

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Health research and development demonstration projects

Report by the Director General

1. The Executive Board at its 136th session noted an earlier version of this report.¹ In particular, the information in Table 2 below has been updated.

2. In May 2013, the Health Assembly adopted resolution WHA66.22, in which the Director-General was requested, *inter alia*: to facilitate the implementation of a few health research and development demonstration projects to address identified gaps that disproportionately affect developing countries; and to report on the implementation of health research and development demonstration projects to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session. In January 2014, the Executive Board considered the report of the Global Technical Consultative Meeting of Experts on the Identification of Health Research and Development Demonstration Projects and the Global Technical Consultative Meeting of Member States on the Identification of Health Research and Development Demonstration Projects.² The Board then adopted decision EB134(5), in which the Director-General was requested, *inter alia*, to start convening meetings with stakeholders with a view to developing the project plan and mobilizing the financial resources necessary for implementation of the projects.

3. In May 2014, the Health Assembly adopted decision WHA67(15), in which, *inter alia*, the Health Assembly noted the progress made in implementation of resolution WHA66.22 and decision EB134(5); and requested the Director-General to expedite the process of the remaining four projects, in addition to the four already agreed, and to report on progress to the 136th session of the Executive Board. In the decision WHA67(15), the Health Assembly also recognized the indicators to measure success in implementing the health research and development demonstration projects, and requested the addition of an analysis of the extent of innovative components being implemented by the projects, including financing, the use of open access models, multisectoral research platforms, and delinkage, among other criteria.

¹ See document EB136/30 Add.1, and the summary records of the Executive Board at its 136th session, ninth meeting.

² Document EB134/27, Annex 1 and Annex 2, respectively.

PROGRESS ON SELECTED DEMONSTRATION PROJECTS

4. In order to facilitate the implementation of the selected demonstration projects, the Secretariat convened stakeholders meetings for the four projects between 7 and 10 May 2014 at WHO headquarters in Geneva. These meetings provided an opportunity to discuss project plans and resource needs.

5. In decision EB134(5), the Executive Board also requested that “the Director-General ... where appropriate, consider coordinating or combining projects that are closely interrelated or target the same disease or type of product, in order to maximize their effectiveness”. In response, and in light of the needs and limitations of the proponents of the United States Food and Drug Administration’s leishmaniasis project, the two leishmaniasis projects were combined into one. The resulting project, “The Visceral Leishmaniasis Global R&D and Access Initiative” is managed by the Drugs for Neglected Diseases initiative in cooperation with United States Food and Drug Administration.

PROGRESS MADE ON THE OTHER FOUR DEMONSTRATION PROJECT PROPOSALS

6. In response to decision WHA67(15), the Secretariat organized a workshop in coordination with the Oswaldo Cruz Foundation. Hosted at the Foundation’s headquarters in Rio de Janeiro, Brazil, on 26 and 27 August 2014, the workshop brought together both technical experts and the proponents of the proposals that had not passed the original assessment made on 10 March 2014 by the former Chair and Vice-Chair of the Consultative Expert Working Group on Research and Development: Financing and Coordination.¹ The list of participants, agenda and detailed meeting report are available online on the WHO website.¹

7. Following the workshop, the Secretariat offered the projects’ sponsors the opportunity to revise their proposals based on the experts’ recommendations. One applicant withdrew their proposal from the process and the other three proponents submitted revised proposals to the Secretariat.

8. On 7 November 2014, the former Chair and Vice-Chair of the Consultative Expert Working Group re-evaluated the revised proposals. The meeting followed the same format and process as the assessment made on 10 March 2014. The original six Member State observers were invited; of these, Malta, Philippines and Sri Lanka participated. Two of the three projects examined were assessed to be in strong alignment with the principles and recommendations of the Consultative Expert Working Group. The third project showed some improvement, but additional clarification was required. The proposal was re-evaluated, but was found to remain below the threshold set for the previously selected demonstration projects. The meeting agenda and detailed results of the assessment can be found online.¹

9. In conclusion, the following two projects meet the requirements to qualify as demonstration projects:

- “Multiplexed point-of-care test for acute febrile illness” – a project submitted by the Translational Health Science and Technology Institute, India.

¹ The results of the original assessment of 7+1 shortlisted demonstration project proposals, conducted on 10 March 2014, are available online at http://www.who.int/phi/implementation/cewg_background_process/en/ (accessed on 18 December 2014).

- “Development of a vaccine against schistosomiasis based on the recombinant Sm14 a member of the fatty acid binding protein: controlling transmission of a disease of poverty” – a project submitted by the Oswaldo Cruz Foundation, Brazil.

10. The project from Council of Scientific and Industrial Research, South Africa (entitled “Demonstration of the potential of a single dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system”) requires further improvement before it meets the requirements for qualifying as a demonstration project.

INDICATORS TO MEASURE SUCCESS IN THE PROCESS

11. As requested by the Health Assembly in decision WHA67(15), the Secretariat is proposing additional indicators for analysing the innovative components of the selected demonstration projects (Table 1).

Table 1. Additional indicators for selected demonstration projects

Score	Innovative components Recommendation of the Consultative Expert Working Group		Description of criteria
	Delinkage		The project clearly delinks the cost of research from the price of the product.
	Open knowledge approaches		The project generates knowledge that is free to use without legal or contractual restrictions and that utilizes open approaches to research and development and innovation (including, precompetitive research and development platforms, open-source and open-access schemes).
	Licensing for access		The project uses licensing agreements or other instruments to ensure that the population in need has access to and can afford any new products.
	Financing		The project uses pooled funds, milestone prizes and other innovative financing mechanisms (including taxes) or sources of funds (such as those from developing countries, disease-endemic countries or the emerging economies).
	Coordination	Multisectoral/ disciplinary research platforms and/or partners	The project links data and information coming from multiple sources and/or engages with a diversified array of partners, particularly in developing and disease-endemic countries.
		Cross-regional	The project involves institutions spanning multiple countries and regions.
	Capacity building and technology transfer		The project builds capacity in developing and disease-endemic countries. The project uses transfer of technologies as a means to increase capacity in developing and disease-endemic countries.

12. The proposed framework assigns the following numerical grades as follows:

- 2: demonstrates a recommendation of the Consultative Expert Working Group
- 1: weakly demonstrates a recommendation of the Consultative Expert Working Group
- 0: does not demonstrate a recommendation of the Consultative Expert Working Group

13. The full assessment of the three demonstration projects against both process and innovation indicators, can be found online.¹ Table 2 below provides a summary of the results.

Table 2. Initial assessment of selected demonstration projects – process and innovation indicators

Scores (maximum)	Visceral Leishmaniasis Global R&D and Access Initiative	Exploiting the pathogen box	Development of easy-to-use and affordable biomarkers as diagnostics for types II and III diseases
A. Process indicators (14)	12	11	11
Part 1 – Project plan (8)	8	8	8
Part 2 – financing (6)	4	3	3
B. Innovation indicators (12)	12	11	11
Delinkage (2)	2	2	1
Open knowledge approaches (2)	2	2	2
Licensing for access (2)	2	2	2
Financing (2)	2	1	2
Coordination (2)	2	2	2
Capacity building and technology transfer (2)	2	2	2
OVERALL (out of a maximum of 26)	24	22	22

14. The scores of the three demonstration projects indicate that significant technical progress has been made in the design of the project plans (all three projects obtained the maximum score under Section A, Part 1 – see Table 2 above). However, in at least two cases, financial resources are not sufficient to bring these plans to completion. The qualitative analysis scores confirm that the selected projects have the characteristics expected for demonstration projects.

15. During the Executive Board's consideration of this subject at its 136th session, Board members generally welcomed the progress made in the implementation and further development of the demonstration projects. Brazil, Norway and Switzerland announced financial contributions to the strategic work plan for improved monitoring, coordination and funding of health research and development. In addition, Switzerland and Norway offered to complement at the level of 50% any

¹ Selected Health R&D Demonstration Projects: Indicators for Measuring Success – Analysis by the Secretariat, available online at: http://www.who.int/phi/implementation/cewg_background_process/en/.

contribution made by a low- or middle-income country, up to a maximum level. South Africa indicated that their financial contribution will be announced at a later date.

ACTION BY THE HEALTH ASSEMBLY

16. The Health Assembly is invited to note the report and provide guidance for future steps.

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