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Proposal for a

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long term partnership between Europe and the developing countries, undertaken by a number of Member States and Norway**

(presented by the Commission)

## **EXPLANATORY MEMORANDUM**

### The global crisis:

Communicable diseases not only cause considerable poverty but are also the consequence of poverty in developing countries, particularly in Sub-Saharan Africa. HIV/AIDS, malaria and tuberculosis (TB) alone cause more than 5 million deaths every year, with 95% of these in the developing world. Since poverty itself contributes to the spread of these diseases, this vicious circle of disease and poverty causes a fundamental public health and economic crisis.

This crisis requires a dramatic solution that is beyond the resources of individual governments and is at the centre of the international political debate with calls for urgent action (EC Round table 2000, G8 Communication of Okinawa 2000, UNGASS 2001). In response to this emergency, the Commission has launched its Programme for Action : Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction. The Council and the Parliament emphasised the gravity of the HIV/AIDS, malaria and TB epidemics and the need to increase support at national, regional and global levels in their response to the policy framework and the Programme for Action presented by the Commission in 2000 and 2001 (Resolutions of 10 November 2000, 14 May and 4 October 2001).

This Programme for Action creates a broad policy framework for a comprehensive, global, multi-sectoral approach to poverty-related diseases based on improving the impact of existing interventions, increasing affordability of key pharmaceuticals, and developing new and more effective health products. In this context the Commission has proposed to establish a clinical trials programme responding to the needs of Developing countries. The goal is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and TB in the Developing countries.

### Current situation:

Member States and Associated States will invest more than € 1 billion for the years 2002-2007 in basic and clinical research to develop new clinical interventions against HIV/AIDS, malaria and TB. However, although vast quantities of relevant research results are being generated, they are failing to be translated into health improvement tools that are applicable in the Developing countries. The decreased efficiency and impact of the individual states' investments is caused by :

- 1) lack of adequate networking and co-ordination between the European national programmes resulting in fragmentation of European research in this field;
- 2) major organisational and economic impediments to conduct clinical trials of sufficient size and ambition to achieve meaningful results;
- 3) insufficient involvement of the Developing countries where the target diseases are endemic, often due to lack of adequate clinical research facilities and trained human resources.

### The European and Developing countries Clinical Trials Partnership

14 EU Member States and Norway have recognised that a political commitment is required to overcome these problems. In order to exploit Europe's investment to confront HIV/AIDS, malaria and TB in the Developing countries, and mobilised and supported by the European

Commission, they are creating the “European and Developing countries Clinical Trials Partnership (*EDCTP*)” as a flagship initiative to accelerate the development of new clinical interventions to fight these diseases, particularly in Sub-Saharan Africa.

The *EDCTP* is unprecedented in scope and ambition and unites practically all the relevant clinical research and development activities undertaken by 14 EU Member States and Norway together with that of the Community. The *EDCTP* will also provide an urgently needed “pull” to encourage and accelerate more basic research and pre-clinical research in this field.

The overall goal of the *EDCTP* is to accelerate the development and evaluation of new vaccines, drugs and other preventive or therapeutic tools against HIV/AIDS, malaria and TB in full partnership between Europe and the Developing countries. Research activities carried out within the framework of the *EDCTP* will respect fundamental ethical principles, including those which are reflected in Article 6 of the Treaty of the European Union and in the Charter of Fundamental Rights of the European Union.

This new partnership builds on a joint programme of clinical research activities in Europe and in the Developing countries. The *EDCTP* has the following three major objectives, which are coherent with EU-research, trade and development policies:

- 1) Networking and co-operation between the participating national programmes to increase their efficiency and impact and overcome the fragmentation of European research in this field. The most powerful means of networking research programmes is by the joint implementation of programmes or large parts of programmes. This will contribute to realising the principles of the European Research Area in this field of research.
- 2) Acceleration of the development of new products by supporting clinical trials in the Developing countries, thus promoting transfer of research into clinical practice thereby strengthening Europe’s R & D excellence on the global market.
- 3) Strengthening clinical research capacities in the Developing countries in the fight against the three poverty-related diseases, in line with European development and co-operation objectives. This aim would also help establish a long term sustainable and genuine partnership between Europe and the Developing countries.

The *EDCTP* joint programme will link and provide a range of services designed to support the networking and co-operation of national programmes, support for clinical trials from the public and private sectors, particularly the establishment of new public-private partnerships to help advance new affordable and effective medical products through clinical trials, and to strengthen the logistic, clinical and laboratory research capacities in Developing countries to conduct clinical trials including training schemes and support to local ethical review systems.

A robust and dynamic legal entity is needed for the *EDCTP* to be able to respond to the challenges in a flexible manner. A European Economic Interest Grouping is seen as a suitable legal structure for the *EDCTP* joint programme, as it specifically allows the creation of new activities based on those of its members.

The participating countries recognise that the *EDCTP* cannot achieve its goal without genuine participation of the Developing countries. The development of new health products should meet the needs of the Developing countries and be determined by them. Without active programmes to strengthen and develop capacity in the Developing countries, those countries

will not be able to play the critical role expected of them in the partnership. Therefore, Developing countries share ownership of this initiative by fully participating in the development and implementation of the *EDCTP* strategic priorities through representation in the *EDCTP* executive structures. In addition the *EDCTP* encourages the participation of WHO and other public or private organisations in the *EDCTP*'s programme.

### Community funding of the *EDCTP*

The report on Macroeconomics and Health commissioned by WHO states a need for 3 billions of Dollars per year for additional investments in biomedical and health research to successfully confront the three diseases through the development of new efficient interventions as global public goods. The development of each new vaccine, drug or other innovative treatments requires large-scale clinical trials in Developing countries costing several hundred million Euros. The financial goal of €600 million in the first five years of the *EDCTP* reflects the dimension of the problem, the need for mobilisation of different stakeholders and the challenges that have to be overcome to significantly advance new clinical interventions.

The Community contribution of €200 million is calculated to be the substantial but minimum investment necessary to initiate the *EDCTP* programme in its first five years. The Community contribution should be seen as a catalyst to ensure that a number of promising new health products are quickly brought into clinical trials, to create the legal structure to establish the *EDCTP*, and to support a capacity building and training programme in the Developing countries. It provides incentives for the co-operation of national activities, and creates added value and critical mass at the European and Developing countries levels. Thus the Community contribution is essential to create this coherent approach bringing together the stakeholders committed to the *EDCTP* objectives, and to help ensure its sustainable long-term development.

### Article 169 as the appropriate instrument for funding the *EDCTP*

The fundamental basis of the *EDCTP* initiative is the joint programme formed by the participating Member States' and Associated State's national programmes and the Community.

Article 169 of the Treaty specifically allows the Community to make provision, in implementing the Framework Programme, for participation in research and development programmes undertaken by several Member States. Therefore the framework of Article 169 is particularly well adapted to implement the *EDCTP* initiative as it allows the participation of the Community in the joint programme.

It ensures the effectiveness of Europe's investment in national clinical research programmes by providing a common platform that can exploit research results to develop new clinical interventions against HIV/AIDS, malaria and TB for the benefit of the Developing countries. The expected impact at the European level will be greater than the sum of the impacts of national programmes. It will achieve the required critical mass, both in human and financial terms, by bringing together the available complementary expertise and resources to accelerate the development of the new medical products urgently needed to reduce the devastating impact of these three diseases.

Furthermore, at the global level it contributes to a unified voice to represent European research contributions in the fight against the three diseases in the Developing countries.

Finally, it promotes a long-term structuring effect both in European and developing countries' research policy and helps to integrate different policies in a coherent context.

The European Community's Sixth Framework Programme for Research makes provision to establish a clinical trials programme. Article 169 of the Treaty is the appropriate instrument for the Community to support the *EDCTP* initiative since it allows for both the coordination of national research programmes and the participation of the Community in the joint programme.

#### Time-scale of this initiative

Since June 2001, representatives from 14 Member States - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden and the United Kingdom - and Norway - have been working together with the Commission to develop the concept of the *EDCTP* in close partnership with Developing countries. They have developed and agreed a strategic "Concept Document" as a starting point for further elaborating the initiative. This document, which accompanies this proposal without being part of it, describes the concept of the partnership and the foreseen *EDCTP* joint programme goals, activities and implementation modalities.

Based on this Concept Document the participating States are developing the legal, financial and operational procedures to allow *EDCTP* activities to begin in Spring 2003, and initiation of the first *EDCTP*-funded clinical trials and capacity building and training programmes by the end of 2003.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 169 and 172, second subparagraph, thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>2</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>3</sup>,

Whereas:

- (1) Decision .../.../EC of the European Parliament and of the Council of ... concerning the Sixth Framework Programme of the European Community for research, technological development and demonstration activities aimed at contributing toward the creation of the European Research Area and innovation (2002-2006)<sup>4</sup> (hereafter referred to as "the sixth framework programme") provides for Community participation in research and development programmes undertaken at the initiative of a number of Member States, including participation in the structures created for the execution of those programmes, within the meaning of Article 169 of the Treaty.
- (2) On 30 May 2001, the Commission presented a communication on the application of Article 169 and the networking of national programmes<sup>5</sup>.
- (3) In its Resolutions of 10 November 2000 and 14 May 2001, the Council underlined the gravity of the HIV/AIDS, malaria and tuberculosis epidemics and the need to step up efforts to increase aid at national, regional and world level.
- (4) The European Parliament has adopted a resolution and produced a report<sup>6</sup> concerning the Commission communications on accelerated action on the main communicable diseases in the context of poverty reduction.

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C [...], [ ...], p. [...].

<sup>3</sup> OJ C , , p. .

<sup>4</sup> OJ L [...], [...], p. [...].

<sup>5</sup> COM(2001)282 final

- (5) In its conclusions of 30 October 2001, the Council called on Member States to select specific areas for pilot programmes, for which Community participation in research and development programmes undertaken at the initiative of a number of Member States within the meaning of Article 169 of the Treaty would be appropriate, if necessary in close collaboration with the Commission.
- (6) In connection with its communications to the Council and the European Parliament of 20 September 2000<sup>7</sup> and 21 February 2001<sup>8</sup>, the Commission has presented an action programme aimed at combating the global problem of HIV/AIDS, malaria and tuberculosis and identifying various strategies to be implemented. This action programme has a research and development part aimed among other things at developing, in coordination with the application of this decision, new clinical interventions to combat the three diseases through a long term partnership between Europe and the developing countries.
- (7) In their Decision No 36/2002/EC of 19 December 2001<sup>9</sup> the European Parliament and the Council decided that the Community would contribute €60 million for the year 2001 to the global fund to fight HIV/AIDS, tuberculosis and malaria.
- (8) Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom (hereafter known as "the participating States") are undertaking individual national research and development programmes or activities aimed at developing new clinical interventions to combat the global problem of HIV/AIDS, malaria and tuberculosis. These programmes or activities, the required funds for which have been granted, form part of a long-term partnership.
- (9) At present, the research and development programmes or activities undertaken individually at national level are not the subject of coordination at European level and do not allow a coherent approach at European level for an effective campaign against HIV/AIDS, malaria and tuberculosis.
- (10) Wishing to have a coherent approach at European level and to act effectively against HIV/AIDS, malaria and tuberculosis, the participating States agreed to establish a partnership on clinical trials between European countries and the developing countries in order to obtain a critical mass in terms of human and financial resources and the combination of additional expertise and resources available in various countries across Europe.
- (11) To give effect to this partnership, the participating States have developed, with developing countries, a research and development programme entitled "The European and Developing countries Clinical Trials Partnership (hereafter referred to as the EDCTP Programme).
- (12) The objective of the EDCTP Programme, the cost of which is estimated by participating States at €600 million over a five year period, is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and

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<sup>6</sup> A5-0263/2001

<sup>7</sup> COM(2000)585 final

<sup>8</sup> COM(2001)96 final

<sup>9</sup> OJ L 7, 11.01.2002, p. 1.



tuberculosis in the developing countries, particularly in Sub Saharan Africa. The EDCTP Programme has been drawn up with a view to stepping up cooperation and the networking of European national programmes, accelerating clinical trails of new products in the developing countries, helping to strengthen capacities in the developing countries and obtaining additional funds to fight these diseases.

- (13) The participating States have agreed to develop jointly activities aimed at contributing to the EDCTP Programme for a period of five years. The overall value of their contribution is estimated at €200 million.
- (14) Activities linked to obtaining additional funds, whether public or private, estimated at €200 million are provided for in the implementation of the EDCTP Programme.
- (15) In order to increase the impact of the EDCTP Programme, the Community should participate in this programme with a financial contribution of €200 million.
- (16) The participating States have decided to create a common structure to implement the EDCTP Programme which will be the sole beneficiary of the Community contribution. This structure is a legal entity which will guarantee the Community dimension in carrying out the EDCTP Programme.
- (17) Given that the EDCTP Programme meets the scientific objectives of the sixth framework programme and that the research field of the EDCTP Programme falls within the priority theme "Life sciences, genomics and biotechnology for health" of the sixth framework programme, the financial contribution from the Community should be taken from the budget allocated to that priority theme.
- (18) As the EDCTP Programme is being undertaken jointly by several participating States, it should be stipulated that those states are jointly and severally liable for carrying out the activities undertaken under the programme.
- (19) It is essential that the research activities carried out under the EDCTP Programme conform to basic ethical principles, particularly those set out in Article 6 of the Treaty on the European Union and in the Charter of Fundamental Rights of the European Union.

HAVE ADOPTED THIS DECISION:

#### *Article 1*

1. In implementing the sixth framework programme of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (2002-2006) (hereafter referred to as "the sixth framework programme"), adopted by Decision .././EC, the Community shall make a financial contribution to the research and development programme entitled "The European and Developing countries Clinical Trials Partnership" (hereafter referred to as "the EDCTP Programme") undertaken jointly by Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom (hereafter referred to as "the participating States").

2. The Community shall pay a financial contribution amounting to a maximum of €200 million for the duration of the sixth framework programme.
3. The financial contribution from the Community shall be paid from the appropriation allocated to the priority theme "Life sciences, genomics and biotechnology for health" of the specific programme of the sixth framework programme "Integrating and strengthening Community research".

#### *Article 2*

1. The financial contribution from the Community shall be conditional upon the execution of the activities under the EDCTP Programme referred to in the annex to this decision and the implementation of the research and development programmes undertaken at national level by the participating States.
2. The financial contribution from the Community shall be paid to the structure created by the participating States for the implementation of the EDCTP Programme (hereafter referred to as "common structure") which shall be endowed with legal personality.
3. The arrangements for the financial participation of the Community and the rules relating to intellectual property rights shall be adopted jointly by means of an agreement to be concluded between the Commission and the common structure, in accordance with the financial regulation application to the Community budget.

#### *Article 3*

The participating States shall be jointly and severally liable for carrying out the activities described in the annex.

#### *Article 4*

The Commission and the Court of Auditors may, through their officials or agents, carry out all the checks and inspections needed to ensure proper management of the Community funds and protect the financial interests of the Community against any fraud or irregularity. To this end, the participating States and the common structure shall make all relevant documents available to the Commission and the Court of Auditors.

#### *Article 5*

The Commission shall communicate all relevant information to the European Parliament, the Council and the Court of Auditors, and calls on the participating States and the common structure to forward any additional information required by the European Parliament, the Council and the Court of Auditors concerning the financial management of the common structure.

*Article 6*

This decision is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## ANNEX

### **Description of the activities of the EDCTP Programme**

In cooperation with developing countries, the participating States have drawn up a research and development programme entitled the European and Developing countries Clinical Trials Partnership (EDCTP).

There are several types of activities under the EDCTP Programme to which the Community makes a financial contribution in accordance with the procedures to be laid down in the agreement between the Commission and the common structure:

**1.** Activities linked to networking and coordination:

- of European national programmes;
- of the activities carried out in the developing countries.

These activities are aimed at strengthening the two main components of the EDCTP Programme: programmes/activities in Europe on the one hand and in the developing countries on the other.

**2.** Activities linked directly to the development of new products against the three diseases (HIV/AIDS, malaria and tuberculosis):

- support for clinical trials in the developing countries;
- strengthening of capacities in the developing countries.

**3.** Activities planned to ensure the development, visibility and sustainability of the EDCTP Programme:

- activities to promote the EDCTP Programme to ensure a high profile at European or international level;
- activities linked to obtaining the necessary funds to enable the EDCTP Programme to develop as planned, including beyond the period covered by this decision.

**4.** Basic activities for the EDCTP Programme such as secretariat services and the management of information concerning clinical interventions against the three diseases.

## LEGISLATIVE FINANCIAL STATEMENT

**Policy area: Research**

**Activities: research activities pursuant to the EC Treaty.**

**TITLE OF ACTION:**

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#### **1. BUDGET LINE(S) + HEADING(S)**

*Subsection B6 6 Indirect actions, B6 611 "Life sciences, genomics and biotechnology for health".*

#### **2. OVERALL FIGURES**

##### **2.1. Total allocation for action: €200 million for commitment**

##### **2.2. Period of application**

2003-2006

##### **2.3. Overall multiannual estimate of expenditure:**

- a) Schedule of commitment appropriations/payment appropriations (financial intervention)  
(see. point 5)

€million

	2003	2004	2005	2006	2007 +	Total
Commitments	<u>200</u>				-	<u>200</u>
Payments	<u>20</u>	<u>30</u>	<u>50</u>	<u>60</u>	<u>40</u>	<u>200</u>

This estimate assumes that the EDCTP is fully operational in early 2003.

##### **2.4. Compatibility with financial programming and financial perspective**

- Proposal is compatible with existing financial programming.

- Proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the interinstitutional agreement.

### **3. LEGAL BASIS**

Article 169 of the EC Treaty.

Decision of the European Parliament and of the Council concerning the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area.

Amended proposal for a Council Decision concerning the specific programme "Integrating and strengthening the European Research Area" implementing the Sixth framework programme of the European Community for research, technological development and demonstration activities.

### **4. DESCRIPTION AND GROUNDS**

#### **4.1. General Background**

In Europe, more than 80% of public research work on behalf of the developing countries is carried out at national level, particularly under national or regional research programmes.

There is, however, little in the way of coordination between the national research programmes themselves or with Community programmes.

As endorsed by the Lisbon European Council in March 2000 and fully supported by subsequent European Councils, the objective of the European Research Area project is to remove the barriers between research activities in Europe. To this end, it entails greater coherence and coordination of national research activities.

The most powerful form of networking is the joint execution of complete programmes or major parts of programmes.

An explicit part of the objective of helping to achieve the European Research Area, the Community research framework programme 2002-2006, as proposed by the Commission, provides for Community participation in national research programmes carried out jointly, under Article 169 of the Treaty.

Use of Article 169, which has not so far been used:

- is a particularly appropriate means of implementing, in conjunction with other instruments, a framework programme specifically designed to help achieve the European Research Area;
- is an effective means of stimulating cooperation and coordination of research activities carried out at national or regional level in Europe;

- will also make it possible to achieve results which could not be obtained with the two other new instruments (networks of excellence and integrated projects), because of the scale and diversity of the resources employed and the structural effects of the combination of efforts organised at national level.

Such participation requires well defined actions or initiatives (whether or not they are formally called "programmes"), on a specific theme or in a specific area, allocated a separate budget and implemented over a certain period with the aid of clearly defined procedures.

#### **4.2. Need for Community intervention**

Three major communicable diseases (HIV/AIDS, malaria, tuberculosis) affect the developing countries to an extent that their economic and social development is undermined. Alleviation of poverty in developing countries by combating these three major diseases has emerged as a primary objective of the European Community's policies, and it is one of the seven priorities of the Commission's Action Plan for 2002. In the Commission's policy framework "Programme for Action on Poverty-Related Diseases", one part of the action relates to enhancing public financing and European coordination for the development of new health products to confront the three diseases, especially in the developing world. In this context, DG Research proposes to participate in the creation of the European and Developing countries Clinical Trials Partnership with the ultimate aim of supporting clinical trials for new products to fight HIV/AIDS, malaria and tuberculosis in the developing countries.

At national level, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Spain, Sweden, the Netherlands and the United Kingdom (*participating States*) invest significant resources, amounting to more than €200 million annually, in research programmes and related activities directed at developing new interventions against the three poverty-related diseases. However, while it is recognised that large amounts of important research results are generated, these often fall short of actually being transformed into clinical interventions applicable in the developing countries.

This shortcoming which decreases efficiency and impact of the individual *participating States'* investments in clinical research for HIV/AIDS, malaria and tuberculosis is caused by:

- (1) lack of adequate networking and co-ordination between the European national programmes causing fragmentation of European research in this field;
- (2) major organisational and economic impediments to conducting clinical trials of sufficient size and ambition to achieve meaningful results;
- (3) insufficient involvement of the developing countries where the target diseases are endemic, often due to lack of sufficiently developed local clinical research facilities or sufficiently trained human resources.

#### **4.3. Objectives of the intervention**

To address the above mentioned shortcoming, the participating States have formed the "European and Developing countries Clinical Trials Partnership (EDCTP)" which accordingly is based on the following three major objectives intrinsically linked to overall European policies:

- Improvement of networking and co-operation between the participating national programmes aimed at increasing their efficiency and impact, thus overcoming the fragmentation of European research in this field and contributing to structuring the European Research Area.

- Acceleration of the development of new interventions by supporting and/or funding clinical trials, thus promoting technology transfer from research results into clinical application, thereby strengthening Europe's competitiveness on the global market.
- Strengthening the clinical research capacities in the developing countries for establishing a sustainable long term and genuine partnership between Europe and the developing countries in the fight against the three poverty-related diseases. This will contribute to European development and co-operation policies.

The participating States have agreed to pool the activities of their relevant national programmes that directly contribute to the EDCTP's objectives by subscribing to the EDCTP's Programme of activities.

#### **4.4. Actions envisaged and means of financing**

In cooperation with the developing countries, the participating States have drawn up a research and development programme: "the European and Developing countries Clinical Trials Partnership (EDCTP) with a budget of €600 million over the initial period of five years. €200 million will come from the participating States and €200 million from the Community, the sum of these budgets being sufficient and necessary to launch and develop the EDCTP Programme. Moreover €200 million will have to come from other donors, including industry.

The breakdown of the budget according to type of activity is as follows:

- Basic activities for the EDCTP Programme such as secretariat services (budget of €15 million, foreseen to cover personnel costs of staff members of a modest-sized central office, for office rent and the acquisition of essential office facilities and services, and for the obligatory statutory meetings of the organisation's legal bodies) and management of information on clinical research into new products to combat the three diseases in particular for developing countries (budget of €5 million for informatics infrastructures, set-up and continuous conduct of information surveys).

Activities linked to networking and coordination:

- European national programmes (budget of €15 million to support co-ordination activities such as joint programme meetings and measures for information exchange, and to provide incentives for the joint implementation of clinical research activities including clinical trials as well as to open national programmes for participating groups from other countries);
- activities carried out in the developing countries (budget of €5 million, to establish and maintain an appropriately staffed EDCTP branch office in Africa, for office rent and infrastructure including the essential set-up of satellite telecommunication systems, and to foster South-South networking, in particular the formation of an operational DC Coordinating Committee).

These activities are aimed at strengthening the two main components of the EDCTP Programme: programmes/activities in Europe on the one hand and in the developing countries on the other.

Activities linked directly to the development of new products to combat the three diseases (HIV/AIDS, malaria and tuberculosis):

- Support for clinical trials. Whereas in the EDCTP programme, the budget allocated for clinical trials is €400 million, it is estimated that €250 million is sufficient and



necessary to launch and develop this activity (initially, €250 million can support 10-20 extended efficacy trials to be conducted in Africa, including trials sites maintenance for 3 years); the remaining €150 million have to be generated by other sources, including industry.

- Strengthening of capacities in the developing countries. Whereas in the EDCTP programme, the budget allocated for this purpose is €150 million, it is estimated that €100 million is sufficient and necessary to launch and develop this activity, covering costs for research support to build up/strengthen an initial number of about 10-20 centralised clinical testing facilities, and to finance a number of training schemes for African clinicians, scientists, and technical personnel both in Europe and in Africa. The remaining €50 million will have to be generated from other sources.

Activities planned to ensure the development, visibility and sustainability of the EDCTP programme (€10 million):

- Activities to promote the EDCTP programme to ensure a high profile and to develop the following activities: costs for professional internet presence, production of information material, conduct of press conferences and representation of the EDCTP at meetings of other global initiatives and relevant international scientific meetings);
- Activities linked to seeking the necessary funds (which may come from industry or other donors) to enable the EDCTP programme to develop as planned (costs of a number of professionally conducted fund-raising campaigns which require contracting consultant and media services);

*The participating States* will create a European Economic Interest Grouping, the «EDCTP–EEIG» as a dynamic and flexible legal entity to execute the EDCTP’s Programme.

Community funding as well as contributions from other donors and industry will be directed to this *EDCTP–EEIG* as the legal structure responsible for the execution of the EDCTP Programme’s activities.

## 5. FINANCIAL IMPACT

### 5.1 Total financial impact on Part B (over the entire programming period)

#### 5.1.1 Financial intervention - Commitments in € million

Breakdown by objective	Total
Integrating and strengthening Community research	<u>12 585</u>
Life sciences, genomics and biotechnology for health	<u>2 255</u>
Life sciences, genomics and biotechnology for health 2003	<u>477.9</u>
<b>Budget allocated under the EDCTP programme</b>	<u><b>200</b></u>

## 6. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

Administrative follow-up of the EDCTP programme during the initial five-year phase comes under total administrative costs for research.

## 7. FOLLOW-UP AND EVALUATION

### 7.1 Follow-up arrangements

The EDCTP programme will be followed up in accordance with the arrangements set out in the agreement between the Commission and the *EDCTP-EEIG*.

### 7.2 Arrangements and schedule for evaluation

- **Evaluation of the EDCTP programme:** The Commission, where appropriate with the aid of suitable experts, constantly monitors the progress of the EDCTP programme in relation to the objectives set. In particular it assesses whether the objectives, priorities, activities, financial means and management are always in line with the reality of the situation.
- **Annual report:** The situation with regard to implementation of Article 169 of the Treaty is published in the annual report on the Framework Programme presented to the European Parliament and Council pursuant to Article 173 of the Treaty. This will include among other things the results of the evaluation of the EDCTP programme, a description of the activities carried out in connection with research and technological development, creation of the European Research Area and dissemination of results during the previous year and the work programme for the current year.

## 8. ANTI-FRAUD MEASURES

In submitting the reports which could lead to the consolidation of revenue in the accounts of the *EDCTP-EEIG*, the participating States and the *EDCTP-EEIG* will have to make the whole of the financial documentation available to the Commission to enable it to carry out its financial audits, indicating the timetable and consolidation of accounts for the *EDCTP-EEIG*.

The Commission will where necessary carry out such financial audits, in particular if it has reasons to doubt the accuracy of the accounts in relation to the progress of the work described in the activity reports.

The financial audits of the Community will be carried out either by its own employees or by qualified accountants approved under the legislation governing the *EDCTP-EEIG*. The Community will be free to choose the latter while however avoiding the risks of conflicts of interests which could be pointed out by the participant who is the subject of the audit.

Moreover, in carrying out the research activities, the Commission will ensure that the financial interests of the European Communities are protected by effective checks and, where irregularities are detected, by proportionate and dissuasive measures and penalties.

To this end, rules concerning checks, measures and penalties, with references to Regulations Nos 2988/95, 2185/96, 1073/1999 and 1074/1999, will be set out in the agreement signed between the Commission and the *EDCTP-EEIG*.

In particular, the following points will have to be covered in the agreement:

- inclusion of specific clauses to protect the financial interests of the European Communities by carrying out checks and inspections of the funds granted;
- carrying out of administrative checks as part of anti-fraud measures, in accordance with Regulations Nos 2185/96, 1073/1999 and 1074/1999;
- application of administrative penalties to all irregularities, whether deliberate or negligent, in the implementation of the agreement, in accordance with general Regulation No 2988/95;
- the fact that any recovery orders issued in the event of irregularities and fraud are enforceable instruments under Article 256 of the EC Treaty.