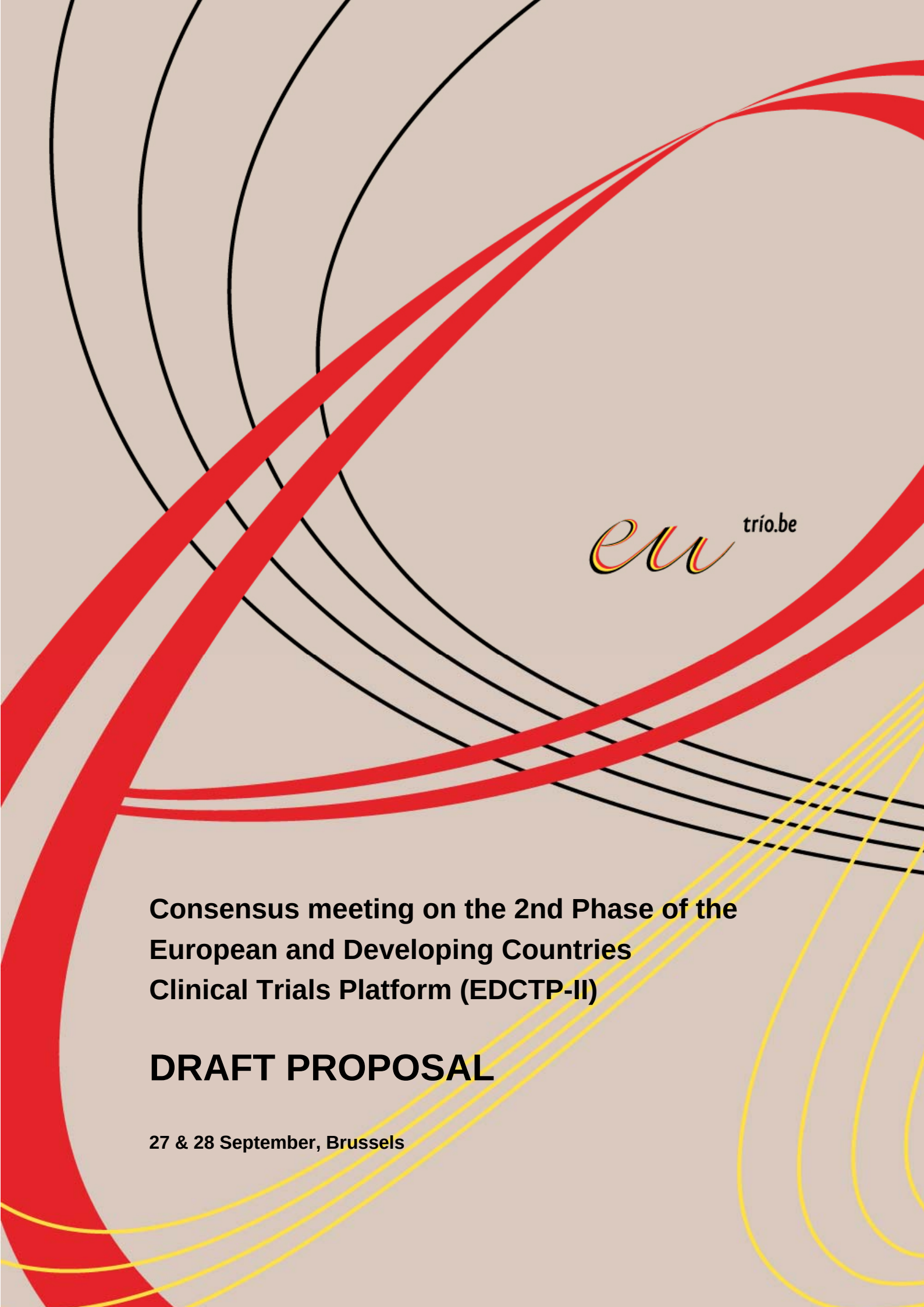

Consensus meeting on the 2nd Phase of the European and Developing Countries Clinical Trials Platform (EDCTP-II)

DRAFT PROPOSAL

27 & 28 September, Brussels

European & Developing

Countries Clinical Trial Partnership

EDCTP

THE NEXT DECADE:

Towards a Collaborative ERA fighting AIDS, malaria, tuberculosis & tropical diseases

Proposal for EDCTP-II

to the European Council and Parliament

Draft submitted by the General Assembly

to a European consensus meeting 27-28 September 2010

Executive Summary

This paper is a proposal for a second phase (2011-2020) of the European and Developing Countries Clinical Trials Partnership (EDCTP). It was drafted by a core group of participating Member States as baseline document for discussion at a meeting of European political decision makers on 27-28 September 2010, called by the Belgian EU Council Presidency. This meeting should result in a consensus proposal to the Competitiveness Council on 26 November 2010, and will allow the Member states as well as the Commission Services to provide further input and amendments. Depending on the progress made in the Council, it is hoped to submit the final proposal to the European Parliament in the course of 2011. While intensive consultations with the African and scientific stakeholders have preceded the drafting, it should be noted that this paper is part on an intra-European political process. The intended result is a principle decision that should provide the legal and financial framework for the European contribution to the "Joint Programme", that obviously will be planned in close collaboration with the African partners and the scientific community.

EDCTP was the first European project under Article 169 (currently 185), which enables the Community to co-fund research programmes undertaken jointly by several Member States. It was established in response to the global health crisis caused by HIV/AIDS, tuberculosis and malaria. EDCTP coordinates European national research programmes on clinical trials against these diseases, in collaboration with their African counterparts and like-minded organisations. The first phase started on 15 December 2003, with a European Economic Interest Group (EEIG/EDCTP) governed by the participating Member States[1] as contractor. The current EDCTP programme (EDCTP-1) comes to an end on 14 September 2010. The EC has agreed to a no-cost extension until May 2015 for the ongoing programme. Community co-funding of a new programme requires a decision of the European Parliament and the Council. Continuation has been recommended by an Independent Expert Review and an Impact Assessment including a public consultation. The assessments point to an innovative and strong partnership with Africa and a greatly improved programme over the years, with remaining challenges regarding full integration of Member State programmes and transparent co-funding.

The global health landscape and the European perspective therein have changed considerably since the initiation of EDCTP. Research and aid budgets for international health development have substantially increased, although funding still remains insufficient under new pressure. Many other "Global Health Initiatives" are active and emerging economies such as China, Brazil, India and others are claiming a more important role in global health. The EU is one of the largest donors in international health assistance and research, but fragmentation still compromises its impact and visibility. A number of recent policy declarations, programmes and reports highlighted the key role of EDCTP, in its own right and as a catalyst model for other programmes aiming at coordinated international collaboration.

[1] AT, BE, DE, DK, EL, ES, FR, IE, IT, LU, NL, PT, SE, UK, plus Norway and Switzerland. The core drafting group for this paper consisted of BE, ES, NL, SE and UK.

EDCTP is now indeed one of the most visible global health initiatives emanating from Europe, a vital element of its research programme for poverty-related diseases, and one of its strongest instruments for fostering the cooperation with Africa. The partnership model of EDCTP could progressively be extended to broader clinical and intervention research on a wider range of poverty-related diseases.

The proposal is based on a future vision which by 2020 should lead to reaching the following objectives:

- EDCTP will be an open and collaborative ERA structure for clinical and intervention trials (including diagnostics and health service delivery) against AIDS, malaria, tuberculosis and, in addition, other tropical diseases.
- By 2020, EDCTP will be governed by a legal structure in which the African ownership as well as the European partnership is fully embodied.
- By 2020, contributions for research and capacity building by MS, African partners and third parties will be accounted for in a transparent system that guarantees compliance with co-funding rules and promotes integration of national programmes.

By building on the progress made under EDCTP-1, intensifying the work on the current focus (including large-scale phase-III trials), and extending to related domains (including diagnostics, other tropical diseases, intervention and health services research), will maximize returns on investment as well as the impact on health and health care. Extension to other geographical areas is not being considered in the medium term as it would require a different political framework and vast additional resources. The inclusion of new EU member states into EDCTP is actively sought and would greatly enhance political cohesion and scientific power.

The co-funding of EDCTP-2 will be simplified through progressively increasing upfront and binding financial commitment of member states. Governance would be strengthened particularly in view of ensuring ownership, voting rights and accountability of the African partners. The operational planning and execution of EDCTP-2 will be divided over three periods of 3-4 years, each with specific objectives, scope extensions, deliverables and milestones. As a preliminary estimate, total funding excluding the African input would amount to 1.5 billion € over a 10-year period, of which 500 M€ each by the Member States and the Commission, and 500 M€ by third parties. A majority of these funds would not require new budgetary efforts, as many member state contributions would consist of joining or reorienting existing activities and resources, and the EC contribution can partly be shifted from FP calls.

1. Purpose

This paper contains a strategic proposal for a second phase of the European & Developing Countries Clinical Trial Partnership (EDCTP). The contract and funding for the first phase, started on 1 January 2004, comes to an end on 14 September 2010. The EC has agreed to a no-cost extension until May 2015 for the ongoing programme, including management costs. New activities can only be co-funded by the EC under a new programme and contract, which must be approved by the European Council and the European Parliament. Meanwhile, an independent evaluation report of the first phase (EDCTP-I) has been released and an impact assessment including a public consultation is ongoing.

The current proposal is based on a meeting of EDCTP General Assembly (GA) members on 8 June 2010. It was further developed by a small writing group (BE, SE, UK, NL, ES) and submitted for comments and approval to the full GA. The proposal is to be submitted for discussion and amendments to a meeting of representatives from member states and the EC on 27-28 September 2010, called by the Belgian EU Council Presidency. This meeting should result in a final consensus proposal to the Competitiveness Council on 26 November 2010. Depending on the political progress, the EDCTP-II proposal could then be discussed and voted upon in the European Parliament in the course of 2011. This proposal is addressed to political decision makers and therefore focuses on strategic, governance and financing issues. The intended result is a principle decision that should provide the legal and financial framework for the European contribution to the "Joint Programme", that obviously will be planned in close collaboration with the African partners and the scientific community.

2. Background

EDCTP was the first and, under FP6, the only Article 169 Programme of the EU. This article (now 185) of the EC Treaty enables the Community to participate in research programmes undertaken jointly by several Member States, including participation in the structures created for the execution of the joint national programmes. The Community participation in EDCTP was approved in 2003 by co-decision [2] of the European Parliament and of the Council. It aimed to establish a "research and development programme for the development of new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries". EDCTP was to be part of a European accelerated and coordinated response to AIDS, malaria and tuberculosis (TB) in developing countries, involving the Directorates for Research, Development and Trade. The specific objective was to integrate and co-fund member states' national programmes for clinical trials of new and improved products against AIDS, malaria and tuberculosis in Sub-Saharan Africa.

All the member states at that time, except Finland, co-founded EDCTP i.e. Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the United Kingdom, and Norway joined in. Given the uncharted territory, the EC played a major role in the start-up of the organisation. In 2005, Switzerland joined as an associated member. Over the past few years, consultations have taken place with the new EU member states which mostly expressed scientific and political interest to join EDCTP.

[2] Co-decision 1209/2003/EC of 16 June 2003.

EDCTP was formally established on 15 December 2003 as a European Economic Interest Group (EEIG) [3], with seat in The Hague (Netherlands). It is governed by a General Assembly (GA) in which the participating states are legally represented by ministries or institutions. Other structures include an Executive Secretariat (ExS), a Partnership Board (PB) and a Developing Country Coordinating Committee (DCCC) [4].The EEIG / EDCTP concluded a grant agreement with the EC for a maximal Community contribution of 200 million €, to be matched by an equal amount of member state contributions to a "Joint Programme" over the lifetime of the project, initially 1 January 2004 - 31 December 2008. In 2006, the parties agreed to a no-cost extension until the 14 September 2010. In July 2010, a new cost-extension was granted until 14 May 2015, to cover activities approved by 31 December 2010.

In spite of a preparatory Accompanying Measure project, EDCTP had to play a pioneering role with regard to co-funding mechanisms and the identification, coordination and integration of national programmes. The EC lacked benchmarks too, and the concerted action with the Directorates for Development and Trade did not materialise. The start-up of the organisation and the activities was therefore slow and cumbersome, leading to management crises and strained relations with the EC. In 2006, a fresh start was taken with a roadmap spelling out a path for the execution of the programme, the disbursement of funds and the co-funding by the member states. A new management took on the challenges and presently EDCTP can boast major scientific achievements, strong partnerships and international respect. A first and critical Independent Evaluation Review (IER) in 2007 [5] acknowledged both the initial problems and the fresh start. The second IER in 2009 [6] recognised the remarkable achievements since then but also several remaining challenges. A recent interim report [7] of the ExS further updates the considerable progress made so far, in terms of science as well as partnership and African co-ownership. An impact assessment, including a policy framework as well as a public consultation on the future of EDCTP, has just been finalised [8] [9] [10].

A major, partly technical or legal problem remains the definition, certification and management of national co-funding. While the set target of 200 million € co-funding has been reached, the largest part is still "in kind" and "virtual cash" (i.e. disbursed and spent in the MS), as certified by the MS themselves. The largest part of the co-funding has been provided by 7 out of 16 members, and still fewer were able to make meaningful unearmarked cash contributions to a "true" common pot. Moreover, most national research funds cannot readily be used for capacity building elsewhere and only some countries were able to merge national development funds in their contribution. Whereas many trials funded by member states are now co-funded by EDCTP, integration of national programmes and projects into one strategically coherent "Joint Programme" remains largely to be achieved. A majority of members is committed and able, however, to accelerate further integration of existing national programmes and to increase their contributions, including "true" common pot cash.

[3] EDCTP/EEIG Statutes
[4] Internal Regulations EDCTP
[5] EDCTP IER Report 2007
[6] EDCTP IER Report 2009
[7] EDCTP Achievements Update July 2 2010
[8] Roadmap Impact Assessment of EDCTP-II. EC, March 2010.
[9] Assessment of the need for a renewed EDCTP. Analysis of results from the public consultation. August 2010
[10] Analysis of the impact of a new EDCTP. Report of the Independent Expert Panel. August 28, 2010

3. Current context

The international health landscape has changed considerably since the initiation of EDCTP. Research and aid budgets for international health development have substantially increased, even if they are not yet sufficient to fill all needs and may come under new strain from the current financial crisis. A great number of "Global Health Initiatives" and Public-Private Partnerships are active in or near the field of the EDCTP (cfr. chapter 8). In recent years, emerging economies countries as China, Brazil, India and others are also claiming an important role in global health, in terms of aid, research and not least trade.

The EU is arguably the largest donor and strongest player in international health aid and research, but due to fragmentation its influence and visibility is not proportional. Over the past years, a number of policy statements and collaborative agreements have laid the foundation for a stronger position of the EU. Recently, the Commission Communication [11] and Council Conclusions [12] on the Role of Europe in Global Health (2010) have established a conceptual framework, with emphasis on strengthening national health systems, maternal health and the continued fight against AIDS, malaria and TB. The 2007 EU Programme for Action [13] and its 2009 Progress Report [14] highlighted the key role of EDCTP, in its own right and as a catalyst model for other programmes aiming at coordinated international collaboration. EDCTP is now one of the most visible global health initiatives emanating from Europe, a vital element of its research programme for poverty-related diseases, and one of its strongest instruments for fostering the cooperation with Africa [15].

Regarding aid policies, EDCTP is one of the few international research organisations that explicitly pursue the principles of the Declaration of Paris on Aid Effectiveness (2005) and the Accra Agenda for Action (2008) [16], by fostering country ownership and integrating donor programmes. These OECD principles are at the very heart of EU's international partnerships, especially with Africa. The Africa-EU Strategic Partnership, emanating from the 2007 Lisbon Declaration [17] and re-emphasized in the Europe 2020 Strategy [18], identifies EDCTP as an important actor in its first Action Plan for Implementation [19] especially in the Eight Partnership on Science, Information Society and Space.

In order to maintain the European effectiveness, visibility and coherence in international health research, there can be no reservation about the consolidation of EDCTP, or continued support from member states and commission. In addition, its partnership model could in the long term be extended to broader clinical and intervention research to all poverty-related infectious diseases. EDCTP can evolve to a truly "Open" European Research Area, as envisaged for EU's international science and technology cooperation programmes [20].

[11] Commission Communication: The EU role in Global Health, March 2010
[12] Council Conclusions on the EU role in Global Health. Brussels, May 2010
[13] European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis (2007-2011), May 2005
[14] Progress report on the implementation of this Programme, 2009
[15] European Union conference on poverty-related diseases research. Lancet Infectious Diseases 2009, 9:334-337
[16] The Paris Declaration on Aid Effectiveness and the Accra Agenda for Action, OESO 2005 and 2008
[17] Lisbon Declaration EU-Africa Summit, December 2007
[18] Commission Communication: Europe 2020: A strategy for smart, sustainable inclusive growth, March 2010.
[19] First Action Plan (2008-2010) for the Implementation of the Africa-EU Strategic Partnership, September 2007
[20] Commission Communication: Strategic framework for International Science and Technology Cooperation, 2008

4. New challenges and opportunities

In September 2010, the United Nations will take stock of the Millennium Development Goals (MDG), with 5 years to go until the 2015 deadline. In terms of health (MDG 4, 5, 6), important but uneven progress has been made. Particularly in Sub-Saharan Africa, enormous challenges are still to be confronted including the fight against AIDS, malaria and TB [21]. Therefore, the current geographic focus of EDCTP still reflects the greatest urgency. Sub-Saharan Africa also remains in great need of capacity strengthening for clinical research and regulatory mechanisms. Obviously, a geographical extension to other continents would be of great interest, but would require a different political framework and considerable resources.

Apart from weak health delivery systems and inadequate prevention, major hurdles in the fight against AIDS, malaria and tuberculosis remain the lack of affordable, efficacious and safe drugs. Not only new compounds, but also simpler formulations such as single-dose and / or fixed combination therapies are highly needed to increase efficacy, lower the burden on health systems and avoid the emergency of resistant strains. Significant progress has been made in the development of vaccines and microbicides, but preventive trials especially Phase III require enormous investments, capacity and tenacity. Improved case detection is crucial for the rational use of drugs; an extension of EDCTP to diagnostics would therefore be highly consistent with its mission and expertise.

In the past years, the international community has woken up again to the notion that functional health systems are key to the efficiency and sustainability of disease control. The social, economic and qualitative disciplines of health systems research are not within EDCTP's scope. However, within its product-oriented objectives and competencies, it can extend its portfolio to operational research on delivery and uptake of medical products, including post-marketing (phase IV) trials, pharmacovigilance and controlled community-based interventions. This extension would increase the direct relevance of EDCTP for health services and development agencies, as highlighted in the recent conference "Connecting the Chain" [22].

African health services have to deal not only with AIDS, malaria and tuberculosis, but also with many other neglected tropical diseases (NTDs) for which no adequate diagnostics, drugs or vaccines are available, such as sleeping sickness, leishmaniasis, helminths, leprosy and Buruli ulcer. Co-morbidities are the rule rather than the exception. The capacities needed for clinical research on NTDs are similar to those for AIDS, malaria and tuberculosis. An extension of EDCTP to NTDs could boost its relevance, efficiency and credibility. Moreover, it would substantially broaden the opportunities for collaboration and co-funding.

A European research area in matters of global health should by definition engage all member states. The inclusion of new EU member states in EDCTP is vital for its political cohesion and scientific power, the more as several of them have considerable experience especially with the clinical management of HIV and tuberculosis. Preliminary consultations with these 12 member states have indeed indicated substantial scientific and political interest.

[21] The African Health Monitor, 11, January 2010. Achieving the Health Millennium Goals in African Region.
[22] EDCTP Conference "Connecting the Chain II", Brussels 9 June 2010 - Meeting Report

5. General objective of EDCTP-II

The scientific and political relevance of EDCTP is thus greater than ever. As stated by the IER 2009 and the Impact Assessment 2010 (see above), EDCTP has brought a new model of international research cooperation, and has optimized its governance and management. It has built up a large and unique portfolio of high-quality clinical trials, of which new products are emerging that can benefit millions of the poorest on earth. Its bold approach to scientific, institutional and ethical capacity strengthening has led to unprecedented successes in this regard, with African scientists feeling true ownership as well as genuine partnership from European partners. The expectations for consolidation as well as growth and extension are great and cannot be frustrated. Clinical research for better drugs and vaccines remains crucial to strengthen and sustain the achievements already made in the fight against AIDS, malaria and tuberculosis. Moreover, extensions of EDCTP's remit to diagnostics, intervention research and neglected tropical diseases, and of its membership to new European member states and African and other stakeholders, provide great opportunities to increase its impact, efficiency and visibility. EDCTP-II should not merely be a continuation of EDCTP-I, but have the bold ambition to create a broad, open and robust European Research Area for clinical and operational trials against HIV/AIDS, tuberculosis, malaria and other tropical diseases. The objective of EDCTP-II is therefore:

By 2020, EDCTP will be an open and collaborative ERA structure for clinical and intervention trials against AIDS, malaria, tuberculosis and tropical diseases

EDCTP would thus unite all "midstream" research by EU members and African partners against HIV/AIDS, malaria, tuberculosis and NTDs. It could encompass clinical trials including phase IV of new or improved drug regimens, vaccines and diagnostics, as well as research on the application of these products in health services and disease control programmes, with studies on pharmacovigilance, delivery or accessibility and controlled community-based interventions, all according to the high standards imposed or inspired by clinical trial regulations (GCP, Good Clinical Practices).

"Upstream" (basic and translational) and /or "downstream" (health systems) research are scientific fields with distinct infrastructures, disciplines and cultures, and should for now be managed by their own constituencies, possibly under a common umbrella structure.

The evolution from EDCTP-I over EDCTP-II to a broader ERA will follow a progressive, stepwise approach with clear commitments, responsibilities, timelines and deliverables in a transparent and realistic Logical Framework. The co-decision would be taken for the full period and budget of EDCTP-II (2012-2020). However, they would be divided over terms of three or four years, each with specific objectives and targets, strategic and action plan. Progress will be monitored on a six-monthly basis and evaluated at the end of each term, (re)defining the logical framework and (co-)funding provisions for the next term. The interim contract renewals would be a transaction between the EEIG / EDCTP and the EC, without requiring new co-decisions.

6. Governance of EDCTP-II

In terms of funding, governance and partnerships, EDCTP-II would from the European side build on the principles of Article 185 (ex-169), i.e. increasing programmatic coordination and integration of national efforts, progressive transfer of project-based funding to a common pot with single review, co-funding and co-management by the EC. However, EDCTP is much more than an ERA; in fact, the EEIG can only be its collaborative European arm. The EDCTP programme as such takes place in, and belongs indeed to the African partner countries. Apart from the considerable input from Sub-Saharan African institutions, communities and ministries, the ultimate authority over the activities befall to the governments representing the populations which take part in the research and who should benefit from its results. In line with the Paris-Accra principles and the EU's Strategic European Framework for International Science and Technology Cooperation, EDCTP-II will further develop a governance structure that respects the African ownership as well as the European partnership and input.

By 2020, EDCTP will be governed by a legal structure in which the African ownership as well as the European partnership are fully embodied

For the sake of continuity and momentum, EDCTP would for at least one or two three-year terms maintain its EEIG format. However, it would on the short term further streamline its governance and management, and optimise within current legal boundaries the representation of African partners the EC in the General Assembly (GA).

In the GA, only member states that contribute a firm upfront commitment (see below) will have full EEIG member status. Other European members will be associated members, upgradable once their upfront commitments are satisfactory. The GA will delegate specific powers to a small Executive Board (EB), with a majority of full members. A lean ES will be fully responsible for the execution of the Programme and be accountable to the GA and/or EB. The Partnership Board will be transformed in a Scientific Advisory Board (SAB) focusing on research priorities, including capacity needs and relations to third parties. The Developing Countries Coordination Committee will, in consultation with the African GA members, transform itself into a structured and mandated representation of the participating African countries and institutions. This African representation should eventually become an equal counterpart of the European EEIG. In the second or third term of EDCTP-II, the legal format of EDCTP will be reconsidered so as to allow an equitable governance system. In the new format, the European EEIG, or its successor, and its African counterpart should take full authority and responsibility for their respective contributions and resources.

An annual conference, to be held alternately in Europe and Africa will also serve as a democratic forum in which researchers can have direct input in strategies and governance.

7. Co-funding principles of EDCTP-II

Apart from the EC contribution, the resources of EDCTP consist mainly of (1) In-kind and cash resources of national programme activities linked to EDCTP, managed by the MS; (2) Cash contributions of EU member states to a common pot at EDCTP; (3) In-kind and cash contributions of African partners to EDCTP; (4) Contributions from third parties. Resource types 1 and 2 were, and remain the most important in political and legal terms, as they constitute the MS co-funding conditional to the EC contribution. EDCTP-II must acquire an innate, robust and transparent and predictable co-funding system. In addition, development aid agencies at national and community level should contribute to capacity building, while science agencies should mainly cover the research *per se*. The resources coming from African and external partners (type 3-4) must become more visible, structured and important.

By 2020, contributions for research and capacity building by MS, African partners and third parties will be accounted for in a transparent system that guarantees compliance with co-funding rules and promotes integration of national programmes

During EDCTP-I, the acquisition, certification and management of national co-funding has been assured on a project-by-project and member-by-member basis. This approach has been extremely complex and burdensome for all stakeholders, not least the scientists and African partners. Whereas conditional co-funding in EDCTP-II will remain inherent to the 185 principles, the system must become more transparent, predictable and manageable. A first prerequisite is binding and substantial upfront, auditable commitments by at least a number of MS to the joint programme. Only MS which comply with this requirement will have the status of Full Member; their programmatic co-funding will exempt them from project-by-project co-funding. Other participating MS must provide a credible indication of additional resources on a call-year-by-year, call-by-call or project-by-project basis. They will have the status of Associated Member, and still have to ensure co-funding on a project basis. MS commitments can be in kind or in cash, to a virtual or a true common pot, for research and/or for capacity strengthening. However, minimal and gradually increasing requirements will be determined for upfront, cash and true common pot contributions, for the MS as a group and for each MS individually. The common and individual co-funding efforts will be monitored and audited annually; consistent shortfalls will be penalised.

The Joint Programme of EDCTP will be considerably extended and reinforced. In addition to a programme for joint project calls, it will explicitly describe a common strategy to pursue EDCTP objectives, how national efforts are or will be aligned, and how they fit into the joint programme. The progress of these national activities, and of how they are further integrated in the joint programme, will be part of EDCTP's reporting and monitoring system. Contributions that remain under MS administration are eligible as co-funding on condition that the national projects they relate to are explicitly framed in the joint programme. The redefinition of the African representation will be combined with an evaluation of the African contributions to EDCTP, to be further monitored with no bearing on the principle of African programme ownership. The longer term perspective, extended mandates and renewed partnership vision of EDCTP-II will be used to strengthen and increase strategic alliances, attract money from other funding sources and implicate aid agencies.

8. Tentative roadmap of EDCTP-II

EDCTP-II will pursue its objectives with a step-wise approach over a period of ten years, including one preparatory year (2011). The nine activity years will be divided over terms of three or four year each. The strategic vision will be translated in a logical framework that will guide actions, monitoring and evaluation. The contract between EC and EDCTP will be updated for every term. Depending on achievements and external circumstances, the subcontracts for the next term including budget allocations may be adapted. The continuation of EDCTP-I will partly coincide with EDCTP-II. The two programmes will remain separated in financial and administrative terms, but obviously integrated as to strategy and coordinated as to operations. In a still tentative time frame, anticipated and preliminary milestones include:

2011: Co-decision on EDCTP-2
Definitive agreement on upfront commitments
Preparation of programme details and contract under prevailing FP rules
Negotiation of alliances for extending further to diagnostics (TDR, FIND, BMGF,...) [23]

2012: Launch of EDCTP-2 (first term)
Extension to diagnostics and Phase IV

2013: EDCTP-2 up and running as successor to EDCTP-1

2014: African contribution and representation proposed
Negotiations of alliances for extension to NTDs (TDR, DNDi, BMGF, ...)
First term assessment and second term signature

2015: Launch of second term
Extension to NTDs
African contribution and representation agreed, adapted legal format investigated
Negotiation of alliances for intervention research (TDR, BMGF, GFAMT, MMV, IAVI, TB-Alliance, AERAS, DNDi, ...)

2016: Extension to intervention research
African representation equalised, possibly with adapted legal format

2017: Second term assessment and third term signature

2018: Expanded EDCTP-II fully operational

2019: Preparation for new programme period including IER and Impact Assessment

2020 New co-decision and contract for third programme period as structured ERA

[23] Acronyms of organisations cited: TDR = WHO Special Programme for Research and Training in Tropical Diseases; BMGF = Bill and Melinda Gates Foundation; FIND = Foundation for Innovative Diagnostics; DNDi = Drugs for Neglected Diseases initiative; GFAMT = Global Fund to fight AIDS, Malaria and Tuberculosis; MMV = Medicines for Malaria Venture; IAVI = International Aids Vaccine Initiative; TB-Alliance = Global Alliance for TD Drug Development; AERAS = Global TB Vaccine Foundation)

9. Budgetary projections

During EDCTP-I, the total expenses including MS contributions will exceed 500 million € over a period of 7 years. In view of the slow start-up, at cruising speed the budget for maintaining and consolidating the current activities can be roughly estimated at 100 million € annually. For ten year period, the total budget for the current core tasks of EDCTP would thus amount to 1 billion €.

As the programme unfolds, however, even within the current three-disease portfolio there will be an increasing need for fully-fledged Phase III trials and considerable extra resources. This is particularly the case for vaccine trials as these require very large study populations, intricate surveillance and long-term follow-up. In a conservative estimate, a few of such trials would increase the budgetary needs by 50 to 100%. As these needs would grow progressively, an additional sum of 500 million € over the ten-year period would seem a minimal ball park figure.

The extension to diagnostics could partly capitalise on existing capacities; on the other hand, investments in disease-specific and/or multivalent reference laboratories would greatly enhance general clinical trial capacities. Similar considerations can be made for the thematic extensions to NTDs and intervention research. While closer estimates can and should be made, it is reasonable to project for these three extensions a budget similar to the current narrow scope of phase 2/3 trials for AIDS, malaria and TB, i.e. another 1 billion €.

As a very preliminary ball park figure, the total budget for a full EDCTP-II programme as described above would thus be in the range of 2.5 billion € over a period of 10 years or an average of 250 million € annually, to be shared by the EC (1 billion €), the MS (1 billion €) and and third parties (0.5 billion €). This estimate does not yet include the in-kind and cash contributions of the African partners. The annual budget would grow over the years as the programme develops. Envelopes could be negotiated and allocated per term, depending on progress and circumstances e.g. with following projections:

Term	Period	Scope extension	Contributions		
			MS	EC	3d parties
1	2011-2014	DIA + Ph-IV	250 M€	250 M€	100 M€
2	2015-2017	NTD + Intervention	350 M€	350 M€	150 M€
3	2018-2020	Completed	400 M€	400 M€	250 M€
Total	10 years		1,000 M€	1,000 M€	500 M€

It should be noted that a considerable, probably the larger part of this budget may not constitute or require new resources. Consistent with the 169 / 185 principles, the MS would in the first place coordinate and integrate existing activities (including the scope extensions) and resources, possibly with a partial and progressive re-orientation to a common pot. The EC contribution could partly be drawn from current calls on poverty-related diseases and health services research. Not least, as envisaged in the Connecting the Chain meeting, national international aid ministries and DG Development would substantially contribute to the capacity strengthening component of the programme.

10. Reminder: conditions and options for EDCTP-II

A. CONDITIONS FOR EDCTP-II, ACCORDING TO IER 2009:
[in principle (to be) met in above proposal]

1. Satisfactory Implementation of the IEE 2007 recommendations for EDCTP1
2. Agreement on annual performance criteria for EDCTP2
3. Solid upfront financial commitment by individual participating Member States
4. Agreements on a common financial pot in cash and rules for in kind contribution

1. Satisfactory Implementation by EDCTP of the IEE recommendations for EDCTP1:

To EDCTP:

a. Define a clear, convincing and realistic EDCTP strategy with a common shared vision, clearly defined contributions from each partner and equitable sharing of results
b. Make the General Assembly more political
c. Expand association with major Product Development Public/ Private Partnerships for ac cess to know-how and to provide visibility and avoid unnecessary duplication
d. Simplify and streamline co-funding, from a virtual to an actual common pot, in order to reduce operational complexity and allow African initiation of EDCTP projects.

To EDCTP Member States:

a. Interested Member States should directly finance an EDCTP "common funding pot"
b. Member States should refrain from imposing national criteria, and accept one integrated scientific and ethical evaluation conducted by EDCTP, utilizing a pool of the best experts

To the European Commission:

a. Create joint DG Research / DG Development platform to engage dialogue with EDCTP.

B. POLICY OPTIONS PROPOSED BY EC IN IMPACT ASSESSMENT ROAD MAP
[option retained = from 3 to 4]

1. **No Policy:** no successor programme, no alternative funding
2. **Programme based:** no successor programme or MS integration, funding alternatives
3. **Actual situation:** successor programme under same terms
4. **Expanded:** 3 + (i) other diseases, ii) other CT stages, iii) other geographical areas

ANNEXES: SEE FOOTNOTES