

**2nd Technical Meeting of African Network for Diagnostics and Drug Innovation – WHO-
WHA Demonstration Project on Diagnostics Development**

7th-8th September 2016

Shanghai, China

Background

An award from the WHA, the WHO Demo project entitled “*Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases*” is a collaborative project between ANDI and partner institutions in Africa and China. Through this project, ANDI is facilitating open innovation (using open knowledge management platforms), technology transfer, capacity building (through workshops and fellowships) as well as South-South and North-South collaboration in support of diagnostics development, production and access for neglected diseases in Africa.

Following initial consultations and planning on project implementation in February 2016, this meeting brings together partner institutions to review progress and chart out next steps. Among others, this 2-days workshop aims at:

- a. Reviewing progress in project performance and implementation of action points from the 1st Technical Meeting in Lagos;
- b. Defining the regulatory strategy for the project;
- c. Discuss opportunities for resource mobilization to ensure sustained implementation and expansion of scope of project building on the network and partnership established by the Demo project;
- d. Brainstorm on better communication among implementing partners for improved coordination and agree on next steps;

For meeting agenda and list of participants see Annex I and II.

Welcome and Introduction

Prof. Xiao-Nong Zhou, Director of the National Institute of Parasitic Diseases, Chinese Center for Disease Control and Prevention welcomed participants to the workshop. In his welcoming speech, Prof Zhou highlighted his institutions track record on the control and elimination of tropical diseases and its role as a WHO Collaboration Centre for malaria, schistosomiasis and filariasis since the 1980’s. He also touched upon the China-Africa collaboration on elimination of schistosomiasis which is focusing on two priorities, i.e. capacity building and work on snail (intermediate host) control. He further went to discuss opportunities to enhance this collaboration through the WHO Demo project by way of expanding potentials for partnership between Chinese and African Governments and Institutions.

Progress and updates from collaborating institutions

After the welcoming speech partner institutions gave a brief summary of the work they have done since the Lagos Meeting and some of the challenges they encountered in project implementation.

1. ANDI

Dr. Takele Geressu

- Plan of action for Year one of the project developed with inputs from participating institutions;
- Memorandum of Understanding signed between ANDI and collaborating institutions such as KEMRI and China NDI partners and funds transferred;
- Preparations for fellowship for 5 candidates from collaborating institutions completed and program started in NIPD this week;
- Periodic communications with partner institutions to oversee follow up actions after Lagos meeting in February 2016;
- A project proposal developed building on the work and collaboration of the WHO demo project to the German Ministry of Education and Research (BMBF);
- As discussed in Lagos, ANDI has expanded the partnership base for this project by bringing on board the University of Ibadan currently working on an innovative malaria diagnostic test.

Issues: despite initial pledges to support this project over a rolling five years, WHA has not raised enough funding for the second year of the project. This is a concern for the project and to avoid gap on implementation coupled with delays in signing of project agreements with some African partners, a no cost extension has been requested by ANDI.

2. NIPD

Dr. Chen Junhu and Kassegne Kokouvi

- Updated database on genes, proteins and omics from malaria and schistosomiasis target antigens
- Developed specific screening standard operating procedures
- Preparations completed for a fellowship for young African scientists from participating institutions and Fellows from collaborating institutions (KEMRI, UoL, TBRI and UHAS) have started the 5 weeks fellowship program on Sep 6, 2016. Training covers four main areas, a) Laboratory biosafety, b) Molecular biology techniques including DNA extraction and PCR amplification, c) protein micro array and data analyses, and d) SOP development.
- The presentation from NIPD also included a review of the immunomics approaches for Ag discovery of human parasites with particular focus on malaria.

3. Fudan University

Prof. Wei Hu

- Fudan University School of Life Sciences hosted a visit by a team from ANDI and UHAS on an exploratory mission for potential collaboration of mutual interest.
- SOP prepared for collection of specimen for *Schistosoma Japonicum*
- Established screening platform including sera cDNA library, sera protein chip and proteomics from egg and adult worm secretion to improve screening;
- *S. Japonicum* rapid diagnostic test on the way for commercialization

Dr. Jingwen Wang

- Submitted a proposal to “investigate interactions between Malaria vector (*Anopheles*), gut microbiota and *Plasmodium* and try to characterize factors influencing mosquito vector competence” in response to ANDI’s call for local technologies.

4. EASE Medtrend

Dr. Peter Chun

- Presentation focused on a mobile app for POC diagnostics that eliminates the need for sophisticated instrumentation, especially as additional technology platforms are added to support rapid diagnostic testing at point of care.
- Advancing this technology for a wider access largely depends on assembling evidence from the field for evaluation of feasibility and this is leveraging the sample collection work being undertaken at various ANDI CoEs. This will demonstrate to governments and development partners that the application does what it is supposed to do.

5. TBRI

Prof. Hanan Elbaz and Mohameed Elzallat

- Approval from the IRB obtained for specimen collection which will have to be coordinated with the Ministry of Health.

Issues: Funding agreement not yet signed with ANDI due to internal procedures at TBRI. Due to standing regulations, it may not be possible to transport specimens out of Egypt for the purpose of this project.

6. University of Lagos (UNILAG)

Prof Wellington Oyibo

- The University has identified endemic areas for schistosomiasis in collaboration with relevant departments in the Ministry of Health
- Standard operation procedures (SOPs) have been developed for sample management including field collection, storage and transportation and approval obtained from the internal review Board (IRB) in August.

Issues: UNILAG seeks clarity on the type (blood, urine and stool) and volume of specimen required for the project by the reference lab in China. Similarly they would like to see an agreement on the amount of samples to be kept at the referring lab for future tests and validation.

7. KEMRI

Dr. James Kimotho

- IRB approval secured and consent obtained from relevant institutions for sample collection. Also had community sensitization to facilitate specimen collection
- Mou signed with ANDI, first tranche transferred and project coordinator hired
- Study participants registered and 25% of required specimen collected so far

Issues: sample collection coincided with exam schedules in schools and had to be slightly delayed. Expectation from patients for travel allowances to submit specimens. KEMRI plans to continue to collect all required specimens and ship to China by mid-April 2017

8. University of Health and Allied Sciences (UHAS), Ghana

Prof Peter Atadja and Kwabena Duedu

- Established in 2011, UHAS has a vision to become a pre-eminent and practically oriented health educational institution dedicated to community service. UHAS partners with ANDI by way of implementing field trials of various technologies and biomarker discovery for NTDs and other diseases.

9. University of Ibadan

PROF. GRACE GBOTOSHO

An ANDI center of excellence for malaria translational research, the University of Ibadan is currently working on a novel diagnostic test for malaria from saliva specimens. The University has been identified as an additional partner for the WHO Demo project.

Closing Session and Follow up Actions

Building on the discussions that the Workshop deliberated during the last two days, Dr. Solomon Nwaka, ANDI Executive Director, underlined the importance of continuing on the joint collaboration through the WHO demo project particularly in the light of lack of clarity on funding from WHO/WHA for the second year of the project. He emphasized that ANDI is expecting final word from WHO on the NCE and this NCE will result in extension of the dates for the project till June 2017. NCE will also involve budgetary adjustment for the partners to ensure that the project is not prematurely terminated due to lack of funding, especially for the coordination part of the work. With this in focus the consensus from the Workshop was for partners to work together towards resource mobilization by leveraging work in the institutions represented at the meeting and other partners. Some of the ongoing work that have been identified for resource mobilization were; the Mobile APP platforms and other concrete products/biomarkers coming out of the work in Africa and China, b) schisto diagnostics using monoclonal antibodies, c) Genomics work in Fudan University and NIPD, d) Malaria diagnostics using saliva from University of Ibadan.

Other follow up measures:

1. Partner institutions to submit their activity reports on WHO Demo project to ANDI before end of September (Note that this is a pre-requisite for our No-cost extension request (NCE) to WHO)
2. ANDI to continue to work with WHO to obtain approval for the NCE. ANDI will then follow up with partners to change dates in the agreements and budget. Recall that existing project agreements will end by the end of October 2016.
3. NIPD and Fudan to draft and share SOP for specimen collection including type and amount of specimen, timeline, transportation, etc.

4. Review regulatory requirements for the diagnostics and the mobile APP in each of the countries represented by partner institutions
5. All partners to develop a database of their own; NIPD and ANDI to work together to build the project database.



**Annex I: Agenda: 2nd Technical Meeting of ANDI Demonstration
Project on Diagnostics Development**

7-8 September, 2016
Shanghai, China

Meeting Objectives:

- e. Review progress in project performance and implementation of action points from the 1st Technical Meeting in Lagos
- f. Define the regulatory strategy for the project
- g. Discuss opportunities for resource mobilization to ensure sustained implementation and expansion of scope of project building on the network and partnership established by the Demo project
- h. Brainstorm on better communication among implementing partners for improved coordination and agree on next steps

Project partners:

- African Network for Drug and Diagnostics Innovation (ANDI)
- National Institute for Parasitic Diseases (NIPD), China CDC
- Fudan University
- Ease-Metrend China
- University of Lagos
- Kenya Medical Research Institute (KEMRI)
- Theodor Bilharz Research Institute (TBRI)
- University of Health and Allied Sciences, Ghana
- University of Ibadan, Nigeria
- World Health Organization
- African Regulatory Harmonization Initiative (NEPAD)

DAY 1

Wednesday, Sep 7, 6 2016 Venue: NIPD, Shanghai China		
09:00- 09:30	Welcome and Introductions	NIPD
9.30 – 10.00	Project Overview, Updates, Meeting Objectives and Expected Outcomes	ANDI
10:00-10:30	Coffee	
10:30 – 12:30	Updates in Project Performance from Partner Institutions	National Institute for Parasitic Diseases (NIPD) China CDC Fudan University
12:30-14:00	Lunch	
14.00 – 16.00	Updates in Project Performance from Partner Institutions	EASE-Metrend China University of Lagos Kenya Medical Research Institute (KEMRI)
16.00 – 16.20	Coffee	
16.20 – 18.00	Updates in Project Performance from Partner Institutions	Theodor Bilharz Institute Egypt (TBRI)
18:00	End	

DAY 2

Thursday, September 8, 2016 Venue: NIPD, Shanghai		
09:00-09:45	Discuss and Define the Regulatory Strategy for the Demo Project	ANDI NIPD/Other Chinese Institutes TBRI
09:45-10:00	A Relevant New Project from an ANDI CoE	University of Ibadan
10:00-10:30	Coffee	
10:30-12:00	Summary Plan for Year One including the NCE Period	All
12:00-13:00	Agree on Ways Forward and Action Points: <ul style="list-style-type: none">• Resource Mobilization• Communication for better coordination	ANDI/NIPD
	Next Steps and Vote of Thanks	ANDI/NIPD
13:00-14:30	Lunch	

Annex II: List of participants and their affiliations

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