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**

(re-submitted draft version of 31 January 2013)*

(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 further strengthened in several respects. First, it should better explain why the expected levels of third party funding were not realised under the current Programme. Second, it should still further clarify why extension of the scope beyond sub-Saharan Africa is not considered. Third, it should clarify how and why the specific targets, such as carrying out 120 clinical trials, were chosen and better explain how these address the problems drivers. Fourth, it should explain the role and expected level of third-party funding (such as from African countries themselves or the private sector). The report should clarify how the extra budget will contribute to the goal of developing a new vaccine and how the overall performance of the programme will be measured.

(C) Main recommendations for improvements

(1) Further strengthen the problem definition. While the problem definition has been improved, the report should still better explain why the expected levels of third party funding were not realised under the current Programme. The report should also strengthen further the linkages between this programme and the EU's external aid policies (e.g. DCI and EDF). It should still better explain the link to the Multi-annual Financial

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

Framework process and the extent to which that decision affects the scope of the options considered. It should explain to what extent the budget foreseen for the current programme was eventually used. The report should outline in a more consistent way how projects are cleared ethically, to cover adequately the concerns raised in the public consultation. It should also outline in more detail which risk mitigating strategies are used during the clinical trials phase of projects (e.g. how the programme deals with the possible occurrence of drug-resistant strains).

(2) Clarify the objectives. The report should still better explain why extension of the scope beyond sub-Saharan Africa is not considered. It should also explain the basis for the various targets set under operational objectives such as achieving 1000 peer reviewed scientific journals and at least 120 clinical trials supported. It should clarify how and why these targets were chosen and explain their relationship to the specific problems. For example, how does achievement of these targets address the underlying problem drivers such as lack of investment and fragmented public support? It should explain why targets for third-party funding (such as from African countries themselves or the private sector) are not included. Any inconsistencies between the operational targets and the monitoring indicators proposed for the purposes of evaluation should be removed (e.g. the number of clinical trials to be carried out is not the same).

(3) Strengthen the assessment of the impacts. The report should further clarify what the impact of the increased budget is expected to be. For example, the key difference according to the report between the preferred option and other options is that the increased budget would have the magnitude and position to support 'ambitious' clinical trials including development of a TB vaccine. However, the report should clarify how the extra budget will contribute to that goal and what exactly the contribution of this programme will be. In that context, how the performance of the programme will be measured should be better explained. The role of the private sector in the clinical trials process should also be clarified particularly given the potentially significant economic benefits for the pharmaceutical sector arising from the development of a new vaccine for TB, as mentioned in the report.

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	Written procedure The present opinion concerns a resubmitted draft IA report. The first opinion was issued on 7 December 2012