R&D Demonstration Project\(^1\)

*R&D demonstration projects were selected as per the Executive Board decision EB134(5) following review by the former Chair and Vice-Chair of the CEWG*

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1. **Title of the project:**

   Multiplexed Point-of-Care test for acute febrile illness (mPOCT)

2. **Proponent/s of the project:**

   Translational Health Science and Technology Institute (THSTI), India

3. **Project executive summary:**

   Acute febrile illness (AFI) is common in the tropics and sub-tropics and can be caused by very diverse pathogens. Differential diagnosis of these etiologies based on clinical criteria alone is not possible as clinical signs and symptoms of most of these infections are very similar and the correct diagnosis is only possible using pathogen specific diagnostic tests. In low income countries, many preventable deaths occur because of delayed or lack of correct diagnosis. Based on these facts, the availability of multiplex test which can quickly identify a pathogen from a group of pathogens that cause similar symptoms is of paramount importance. Infectious diseases which causes major burden of AFI in tropics and subtropics and are also amenable to multiplexing include, Malaria, Dengue, Typhoid/Paratyphoid, Leptospirosis, Scrub Typhus, Chikungunya and very recently Zika virus. Despite the strong need, no multiplex POCT is available in market, which can be used in resource-limited settings for the detection of multiple etiologies of tropical fevers. Although, individual (singleplex) POCTs for these infections are commercially available but most of these tests are of poor quality. Only some of the POCTs for malaria, and to some extent Dengue NS1 Ag, fulfill WHO ASSURED criteria. Because of the issues in available singleplex tests, we are not only developing a multiplex POCT for different etiologies of fever but also incorporating high quality diagnostic intermediates in the test so that the performance for each target can be improved. A very important objective for this project is also to generate high quality reference/sera panel for evaluation and quality control of manufactured test. The goal of this project is to develop high quality and vigorously evaluated multiplexed POCT for tropical fevers.

   The successful development and implementation of this multiplexed POCT will not only help health care providers in choosing appropriate treatment option for the patient but will also help in controlling the problem of antimicrobial resistance because of the appropriate use of antimicrobials. This product may also be useful for surveillance purpose.

4. **Innovative aspects of the project**

   - Delinking of R&D cost from the cost of final product
   - Innovative licensing approaches that secure access
   - Capacity building and local production in developing countries

5. **The current status of the project**

   The project is under implementation process using proponents and project partners own resources. The *Ad Hoc* committee has recommended the award, which is yet to be received.

6. **Progress towards activities since the start of the project**

   In last four months of the project, we were able to establish new collaborations for the generation of reference sera panel. There has also been progress on the malaria assay development.

7. **The first-round award received/expected from WHO based on the recommendation of the *Ad Hoc* committee**
Committee

The first-round of award, of USD 997,699 for 10-months, based on the recommendation of the Ad Hoc committee is expected to be received from WHO.

8. Future developments and challenges

We have recently started the project and there is substantial to achieve:

- Generation of reference sera panel for different tropical fever etiologies.
- Generation of multiplex assays cassette.

We estimate a cost of ~18 million USD in addition to the sanctioned sum during the tenure of the project.

9. Other sources of support

Internal resources from THSTI and University of Turku

10. Any additional comments

None.