

PUBLIC CONSULTATION REGARDING A FUTURE PROPOSAL FOR A NEW EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP (EDCTP)

A. RESPONDENT PROFILE

A1. Personal identification

My answers to this questionnaire represent:

- My personal opinion
- The view of an organisation/company
- The view of a public authority

For individuals

- Name
- Age Group (age group 0-17; 18-25; 26-39; 40-64; 65 or older)
- Gender
- Country
- E-mail
- My interest in the EDCTP is as:
 - an interested citizen
 - a researcher
 - an employee of a public organisation
 - an employee of a private non-profit organisation
 - an employee of a private for profit organisation
 - an EDCTP constituent member
 - an employee of a public authority
 - other

If "other" please give further information:

For organisations/companies

- Name of organisation/company
- Country
- E-mail
- Type of organisation:
 - Higher Education Establishment
 - Public organisation
 - Private non-profit organisation
 - Private for-profit organisation
 - EDCTP constituent
 - Other organisation/company

If "Other organisation/company" please give further information:

For public authorities

- Name of public authority
- Country
- E-mail
- Type of public authority:
 - Centralised authority (governmental body)
 - Decentralised, regional authority
 - Other authority

If "Other authority" please give further information:

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; 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? (1= Low level support; 5= High level support)

	1	2	3	4	5	Don't know
i) 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						
ii) Strengthening of African capacity to undertake clinical trials						
iii) 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)						
iv) Advocacy and fundraising						
Governance structure						
Communications						
Please describe any other potential areas of activity: _____						

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

B 5. 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?

- Basic research
- Public health interventions
- Other areas

Please specify in more detail: _____

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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 option?

- 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: _____

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? (1= Low level of engagement; 5= High level of engagement)

	1	2	3	4	5	Don't know
Small and Medium Enterprises						
Large pharmaceutical/biotech/industrial companies						
International funding bodies						

E2. Collaboration with third parties

How should a new EDCTP initiative collaborate with 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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

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.

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

G. SOCIAL AND ECONOMIC IMPACT

G1. Social impact

What level of impact should a new EDCTP have on the following social objectives? (1= Low level of impact; 5= High level of impact)

	1	2	3	4	5	Don't know
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? (1= Low level of impact; 5= High level of impact)

	1	2	3	4	5	Don't know
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 (1= Low level of priority; 5= High level of priority)

	1	2	3	4	5	Don't know
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						

I. GENERAL REMARKS

I1. Other suggestions/ comments

Thank you for your contribution.