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 Secretariat

1. In January 2014, the Executive Board at its 134th session adopted decision EB134(5), in which it requested that the Director-General consider the demonstration projects in the order listed in document EB134/27 and, taking into account the additional information received, with the participation of the Chair and Vice-Chair of the Consultative Expert Working Group, and one Member State from each region, as observers, as appropriate, start convening virtual or direct meetings with stakeholders interested in funding and/or implementing the projects; with those meetings aiming to develop the project plan and mobilize the financial resources necessary for implementation of the projects.

2. In this decision the Board further requested that the Director-General develop, with respect to the mandate of resolution WHA66.22, relevant indicators to measure success in the process and submit them to the Sixty-seventh World Health Assembly.

CONSIDERATION OF THE DEMONSTRATION PROJECTS

3. This report describes the outcome of a meeting convened in Geneva on 10 March 2014 to examine the additional information received on the 7+1 short-listed demonstration projects. In accordance with decision EB134(5), six Member States were invited as observers, one from each region. The purpose of the review was to determine which of the eight proposals had a design that incorporated innovative financing and coordination mechanisms, and were ready to be implemented. The detailed proceedings of the meeting are available on the WHO website.¹

4. Based on the outcome of the review, the Secretariat is proceeding with the convening of stakeholder meetings for the following four projects.

   • The Visceral Leishmaniasis (VL) Global R&D & Access Initiative (proponent: Drugs for Neglected Diseases initiative)

¹ For a summary of the meeting and details of the demonstration project proposals and additional information received see http://www.who.int/phi/implementation/phi_cewg_meeting/en/ (accessed 21 March 2014).
• Exploiting the pathogen box: an international open-source collaboration to accelerate drug development in addressing diseases of poverty (proponent: Medicines for Malaria Venture)

• Development of Class D CpG oligodeoxynucleotides (D35) as an adjunct to chemotherapy for cutaneous leishmaniasis and post kala-azar dermal leishmaniasis (proponents: United States Food and Drug Administration et al.)

• Development for easy to use and affordable biomarkers as diagnostics for types II and III diseases (proponents: African Network for Drugs and Diagnostics Innovation et al.)

5. The Secretariat is organizing a meeting for the proponents of the four remaining demonstration projects to explore their interest in refining their proposals by introducing significant innovative features in the project design, and is taking steps to provide them with the necessary technical mentoring.

6. Information on progress will be reported to the Sixty-eighth World Health Assembly in May 2015, through the Executive Board at its 136th session in January 2015.

INDICATORS TO MEASURE SUCCESS IN THE PROCESS

7. Product research and development is a long process, most often requiring many years of work and investment. The four demonstration projects selected in March 2014 are therefore unable to deliver new products within the one year reporting timeframe prescribed in resolution WHA66.22. Likewise, the efficacy of the specific innovative financing and coordination mechanisms to be deployed as part of the four demonstration projects cannot be fully assessed in less than one year. Therefore, it is proposed that the indicators submitted to the Sixty-seventh World Health Assembly and which will be used to measure success in the report of the Secretariat to the Sixty-eighth World Health Assembly will only focus on process, with success defined as a demonstration project that is fully developed, with identified partners and appropriate funding, and ready for implementation.

8. A successful project needs a clear and robust project plan and a funded budget. A project plan defines:

- the organization or institution responsible for the overall project; in the case of the demonstration projects, this corresponds to the party who has submitted the proposal
- the activities to be implemented in chronological order
- the organizations and/or institutions responsible for each activity
- the timeline for completion of each activity
- the deliverables and/or outputs of each activity
- the major milestones of the project
- the cost of each activity.

The project budget identifies the total cost of the project, including direct, indirect and overhead costs, and the source of funding.
9. The indicators to measure success will concentrate on the following areas:

(a) project plan:

(i) whether the project plan clearly identifies the following key elements: partners, activities, milestones, timelines and deliverables
(ii) whether each activity of the project plan has a responsible implementing partner
(iii) number of implementing partners

(b) financing:

(i) percentage of funds pledged against budget
(ii) number of funders.

The annexed assessment framework provides some further information.

**Evaluation**

10. It is proposed that, besides the report on process to the Sixty-eighth World Health Assembly (see paragraph 6 above), another assessment be conducted during 2017 (three years after the initiation of the projects), focusing on progress towards the development of new products and on review of the efficacy of innovative financing and coordination mechanisms.

11. The overall evaluation of the demonstration projects will consist of a combined analysis of the assessments of the four individual projects and an overall comment setting the analysis in context and highlighting lessons learnt.

**ACTION BY THE HEALTH ASSEMBLY**

12. The Health Assembly is invited to note this report and provide guidance on the indicators to be used for reporting to the Sixty-eighth World Health Assembly in May 2015, through the Executive Board at its 136th session in January 2015.
ANNEX

ASSESSMENT FRAMEWORK

Part 1. Project Plan (maximum 8 points)

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<th>Yes</th>
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<td>1 Project plan</td>
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<td>1.1 Major milestones identified</td>
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<td>1.2 Activities to be implemented in a chronological order</td>
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<td>1.3 Organizations and/or institutions responsible for each activity identified, with clear roles for each</td>
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<td>1.4 Coordination mechanisms and governance in place</td>
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<td>1.5 Agreed timelines for completion of each activity</td>
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<td>1.6 Deliverables and/or outputs identified for each activity</td>
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<td>1.7 Cost of each activity identified</td>
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<td>1.8 Number of implementing partners</td>
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Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for number of implementing partners:

- 1 partner = 0
- 2 to 5 partners = 0.5
- More than 5 partners = 1
Part 2. Financing (maximum 6 points)

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<td>2.1 Overall budget defined</td>
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<td>2.2 Percentage of funds pledged for first year of the project</td>
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<td>2.3 Percentage of funds pledged for second and third years of the project</td>
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<td>3 Engagement of donors</td>
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<td>3.1 Number of funders</td>
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Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for funds pledged for the first year of activities:

- Funds pledged corresponding to 0% to 50% of first year budget = 0
- Funds pledged corresponding to 50% to 75% of first year budget = 1
- Funds pledged corresponding to more than 75% of first year budget = 2

Scoring for funds pledged for second and third years of activities:

- Funds pledged corresponding to 0–30% of 2nd and 3rd year budget = 0
- Funds pledged corresponding to 30–60% of 2nd and 3rd year budget = 1
- Funds pledged corresponding to more than 60% of 2nd and 3rd year budget = 2

Scoring for number of funders:

- 1 funder = 0
- 2 to 3 funders = 0.5
- More than 3 funders = 1

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