

**1st Technical Meeting of African Network for Diagnostics and Drug
Innovation – WHO-WHA Demonstration Project on Diagnostics
Development
24th-27th February 2016
Lagos, Nigeria**

Background:

Following the WHO World Health Assembly (WHA) resolution 66.22, and based on “Follow-up of the report of the Consultative Expert Working Group (CEWG) on Research and Development”, ANDI submitted a proposal on the WHO-commissioned health R&D demonstration projects entitled “*Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases*”, in collaboration with Chinese partners and relevant ANDI Centres of Excellence (CoEs). This project works through a systems biology approach to identify a suite of secreted antigens from *select neglected tropical diseases including Schistosoma spp., Plasmodium falciparum and P. vivax* and that are uniquely reactive to sera from individuals in endemic areas, and to translate the identified biomarkers into sensitive, reliable and user-friendly diagnostics. In order to meet a key project outcome of developing diagnostics tools that are easy to use and affordable in rural communities of disease endemic countries, strategies have been defined to delink costs of research and development with market price.

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.

Meeting Objectives and Expected Outcomes:

The three days meeting aimed at bringing all partners to the project, and,

1. Review ongoing activities within partner institutions
2. Agree detailed project activities and responsibilities within partner institutions
3. Agree deliverables from partner institutions with budget for year 1
4. Define next steps including reporting & resource mobilization.

Meeting Agenda is shown in Annex I.

Participants:

A total of 19 participants representing partner institutions were in attendance. See list of participants in Annex II.

Venue

George Hotel, Lagos, Nigeria

Proceedings

Opening session

ANDI's Executive Director, Dr. Solomon Nwaka, opened the meeting by welcoming participants and discussing the background to the genesis of this project and its innovative features. Dr. Solomon particularly recognized the contribution of Prof. Zhou of China NDI to the development of this project. This was followed by a round of introductions.

Presentations and discussions

Africa Network for Drugs and Diagnostics Innovation (Africa NDI)

Dr. Takele Gerresu from ANDI provided a highlight of the WHA Demo project including its objectives, key outcomes and its comprehensiveness in addressing the issues across the value chain. Dr. Takele also presented expectations from the meeting. During this introduction, it was also emphasized that the ANDI-WHA Demonstration Project will play an important role towards realizing regulatory harmonization for diagnostics in Africa since no such framework currently exists. In this case, the WHO prequalification criteria will serve as "gold standard" to facilitate product registration in Africa. Moreover, aspects such as recruitment of additional project partners in Africa and the global North were deliberated.

Ato Alemu Kidane, ANDI Admin and Finance Officer presented the project budget for year one aligned with detailed activities. In terms of financing, ANDI will disburse year 1 funding based on described need and most importantly, depending on the progress of project.

Following the opening and introductory presentations that set the stage for the meeting, representatives from research institutions made presentations showcasing their capabilities, expertise and specific areas of collaboration for the project.

China Network for Drugs and Diagnostics Innovation (China NDI)

Prof. Zhou, Director of NIPD, China CDC – WHO Collaborating Centre for Tropical Diseases – highlighted the pioneering role of his institution in diverse epidemiological studies on neglected tropical diseases, and in developing novel approaches for prevention and control for schistosomiasis and other parasitic diseases.

Prof. Hu, Group Leader at Fudan University further highlighted the collaborative work in developing novel schistosomiasis diagnostics under the umbrella of the China Network for Drugs and Diagnostics Innovation (China NDI). She detailed both

upstream and downstream aspects on an integrated high-throughput screening platform based on genomics, proteomics and transcriptomics technologies for schistosomiasis diagnostics development. With partners, this approach has led to identification of a novel biomarker for *S. japonicum*, Sj-SP13, which is currently the lead diagnostics target for further evaluation. A rapid diagnostic test (RDT) based on this and another recombinant protein, Sj-P32, as well as a target screening system will be translated for novel biomarkers discovery of *S. mansoni* and *S. haematobium*, which are the worm species endemic in Africa. Moreover, it was highlighted that the China NDI consortium will organize a capacity building platform for African scientists to develop omics-based capabilities, and the setup and unification of bio banks and database infrastructure with African institutions. Participants highlighted that there is no health product currently in the market that has been developed using a genomic approach, and this therefore provides a clear area for impact through this Project.

Dr.Chen, Group Leader at NIPD, China CDC, gave a presentation on the methodology of the afore-mentioned omics-based technologies however for developing a biomarker-screening platform for malaria (*P. falciparum* and *P. vivax*). A variety of leads will be evaluated in Africa and Asia to develop diagnostics for *P. vivax* and *P. falciparum*.

Kenya Medical Research Institution (KEMRI), Kenya

Dr. Kimotho (Head Production Unit, KEMRI) gave a presentation about the capabilities of his unit and potential areas for collaboration in this Project. He highlighted that KEMRI in general has strong clinical trials expertise for malaria and has also developed capabilities in specimen banking in collaboration with the USA partners. The KEMRI Production Unit has also positioned itself as a leader in biological products manufacturing in the East Africa region. Currently they produce, among other things, laboratory disinfectants, polymerase enzymes, and ELISA and RDT kits for HIV and hepatitis diagnostics.

University of Lagos (UoL), Nigeria

Prof. Oyibo (University of Lagos) highlighted the collaborative work his institution was engaged in the area of malaria diagnostics. He showcased a novel urine-based *P. falciparum* malaria diagnostics test evaluated in Nigeria in partnership with a US-based company. Through this collaboration UoL has developed expertise in; a) navigating the regulatory space for product evaluation and registration, and, b) developed expertise in biobanking to support product evaluation. His institution currently has 5 WHO certified diagnosticians for malaria, leading the way in Africa, and has recently been named as WHO collaborating center for malaria diagnostics. Issues of diagnostics multiplexing using interdisciplinary capabilities were also discussed, as well as issues of ethics during evaluation studies. He also elaborated the work of the

University of Lagos Research and Innovation Center in support of the art of intellectual property (IP) and tech transfer. Discussions with University of Lagos Vice Chancellor (VC) also highlighted the need for concerted efforts in bridging outputs from bench research to the market so as to impact humanity. The VC also supported and encouraged the work of ANDI.

Theodor Bilharz Research Institution (TBRI), Egypt

Prof. El Baz and Prof. Demerdash, gave presentations on TBRI's work in developing novel schistosomiasis diagnostics. Their proposed technology employs anti-*S. mansoni*, and/or anti-*S. haematobium* monoclonal antibodies (mAbs) against Circulating *Schistosoma* Antigens (CSA) as diagnostic probes. The mAbs in such assays will be produced by hybridoma technology, conjugated with gold nanoparticles and employed in sandwich ELISA or a sandwich immunochromatographic strip (immuno-strip) for accurate diagnosis of *Schistosoma* spp. infection. With a bioreactor, the TBRI team will be able to provide mAbs to support 16 million patients every month based on a fully developed kit. To successfully achieve this, TBRI needs an entity for commercialization of this product. TBRI is considered a reference centre for *Schistosoma* diagnostics in Egypt in this respect, and they are now in preparatory stages of evaluating this technology in Kenyan and Nigerian ANDI CoEs. In consideration of ease of use and costs, whether urine samples could be used for this test was discussed and TBRI colleagues agreed to follow on that.

In a discussion that followed pertaining to intellectual property, patent rights and whether TBRI could establish a centre to produce this novel diagnostic use for market access or needs to partner with an industry was deliberated at great length. The consensus was for TBRI colleagues to explore opportunities and consult with ASRT and other TBRI colleagues and decide way forward. In the event that TBRI decides to partner with industry for production and market access, ANDI would broker partnerships with potential partners

EASE Medtrend China LTD

Prof. Atadja (UHAS, Ghana) delivered a presentation on behalf of Dr. Peter Chun (EASE Medtrend China LTD.) entitled "diagnostics leapfrogging in Africa using (smart) mobile phone devices" EASE Medtrend have developed a cloud-computing platform, which will allow integrating, reading and interpreting existing diagnostic test results from scanners or image acquisition devices in the field. Using a dedicated app, data output from such diagnostics tests will be analyzed on the phone or transmitted securely to a cloud server for analysis, allowing real-time monitoring of diseases, objective reading of results, replacing sophisticated readers, and allowing big data accumulation. Aside from some concerns on data security, participants saw this

innovation as a great advancement for expanding access to point of care diagnostics without need for expensive equipment.

National Institute for Pharmaceutical Research and Development (NIPRD)

On behalf of Prof. Gamaniel (CEO, NIPRD), Dr. Egharevba discussed the capabilities of NIPRD and introduced the different platforms in phytomedicine available in the institution from purification to evaluation and product registration. A flagship product, NIPRISAN, for sickle cell disease control was developed at this institution and is now distributed to patients based on need by the Nigerian Government.

Meeting Outcomes and way forward:

1. ***Plan of action for year one;*** participating institutions agreed to develop a detailed activity plan for year one of the work that they plan to accomplish in their respective institutions through and for the WHO Demo project and a budget breakdown. Agreed budget will then form basis for MoU to be signed to effect fund transfer.
2. ***Ethical approval;*** Respective institutions to obtain approval from their Institutional Review Boards for specimen collection and other ethical issues. Prof. Wellington agreed to share lessons and relevant WHO guideline to that effect.
3. ***Specimen collection:*** Participants agreed to unify protocols for specimen collection, develop specimen banks and database capabilities to exchange information between partners.
4. ***Capacity building:*** China NDI agreed to host a training program on developing microarray and other omics-based capabilities to young African scientists from participating institutions.
5. ***Expanding partnership base;*** considering disease burden and seasonality of transmission in schistosomiasis and most importantly malaria that could affect collection of required specimens for development and evaluation of the proposed diagnostics, a consensus was reached to consider inclusion of institutions from countries most affected by schistosomiasis and malaria. The need for inclusion of institution from the global north was also entertained particularly during the production phase.
6. ***A joint TBRI/ANDI Technology Incubator;*** TBRI colleagues will discuss internally the feasibility of in-house production of monoclonal antibodies (mABs) for schistosomiasis Ag detection and establish a joint ANDI/TBRI technology incubator based in TBRI. Should TBRI decide to negotiate diagnostics production with industry ANDI has agreed to broker partnership
7. ***Follow up meeting;*** China NDI agreed to host a follow up meeting in Shanghai to discuss among other things, Sample SOP harmonization, setting up specimen (bio) bank and further discussion of QA/QC and ethics issues. More partners particularly

WHO and NEPAD's AMRH (Africa Medicines Regulatory harmonization) will join meeting.

Other outcomes of the Meeting;

In addition to follow up measures regarding the WHO Demo project outlined above, participants deliberated on a number of related opportunities to expand the scope of partnership among African and Chinese partners. We provide a summary of the key outcomes below.

1. ***Maximize the OMICS based technology;*** China NDI and ANDI have agreed to follow up opportunities to maximize the OMICS based technology to further understand emergent infections and zoonoses.
2. ***A novel approach to control vector borne disease;*** Dr. Jingwen Wang from Fudan University agreed to prepare a two pager concept note to help develop a joint proposal with ANDI to understand the process through which malaria and other parasites establish themselves inside the vector before rendering it infectious.
3. ***Developing a natural products database;*** Dr. Peter Atadja (University of Health and Allied Sciences (Ghana) agreed to further build on ANDI's proposal on natural product development to initiate the development of an annotated African Natural Products Library. NIPRID (Nigeria) and NIPD (China) agree to provide inputs to proposal development.



Annex I: List of Participants

	Name	Email	Institution	Country
1	Chimere Agomo	agomoco@hotmail.com	University of Lagos	Nigeria
2	George Rugarabamu	George.Rugarabamu@unige.ch	ANDI	Tanzania
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15	Zeinab Demerdash	zeinabdem@hotmail.com	TBRI	Egypt
	ANDI Secretariat			
17	Alemu Kidane	Alemuk@unops.org	ANDI	Ethiopia
18	Beakal Bisrat	Beakalm@unops.org	ANDI	Ethiopia
19	Solomon Nwaka	Solomonn@unops.org	ANDI	Ethiopia
20	Takele Geressu	Takeleg@unops.org	ANDI	Ethiopia



Annex II: Meeting Agenda

Objective:

- Review ongoing activities within partner institution
- Agree detailed project activities and responsibilities within partner institutions
- Agree deliverables from partner institutions with budget for year 1
- Define next steps including reporting & resource mobilization

Project partners:

- African Network for Drug and Diagnostics Innovation (ANDI)
- National Institute for Parasitic Diseases (NIPD), China CDC
- Fudan University
- Ease-Metrend China
- Other institution from China?
- University of Lagos
- Kenya Medical Research Institute (KEMRI)
- Theodor Bilharz Research Institute (TBRI)
- Other Africa partners?
- World Health Organization
- African Regulatory Harmonization Initiative (NEPAD)

DAY 1

Wednesday 24 February 2016		
Venue: The George Hotel, Ikoyi Lagos, Nigeria (tentative)		
09:00- 09:30	Welcome and introductions	ANDI & University of Lagos CoE
9.30 – 10.00	Meeting objectives and expected outcomes	ANDI
10.00 – 11.00	Overview of the ANDI demonstration on diagnostics development with innovative aspects of project	ANDI
11:00-11:20	Coffee	
11.20 – 12.50	Updates from partner institutions on status of project related activities within their institutions:	ANDI, National Institute for Parasitic Diseases (NIPD), China CDC Fudan University
12:50-14:00	Lunch	
14.00 – 16.00	Updates from partner institutions continues	EASE - Metrend China Other institution from China? University of Lagos Kenya Medical Research Institute (KEMRI)
16.00 – 16.20	Coffee	
16.20 – 18.00	Updates from partner institutions continues	Theodor Bilharz Institute Egypt (TBRI) Other Africa partner
18:00	End	

DAY 2

Thursday 25 February 2016		
Venue: The George Hotel, Ikoyi Lagos, Nigeria (tentative)		
09:00-11:00	Project planning session: Focused discussion on project activities and responsibilities within partner institutions Deliverables from partner institutions for year 1 Project budget for year	
11:00-11:20	Coffee	
11.20 – 13.00	Project planning session continues	
13:00-14:00	Lunch	
14:00-18:00	Visit to the University of Lagos, ANDI Centre of Excellence on Diagnostics Development Presentation of the work of the centres	University of Lagos
18:00	End	

Day 3

Friday 26 February 2016		
Venue: The George Hotel, Ikoyi Lagos, Nigeria (tentative)		
09:00-11:00	Focused discussions on tangible project results from various partners Reporting to WHO	
11:00-11:20	Coffee	
11:20-13:00	QA/QC and regulatory aspect of the project: WHO PQ support African Regulatory Harmonization Initiative Nigeria NAFDAC and other regulatory support	
13:00-14:00	Lunch	

14:00-16:00	QA/QC and regulatory aspect of the project continues	
16:00-16:20	Coffee	
16:20-18:00	Advocacy & resource mobilization in support of projects Leveraging project for additional resource mobilization Industrial partners & capacity building	
18:00	End	

DAY 4

Saturday 27 February 2016	
Venue: The George Hotel, Ikoyi Lagos, Nigeria (tentative)	
09:00-11:00	Press briefing on project and meeting outcome