R&D Demonstration Project

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

1. Title of the project
Development of Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases

2. Proponent/s of the project
ANDI - African Network for Drugs and Diagnostics Innovation with China NDI and African partners

3. Project executive summary
The overall objective of the project is to demonstrate specific innovative aspects of R&D coordination and financing towards the development of quality assured diagnostic tools for neglected tropical diseases that are easy to use and affordable in rural communities of disease endemic countries.

Specific aims of the project are
i) Development of protein microarrays containing 8000-10,000 selected antigens for individual diseases;
ii) Probe well-characterized infected human sera from China, Africa and identify serodiagnostic antigens;
iii) Develop, evaluate, validate and optimize field deployable tests for each agent and incorporate m/eHealth; and-
iv) Seek regulatory approval and promote use of products in endemic area.

The key deliverables of the project in first five years include:

i) 8000-10,000 gene clones of 4 parasitic diseases;

ii) 8000-10,000 recombinant proteins of 4 parasitic diseases;

iii) Four kinds of biochips of parasitic diseases;

iv) Four diagnostic kits which can meet the current challenges in diseases control and prevention;

v) Three registered diagnostic products based on multicentre evaluation and registration.

This project is based on an innovative South-South and South-North partnership that aims to address the diagnostics development and access challenges of types II and III diseases. The project leverages: i) high-throughput biomarker screening platform developed by China NDI research groups towards the development of suitable diagnostic kits, ii) available capacity for diagnostics development and evaluation in Africa through the ANDI Centres of Excellence and other global partners, and iii) the strength of ANDI in the coordination of R&D, open innovation, technology transfer/licensing, capacity building and access.

The project initially focuses on schistosomiasis, malaria (falciparum and vivax), and sleeping sickness. An m/eHealth component aims to integrate data from the project and available tests into a cell phone based diagnostic platform in Africa. This potentially revolutionary cell phone diagnostics is being implemented in collaboration with EASE-Medtrend Biotech.

4. Innovative aspects of the project

- Collaborative approaches: the project is a novel South South and South North partnerships coupled with open innovation and knowledge sharing mechanism in support of diagnostics development;

- Strengthen R&D and production capacity including through technology transfer in/to developing countries;

- Effective & Efficient coordination: the project promotes coordination among global players;

- De-linkage: cost of final products will be delinked from the cost of R&D;

- Licensing and IP: utilize licensing approaches that secure access to R&D outputs and final product; and,
Some future significant milestones and timelines include:

• Financing: demonstration of pooled financing for R&D.

5. The current status of the project

The project is in the implementation phase. Although the implementation started in mid-2015 with ANDI and China NDI resources, the project agreement was signed between UNOPS/ANDI and WHO in October 2015, and funding was received in November 2015. Therefore the project formally started on November 1, 2015.

As indicated above, the award for the first year of the project from WHO has already been received.

6. Progress towards activities since the start of the project

a) ANDI and partners formally launched the project at the 5th ANDI Stakeholders’ Meeting held in November 2015 in Nairobi Kenya. WHO/PHI and TDR were in attendance. (http://andi-africa.org/index.php/media-corner/press-release/item/189-2015-andi-stakeholders-meeting-concludes)

b) The project had a head start prior to funding from WHO and the following activities have been initiated:
   • Screening of antigens for schistosomiasis, malaria (*falciparum* and *vivax*);
   • Continued development of a schistosomiasis diagnostic kit at the Theodor Bilharz Institute (TBRI), Egypt based on monoclonal antibodies; and
   • Project leveraging existing malaria Bio-bank at partner institutions, e.g. University of Lagos, Nigeria.

c) Implemented a formal kick off and planning meeting with partners in Lagos, Nigeria in February 2016. About 20 participants from partner institutions in China (NIPD, Fudan University, Ease Medtrend), University of Lagos Nigeria, TBRI Egypt, Kenya Medical Research Institute, and others. The meeting achieved the following: i) Partners shared progress on project implementation to date including result of screens in China, status of schistosomiasis diagnostics development in Egypt and capacity building etc., ii) Optimized action plans for year one activities for every partner, iii) Updated the budget for every partner and initiated finalization of agreements and transfer of funds to partners, iv) a cell phone technology for integrating datasets and diagnostic tests was discussed and prioritized by the team. The meeting report is being placed on ANDI’s website.

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

A sum of US$1,672,556 has been received from WHO covering the period November 2015 to October 2016.

8. The first-round financial support requested (for those projects having not received the recommendation of the Ad Hoc Committee)

Not Applicable

9. Future developments and challenges

Some future significant milestones and timelines include:

i) Development or updating of project SOPs for sample collection, ethical review guidelines, updating and integration of existing datasets and databases with associated capacity building (August 2016);

ii) Development of open knowledge platform for information sharing including data, protocols (November 2016);

iii) Four bio-banks of different parasite samples (October 2016 – December 2018);

iv) Twenty African scientists and institutions trained in diagnostics R&D including sample collection, biobank development, developing microarray and other omics-based capabilities etc. (June 2015 - December 2020);

v) Four diagnostic kits which can meet the current challenges in diseases control and prevention by 2020:
   • Evaluation/validity of schistosomiasis diagnostic kit using serum and urine samples from Africa (2016–2018)
   • Development and evaluation of integrated malaria (*falciparum* and *vivax*) RDT (2017 – 2019)
   • Cell phone based diagnosis of neglected diseases (May 2016 – December 2019); and

vi) Two registered diagnostic products based on multicentre evaluation and registration 2020.
A major challenge for this project is financing. The first year of the project was funded by WHO at about 60% of what the project requested. Based on our initial five year funding needs, the project has a funding gap of about US$18,000,000.00 (Eighteen Million US Dollars) over the next five years. ANDI is hopeful that the WHO member states will scale up the funding for this and other demonstration projects.

10. **Other sources of support**

   None at the moment.

11. **Any additional comments**

   We are excited about the potential of this project to support health innovation in developing countries. We hope to be able to extend this project to emergent infections such as Ebola and Zika Virus. The cell phone part of the project promises to integrate results from this project and available RDTs into a single tool that will support rapid diagnosis of disease. The project also promises to deliver an integrated malaria falciparum and vivax to support malaria control and eventual elimination.