EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title **DG RTD - Impact Assessment on a proposal for a Clinical Trials Partnership Programme**

(draft version of 12 November 2012)*

(A) Context

This Impact Assessment Report accompanies the Commission's proposal for a Decision on the participation of the European Union (EU) in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2), requested by the Member States participating in EDCTP in 2010 and reconfirmed in 2012 with the release of the Strategic Business Plan (SBIP), in which the participating European states outline a strategic research agenda and concrete up-front commitment of €500 million. EDCTP was established in 2003 in response to the global health crisis caused by three main poverty-related diseases (PRD) - HIV/AIDS, malaria and tuberculosis - and to the EU's commitment to achieving the Millennium Development Goals (MDG) by 2015. The EDCTP's core objective is to accelerate the development of new clinical interventions (drugs, vaccines, and microbicides) to fight the three major PRD in sub-Saharan Africa, and to improve the quality of research in relation to these diseases, including the ethical review capacities and regulatory environment.

(B) Overall assessment

The report needs to be strengthened significantly in several important respects. First, it should better describe the context for this initiative (Article 185) and provide a brief description of how the current programme works in practice, the roles of key actors and the relationship with EU external aid policies and with the Multi-annual Financial Framework (MFF) process. It should clarify the precise problems that this initiative is intended to address in particular by highlighting the deficiencies of the current programme as revealed by evaluation exercises. Second, the report should set objectives and options that are clearly linked to the specific problems. It should explain the rationale for the chosen geographic scope and diseases to be covered under the preferred option. Third, given the very high costs of conducting clinical trials, the report should demonstrate what the expected impact of the substantially increased EU budget options in terms of effectiveness and efficiency is likely to be. It should explain the assumptions underlying the levels of matching funding from private donors, beneficiaries and participating states and should consider the risks, and the consequences, if this level of funding does not materialise.

Given the nature of these concerns, the IAB requests DG RTD to submit a revised version of the IA report on which it will issue a new opinion.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Better explain the policy context and the specific problems. The report should better describe the context for this initiative and in particular should clarify upfront that it falls under Article 185 of the TFEU which foresees the participation of the EU in the joint implementation of national programmes for research and development. It should provide a brief description of how the current programme works in practice clearly highlighting the roles of the EU, Member States, beneficiary countries and private donors. The report should clarify how the co-funding process is organised, how projects are selected and how they come to life. It should better describe the linkages between this programme and any other financing mechanisms for clinical trials on poverty related diseases. It should also explain the relationship with the EU's external aid policies. The report should clarify the link to the MFF process and whether that decision may affect the scope of the options considered. It should also clearly explain the precise problems that this initiative is intended to address (e.g. the need for more clinical trials, extension of scale of trials and/or geographic scope etc.) in particular by highlighting the strengths, weaknesses and deficiencies of the current programme as revealed by the evaluation exercises. It should explain to what extent the budget foreseen for the current programme was eventually used, and what implication the suggested increase in budget for the follow-up programme would have on co-financing partners.

(2) Clarify the objectives and better explain the options. Based on a revised problem definition, the report should include a revised set of objectives that address in a more focused manner the specific problems that this initiative is intended to address. For example, the report should explain and justify the level of integration of Member States' research activities in this field that is expected to be achieved. In terms of the overall objective of eliminating or reducing the level of poverty related diseases, it should explain why the problems should be tackled by increasing the scope and scale of clinical trials as opposed, for example, to increasing the EU aid budget in this area. In order to strengthen the intervention logic the report should establish clear links between the options, the problems and the objectives, as revised. It should clarify the geographic scope of the new proposals and explain why extension of the scope beyond sub-Saharan Africa is not considered. It should also clarify the increased scope in terms of diseases and clinical trial phases covered, explaining the rational for any changes and demonstrating how these are linked to the problem drivers.

(3) Strengthen the assessment and comparison of the options. The report should better demonstrate, in quantified terms as much as possible, what the added value of the increased budget is expected to be, particularly in terms of the effectiveness of the programme. For example, given the very high costs of conducting clinical trials the report should discuss in greater depth what the expected impact of the increased budget as envisaged under the preferred option, is likely to be. The report should explain why the increased budget does not appear to lead to at least a pro-rata increase in the numbers of clinical trials. It should also explain the assumptions as well as the dependency/conditionality between the level of EU funding and the levels of matching funding from private donors, beneficiaries and participating States. It should discuss the risks and their probabilities in greater depth, in particular, the feasibility of achieving the expected increase in private/3rd party contributions in light of the failure to achieve the target for this category under the previous programme and considering the constraints arising from the ongoing economic crisis. The report should clearly explain the short and long term costs and benefits for all stakeholders including the pharmaceutical sector.

Finally the report should explicitly compare the options in terms of effectiveness, efficiency and coherence.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The views of different categories of stakeholders should be better integrated into the text.

(E) IAB scrutiny process	
Reference number	2010/RTD/016
External expertise used	No
Date of IAB meeting	5 December 2012