

Regarding F1 (Ethics), this question was unclear. Regarding F2 (IPRs), a new EDCTP initiative can set out principles on IPR, but the actual agreement, within current legislation, should be decided by the partners doing the trial.

Governance

Department of International Development (Centralised Authority, UK)

Effectiveness of governance structures is more important than simplification H1 African Government representatives may wish to be involved in policy but without financial liability. So African Government reps could be excluded from financial decisions. There should be a focus on including policy makers early in the process of designing the research programmes whether clinical trials or other types of research to ensure that the results can be used as quickly as possible. Getting research into policy and practice activities must be included in research plans. There should be a clear description of how member states programmes will be coordinated if EDCTP takes this approach - what does it mean and how will it be operationalised? On the face of it is very unclear how this can be done. There needs to be clear definitions of what counts as match funding to EDCTP from member states with clear agreement from the European Court of Auditors in advance of the programme starting.

Harry van Schooten (Netherlands)

Transparency is the proper basis for participatory approaches and appropriate accountability.

Ministry of Foreign Affairs (Centralised Authority, Netherlands)

Regarding governance: the current distinction between full members and associate members is not clear, nor is there any 'phase in' or 'phase out' strategy for associate members. Finally: EDCTP should invest heavily in strengthening its strategic vision over time: currently many proposals are selected based on quality indicators only, whereas there doesn't seem to be a vision on which products should be focussed on. Nor is there a vision on how to move from 'many phase 2 trials' to 'a few good phase 3 trials'. In other words: how to proceed from upstream research to downstream selection of products. The scientific review committee does not have the capacity nor the mandate to set out such a strategy at the moment. This is a huge gap.

Uganda Virus Research Institute (Centralised Authority, Uganda)

1. DCCC should be integrated into the PB to minimise bureaucracy whilst improving effectiveness and efficiency. 2. EDCTP should mandate members from DCCC to ensure that beneficiaries are pro-actively alerted on new funding/training opportunities.

Other suggestions/remarks

Harry van Schooten (Netherlands)

EU has a moral obligation to continue with supporting the building and strengthening of Africa's capacity to deal with and manage CTs of products for diseases which are scourging Africa's most vulnerable population.

Norwegian Directorate of Health (Centralised Authority, Norway)

We have answered "high level of impact" even though social and economic objectives are secondary to the research objectives.

7. MAIN CONCLUSIONS

A public consultation was held from 8 April to 22 June 2010, inviting the EDCTP stakeholders (i.e. researchers, research institutions, regulatory authorities, funding agencies, pharmaceutical companies, etc.) and the public at large to express their views on the need for and nature of a renewed EDCTP initiative. This consultation took place through an online questionnaire to inquire support for different policy options identified and to canvass stakeholders' opinions in targeted areas of particular interest. The questionnaire was accompanied by a Public Consultation Document, a Specific Privacy Statement and links to other supporting material.

In response to the public consultation launched in 2010 the Commission received a total of 235 contributions broken down as follows:

- 175 replies from individuals contributing in a personal capacity. This included 55% researchers, 11% interested citizens, 15% employees of public organisations and authorities, 7% employees of private non-profit organisations and 2% employees of private-for-profit organisations;
- 48 replies from organisations/companies, including 31% from private non-profit organisations, 25% from public organisations, 19% from private for-profit organisations and 13% from other type of organisations;
- 12 replies from public authorities, including 92% replies from centralised authorities (8% others).

The separation into these categories was taking into account when interpreting results to ensure balanced conclusion. Geographically, respondents were distributed as follows: 137 from the Europe, 64 from Africa and 34 from other regions.

As part of this consultation, a set of different policy options for a second EDCTP programme were presented and stakeholders invited to indicate their preference. These options included:

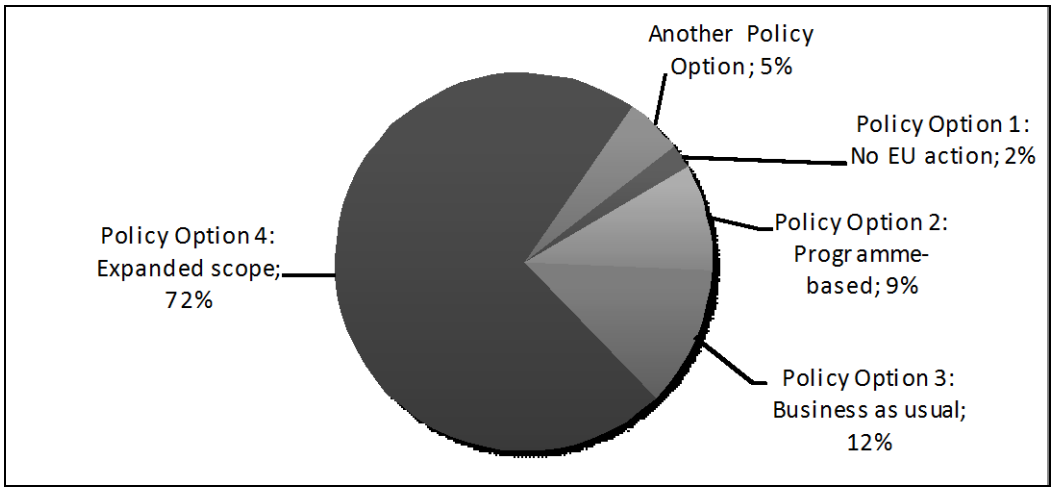
- Option 1 - No EU action: no EU decision to continue participation and financial contribution of the EU to the EDCTP initiative after the expiration of the current funding phase.
- Option 2 - Programme based: no EU decision to continue participation and financial contribution of the EU to the EDCTP initiative after the expiration of the current funding phase. Provision is however made in EU research policies and programmes to support EDCTP objectives.
- Option 3 - Business as usual: a new EU decision continuing the participation and financial contribution of the EU to a second EDCTP programme under the same terms.
- Option 4 - Extended scope: as in option 3, a new EU decision continuing the participation and financial contribution of the EU to a successor EDCTP programme would be adopted. However, the scope of the second EDCTP programme would be expanded, by including other poverty-related diseases (such as neglected infectious diseases), other forms of medical products and interventions (such as diagnostics), all phases (I-IV) of clinical trials, and/or developing countries in other geographical areas.
- Another option

With 72% in favour, the consultation showed a clear support for the option related to a second EDCTP programme with an expanded scope (see figure below). This was the best-preferred option across all categories of respondents (76% among individuals contributing in a personal capacity, 63% among organisations and 50% among public authorities) and regions of origin (87% among respondents from sub-Saharan Africa and 67% among respondents from the EU).

As regard the nature of this expanded scope, strong support was similarly expressed in all social and geographical categories of respondents for expanding the scope of EDCTP:

- to phases I and IV clinical trials: majority of respondents in favour in Europe (79%) and sub-Saharan Africa (85%), as well as among public authorities (75%), organisations/companies (73%) and individuals (81%); and

- to other infections: majority of respondents in favour in Europe (60%) and sub-Saharan Africa (70%), as well as among public authorities (67%), organisations/companies (58%) and individuals (67%).

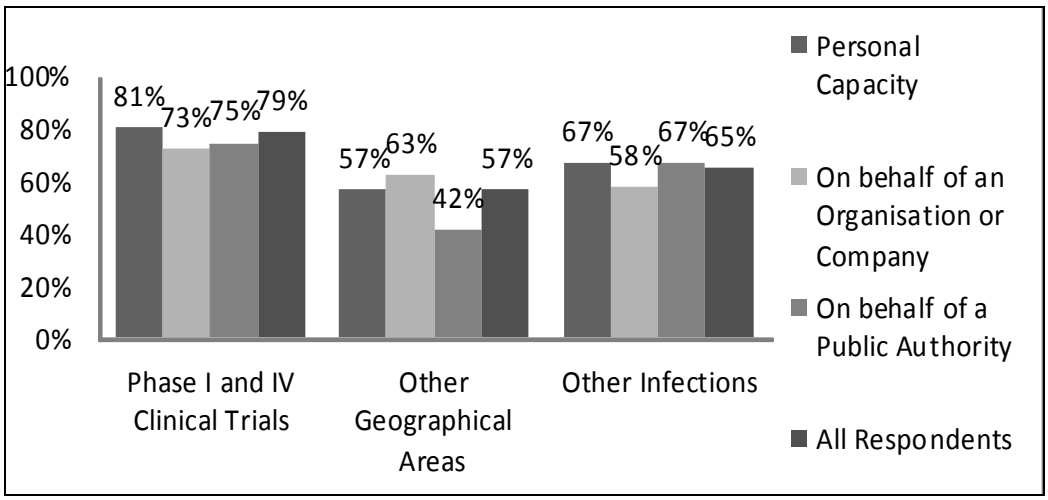


However, the possibility for a geographical extension was rejected by the public authorities (42%) while gaining only a more limited support by the other categories (Figure 2).

As part of the consultation, stakeholders also identified possible objectives to be pursued in the context of a renewed, second EDCTP programme. This notably includes:

- objectives with social impact: help ensure access to the products of research findings (87%), improve health care benefits and equal treatments (87%), improve public understanding of clinical trials (74%), promote cultural exchange through research (72%) and improve public awareness of ethics (72%); and
- objectives with economic impact: promote collaboration between research and development funding institutions (86%), promote academic research (81%), facilitate the introduction and dissemination of new products, technologies and production methods (80%), reducing the cost of clinical trials (68%) and promoting industrial research and facilitating job creation (48%).

Finally, respondents expressed broad support for the creation of a "common pot"[1] to reduce operational complexity and simplify and streamline co-funding (81% in favour) and a better involvement and cooperation with third parties, such as international funding bodies (83%), large pharmaceutical and biotechnology industries (57%), and SMEs (55%).



[1] Under a real common funding pot ("common pot") , national contributions are pooled together and managed by a common implementation structure (such as the EDCTP Secretariat) according to agreed common procedures to select and support the best research proposals identified by peer review and independently of national rules.

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