Stakeholders Meeting on ANDI Demonstration Project:

Development of Easy to Use & Affordable Diagnostics for Types II & III Diseases

Solomon NWAKA

Director, ANDI.

10th May, 2014 – World Health Organization, Geneva
>500 people at ANDI Stakeholders Meetings
Outline of presentation

- Introduction - project rationale, objectives & partners
- 3 integrated platforms – R&D, Access, Networking
- Project deliverables & budget
- Conclusions & next steps
Rationale

- An essential component to evaluating & improving global health is access to appropriate diagnostic tools

- Diagnostics address individual & population needs
  - Case management: clinical decision making; identify patients at risk of severe disease
  - Early detection & treatment of disease
  - Detection ( & prevention) of drug resistance
  - Surveillance
  - Assess efficacy of drugs and vaccines in clinical studies
Diagnostics landscape in developing countries

- Lack of access at point of care & rural communities
- Lack of investment & interest by industry
- Lack of regulatory systems: tests are sold/used without evidence of effectiveness
- Lack of quality standards for test evaluation: claimed accuracy on product insert often misleading
Diagnostics in the Developing World:
Access to health care

Distance to the nearest health facility for the poorest fifth of the population in selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Distance (km)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>7.5</td>
</tr>
<tr>
<td>Bolivia</td>
<td>11.8</td>
</tr>
<tr>
<td>Chad</td>
<td>22.9</td>
</tr>
<tr>
<td>Haiti</td>
<td>8.0</td>
</tr>
<tr>
<td>Madagascar</td>
<td>15.5</td>
</tr>
<tr>
<td>Niger</td>
<td>26.9</td>
</tr>
<tr>
<td>United Republic of Tanzania</td>
<td>4.7</td>
</tr>
<tr>
<td>Uganda</td>
<td>4.7</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>8.6</td>
</tr>
</tbody>
</table>

Limited product R&D: Nwaka et al 2010

<table>
<thead>
<tr>
<th>Disease burden (Million DALYs)</th>
<th>Research articles (Number of articles)</th>
<th>Clinical trials (Number of trials)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>46.7</td>
<td>2,501</td>
</tr>
<tr>
<td>Lower resp. inf.</td>
<td>42.2</td>
<td>299</td>
</tr>
<tr>
<td>Diarrheal diseases</td>
<td>32.2</td>
<td>293</td>
</tr>
<tr>
<td>Malaria</td>
<td>30.9</td>
<td>1,844</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>10.8</td>
<td>894</td>
</tr>
<tr>
<td>Meningitis</td>
<td>5.3</td>
<td>206</td>
</tr>
<tr>
<td>Lymphatic filariasis</td>
<td>2.3</td>
<td>59</td>
</tr>
<tr>
<td>Trypanosomiasis</td>
<td>1.6</td>
<td>126</td>
</tr>
<tr>
<td>Schistosomiasis</td>
<td>1.5</td>
<td>322</td>
</tr>
<tr>
<td>Ascariasis/Trichuriasis</td>
<td>1.2</td>
<td>24</td>
</tr>
<tr>
<td>Trachoma</td>
<td>0.6</td>
<td>91</td>
</tr>
<tr>
<td>Onchocerciasis</td>
<td>0.4</td>
<td>83</td>
</tr>
<tr>
<td>Hookworm disease</td>
<td>0.4</td>
<td>36</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>6.2</td>
<td>485</td>
</tr>
</tbody>
</table>

346.9 31,729 1,627

SOURCE: WHO, Thomson Web of Science, team analysis
<table>
<thead>
<tr>
<th>Disease</th>
<th>Current diagnostic method</th>
<th>Case management</th>
<th>Disease control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>simple, POC format</td>
<td>higher sensitivity</td>
</tr>
<tr>
<td>TB</td>
<td>microscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>microscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis</td>
<td>serology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlamydia</td>
<td>antigen/DNA detection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>antigen/DNA detection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VL</td>
<td>microscopy – in splenic/lymph node biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schisto</td>
<td>microscopy – in stool samples</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAT</td>
<td>microscopy – cerebral spinal fluid for staging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dengue</td>
<td>Culture/RNA detection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Diagnostic needs & gaps (thanks Dr Peeling)
Ideal diagnostics should be quality ASSURED

- **A** = Affordable by those at risk of infection
- **S** = Sensitive
- **S** = Specific
- **U** = User-friendly (simple to perform, minimal training)
- **R** = Rapid/robust (enables action at point of care)
- **E** = Equipment-free
- **D** = Deliverable to those who need it

*J Clin Path 2007;60:376*
Initial disease focus

- Simple, affordable, sensitive, and specific assay for field diagnosis of the four diseases are not yet available and urgently needed in developing countries of Africa.

- Present serum immunological methods cannot distinguish the active infection and cured infection.

- Such a tool is required for enhanced elimination.
Project leverages "OMICS" to address challenges

- "OMICs" platform i.e. genomics, proteomics and transcriptomics techniques to identify novel diagnostics for resource constrained communities
- Investment made by international community in the past decade on sequencing various pathogen genomes

Project objectives

To discover, develop & deliver diagnostics tools that are easy to use & affordable in rural communities of disease endemic countries.

Specific objectives:

- Develop, evaluate, validate and optimize field deployable tests for schistosomiasis, malaria, trypanosomiasis, leishmaniasis

- Demonstrate innovative financing, coordination, delinkage, open innovation etc

- Implement tech transfer, capacity building, local production & regulatory approval of products

- Promote unhindered access to products in developing countries
Core project partners

- ANDI – project coordination & networking
- National Institute for Parasitic Diseases (NIPD), CDC China – screening, evaluation platform & training
- Fudan University – screening, evaluation and training
- Second Military Medical university – screening and evaluation
- EASE-Medtrend Biotech, China – tech transfer, manufacture
- Kenya Medical Research Institute (KEMRI) – evaluation & manufacture
- University of Lagos – evaluation, training
- National Institutes for Food and Drug Control – regulatory support
- PATH – technology evaluation/validation
- SD Diagnostics South Korea – manufacture, tech transfer
- WHO – regulatory support
Platform III Networking:
• Coordination
• Open knowledge database/sharing
• Tech transfer
• Capacity building
• IP management

Platform I
Screening Evaluation Development: Core R&D implementation

Platform II
Access
• Manufacture
• Regulatory
• Procurement
• m/eHealth

Interlinked project platforms
Integrated platforms

Research/Design → Develop/Validate → Approve/Recommend → Introduce/Optimize → Manufacture/Locally

Screening, development & evaluation platform

Access platform

ANDI CoEs

ANDi Health Innovation for Development
Platform I: *Screening, development & evaluation*

- Dr. Wei Hu
- China NDI
- National Institute of Parasitic Diseases, China CDC
- Fudan University
- Stakeholders meeting on WHO demo project, 10th May, 2014.
Biomarker screening

Capability:

- Specimen bank and management system
- Database system: NDI PathDB (open access)
- High Throughput “OMICs” system
Specimen bank

- Pathogen samples
- Human samples: serum, urea, feces, sweater and saliva
- Reference material
- Refrigerator system/cold room
- Data management system

Easy to trace, High quality, High stability, Remote access
Data management & analysis system

Public Database → Genomic sequences → Information warehouse

Genetic marker → Functional genes → Pathways of metabolism and signal

Vaccine → Drug → Diagnosis

Information warehouse → Analysis Mode (multiclass) → Different database

Vista → GLYC → DDIB → MPSS → TMPP → ......

Genetic tags library → Functional gene Database → Metabolic pathway library

Information service

Data query → Information exhibition → Function analysis
ChinaPathDB: critical resource
High throughput “OMICs” system

Genome of Parasites

Data mining using comparative genomics

ESTs of Parasites

Proteome of Parasites

PCR amplification & HT In-Fusion Cloning

Recombinant vector

Cloned ORFs in expression vector

HT cell-free protein expression

Expressed proteome of Parasites

SDS-PAGE / Western

ELISA

Protein Arrays
Biomarker screening platform

**Vector-borne**
(Malaria, Babesiosis…)

**Zoonosis**
(Schistosomiasis, Echinococcosis…)

**Food-borne**
(Clonorchicosis, Trichinococcosis…)

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**Basic databases**
*Schistosoma*
*Plasmodium*
*Clonorchis*
*Echinococcus*
*Babesia*
……

**Specific databases**
Biomarkers
KEGG
Secretary proteins
Membrane proteins
Parasite specific proteins

**Genomics**
(Comparative genomics)
Species/isolates
Drug sensitive/resistant strain

**Transcriptomics**
Coding/Noncoding sequences

**Proteomics/immunoproteomics**
Protein expression
Parasite naïve Ag
Excretory proteins

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Candidate Biomarkers for Vaccine, diagnostics and detection, drugs, genotyping…

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China PathDB

OMICs platform

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**SjSP-13 (S. japonicum) highly sensitive & specific Biomarker**

- Of 204 recombinant secreted proteins, 35 yielded seropositive reactions, eight showed strong immunoreactivity, and only one (SjSP-13) reacted to the entire panel of 14 archived samples.

- Reactivity of SjSP-13 to 476 serum samples 90.4% sensitivity and 98.9% specificity.

Proteomics research of *S. japonicum* (The LANCET infectious diseases, 2014)

<table>
<thead>
<tr>
<th></th>
<th>True Positive</th>
<th>False Negative</th>
<th>True Negative</th>
<th>False Positive</th>
<th>Sensitivity (%) (95% CI)*</th>
<th>Specificity (%) (95% CI)</th>
<th>PPV% (95% CI)</th>
<th>NPV% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>rSP13-ELISA</td>
<td>273</td>
<td>29</td>
<td>172</td>
<td>2</td>
<td>90.4% (85.5 - 93.5)</td>
<td>98.9% (95.9 - 99.9)</td>
<td>85.6 (79.9 - 90.1)</td>
<td></td>
</tr>
<tr>
<td>SEA-ELISA</td>
<td>243</td>
<td>59</td>
<td>161</td>
<td>13</td>
<td>90.5% (75.5 - 84.8)</td>
<td>92.5% (87.6 - 96.0)</td>
<td>94.9 (91.5 - 97.3)</td>
<td>73.2 (66.8 - 78.5)</td>
</tr>
</tbody>
</table>

PPV = positive predictive value. NPV = negative predictive value. SEA = soluble egg antigens. *p = 0.0001. 1p = 0.002 when compared by McNemar’s test.

Table 2: Comparison of diagnostic validity of rSP13-ELISA with SEA-ELISA
**SjSP-13 also sensitive to drug treatment**

**Evaluation of the anti-SP13 antibody response to drug treatment**

**Diagnostic methods & field study outcomes**

*SjSP-13 protein marker sensitive to drug treatment.*
PvMSP1-42 (*P. vivax*) promising biomarker

- Control reactions of wheat germ lysate that lacked vector template (hexagons)
- Reactions of purified PvMSP1-19 with mixed sera or individual serum (circles)
- Positive reactions with target proteins (boxes). P, protein

- Sera from 20 *P. vivax* patient and 10 healthy individuals.
- The response was considered positive:
  1. Relative ratio of signal intensity (SI) > 2.0 (test relative to negative control > 2.0)
  2. Response was statistically significant (*p* < 0.05) compared with negative control SI.

Proteomics research of *P. vivax* (J. of proteome research, 2014)
PvMSP1-42 (*P. vivax*) promising biomarker

**Expression and purification of PvMSP1-42**

<table>
<thead>
<tr>
<th>kDa</th>
<th>Purified</th>
<th>Flow-through</th>
<th>Wash-through</th>
<th>E1</th>
<th>E2</th>
<th>E3</th>
<th>E4</th>
<th>E5</th>
<th>E6</th>
<th>E7</th>
<th>E8</th>
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</thead>
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<tr>
<td>45</td>
<td></td>
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</tbody>
</table>

Measurement of naturally acquired humoral immune responses against the C-terminal region of the *P. vivax* MSP1 (PvMSP1-42) by ELISA

Sensitivity = 92.2% (202/219)
Specificity = 95.6% (152/159)
Output from project gives us head start (RDT reagent)

Schistosomiasis

Echinococcosis

Vivax malaria

Clonorchiasis

Leishmaniasis
Output from project gives us head start (ELISA & PCR)
Platform handles multiple diseases

- To use systems biology approach to classify a suite of parasite antigens uniquely reactive to sera from individuals.
- To screen the antigens with high sensitivity, specificity and the ability to distinguish infection status of the targeted diseases.
- To understanding the basis of naturally-acquired humoral immunity (NAI) to clinical parasitic diseases
- To prospectively analyze the relationship between antibody profiles and protection from the four diseases.

Malaria

Trypanosomiasis

Leishmaniasis

Schistosomiasis
Product development

- **Key objective**: Translate the identified biomarkers into sensitive, reliable & use friendly products start with *SjSP-13 for Schisto & PvMSP1-42 for vivax*

  - A large scale of protein expression & purification system.
  - Sample collection, concentration, preparation (SCCP) system & instruments.
  - Amplification & detection technologies. The emphasis will be the sensitive molecular detection and analyte or signal amplification for nucleic acid and protein markers.
  - Modern data readout, analysis and transfer system.
  - QA/QC quality control system.
Multi-center evaluation

**Aims:**
- To monitor and evaluate the quality of diagnostic kits and activities
- To organize external quality assurance activities
- To develop and assess new diagnostic tools or products
- To conduct training workshop
- To improve capacity building for diagnosis
Scheme of multi-center evaluation

Construction of diagnostic evaluation platform

Set up sample bank
- Parasitological sample bank
- Serum bank
- Control material or panels

Evaluate diagnostic tools or methods
- Sample panels
- Laboratory-based evaluation
- Field assessment
- Apply license from SFDA

Set up reference laboratories
- National reference center
  - Organize external quality control activities and training courses, provide technical support, develop and evaluate new diagnostic tools
- Provincial reference laboratories
  - Participate in external quality control, and training course, monitor the quality of diagnostic works and provide technical support
- Sentinel laboratories at county or city level
  - Participate in external quality control, monitor the quality of diagnostic tools or kits

Strengthen the capacity building of diagnostics
Capacity building & tech transfer

1. Opportunity for cross learning through SS cooperation
2. To provide technical support to establish a framework for the evaluation of diagnostics for the target diseases in Africa
3. To guide or provide support for assessing or monitoring the diagnostic tools in national control program in Africa;
4. To hold training courses to African staffs through remote education, basic and high-level courses, and with senior experts sharing their experiences.
5. To conduct the gap analysis and set priority for research of the four parasitic diseases based on field survey and conference;
6. To develop new diagnostic tools or kits for certification of elimination of the target diseases
Output of multi-centre evaluation kit for S. japonicum

Establishment of Serum bank preparation of serum panels

Preliminary selection (18 diagnostic kits)

9 kits excluded (low Youden index value, production ability)

Lab-based evaluation using serum panels (9 diagnostic kits)

6 kits excluded (lower sensitivity, poor operational characteristics)

Field trial (IHA_JX, DIGFA-SH, ELISA-SZ)
Achievements can be brought to global scale

Four kits got license from SFDA based on this field assessment

- DGIFA
- ELISA
- IHA
- DDIA
Laboratories network of schistosomiasis diagnosis

To strengthen the capacity building and monitor the quality

Reference Center : 1 (National level)
Reference laboratory: 7 (Provincial level)
Sentinal laboratory: 16 (at county or city level)
Summary platform I

- Screening, development & evaluation platform well established in China NDI and will be transferred to Africa through this program

- Transition the schisto & vivax biomarkers to development

- Win-win development and benefit utilizing joint investment and combined resources between China NDI and ANDI

- Capacity can be extended other diseases such TB etc

Thank you
Platform II & III – Access & Networking

Diagnostics Design, Manufacture and Technology Transfer

Peter Chun

EASE-Medtrend Biotech Ltd

Stakeholders meeting on WHO demo project, 10th May. 2014
Basic configuration of RDT

Figure 1. A typical lateral-flow immunoassay test.
Clear-cut design objectives and know-how vs. know-why

✔ Does the final product fulfill the following criteria:
  ✔ Does it do what it is intended to do and what it claims?
  ✔ Does it perform within the prescribed parameters reproducibly?
  ✔ Does it meet cost requirements?

✔ What is the difference between know-how and know-why?

✔ When is it necessary, and who needs the “know why”?

✔ Does the FDA consider it essential and where does that appear in their requirement?
Design controls and manufacturing scheme
Documentation and traceability

1. Raw materials identification and qualification
2. Processes
3. Validation & Audit (including variation /CV and stability )
4. Quality Assurance and Control
5. Labeling
6. Product tracking & Recall Procedures

- Scientific reasons and experimental support for choice of essential components of the test and processes.
- Establishing In-line Q.C. procedures and final release criteria
- Identification of critical points and procedures
- Deviations and tolerances.
Objective reading of RDT, the use of QR codes image analysis and cloud computing

- Reading of RDT by reflectance
- Ability to send interpretation or Raw Image to computer or CLOUD for record keeping and data analysis. (Centralized data collection and analysis possible)
- Eliminates subjectivity
- Consistent reading
- QR codes alongside the test identifies test, parameters, mfg. & exp. Dates (and standard curves if necessary)
- Use of smart phones allows identification of user, time date, and location automatically (GPS).
INTERPRETATION OF RESULTS

Chromogenic Reader

Patient ID: A001
Patient Name: Mary
Birthday: 10/10/1992
Product ID: Chemtrue 6
Product Lot: 980813
Operator: John
Test Date: 10/7/2009
Test Time: 16:50:03
Expiration Date: 2009/12/31

Analysis

Patient Management System

Setting

Item | AMP | C.O.C | MAMP | MOR | THC | BZO
--- | --- | --- | --- | --- | --- | ---
Intensity (RLU) | 6.81 | 8.42 | 9.3 | 28.31 | 13.32 | 23.79
Cut-off (RLU) | 6 | 6 | 6 | 6 | 6 | 6
Result | Negative | Negative | Negative | Negative | Negative | Negative

Update Now
What Differentiates our project infrastructure

- Broad scope of cutting edge technologies.
- Demonstrated successes in identification of biomarkers for detection and test of cure for several infectious diseases of poverty. (eg. NIPD/CDC, Second Military Medical U. of China)
- Successful creation of large scale sample bank and China PathDB
- Successful manufacture and commercialization of several tests in China. (eg. Malaria Ab ELISA; Schisto-Ab & liver fluke Ab POCT)
- Willingness to share our technology globally through this project
- Opportunity for concerted technology transfer and capacity building in support of manufacture, regulation and access in Africa.

Thank you
Access & Networking Continue

◆ James Kimotho
◆ Kenya Medical Research Institute
◆ Stakeholders meeting on WHO demo project, 10th May. 2014
ANDI CoE mapped around values chain (Diagnostics)

http://www.andi-africa.org/
Some manufacturing sites for diagnostics in Africa

VACSERA Production Company

This is a Holding Company in Egypt that is specialized in R&D and Manufacture in the following areas:

◆ Vaccines Antisera & Immunoglobulins (Tetanus antitoxin, anti-snake sera etc.)

◆ Diagnostics (Lateral flow assays)

◆ Media & Tissue Culture

Opportunity for SS and NS cooperation
This facility is part of KEMRI, which is the leading Biomedical Research Institution in Kenya: It has the necessary QMS: cGMP-compliance, ISO 9001:2008, ISO 13485 & ISO 17043.

It has commercialized products based on the following platforms:

- **Immunochromatographic Assays** (HIV, HBV and currently developing rapid test kit for Rift Valley & Yellow Fever for the region (A collaboration with Japanese Agency).
- **ELISA Assays**
- **Molecular biology** (TAQ Polymerase & DNA extraction kits)
- **Ready-use Culture Media**
- **Proficiency Testing Panels for the region**
What ANDI CoEs bring to the project: e.g.

KEMRI

◆ A Diagnostic manufacturing facility - ISO 9001, ISO 13485 & cGMP compliant (with the capacity of producing 300 lateral flow strips per year)

◆ An established commercialization and distribution network

◆ Substantial experience in registration of the diagnostics in Kenya.

◆ Large pool of Scientists (more than 250) to support the R&D activities in development of these diagnostics with more than 250 scientists specialized in various discipline like epidemiology, molecular biology, clinical research among others.

◆ Centers that are specialized in schistosomiasis, malaria, trypanosomiasis, leishmaniasis etc. (These experts can be involved in evaluation of the diagnostics developed in this project).

◆ Close collaboration with Kenya government, national and international partners

◆ Opportunity for tech transfer & capacity building
Challenges facing production, regulation & commercialization of diagnostics in Africa: KEMRI Experience

◆ Lack of clear regulation framework (The production facilities for diagnostics certified by Pharmacy & Poison Board while diagnostics are evaluated by National Public Health Laboratory Services and recently Kenya Medical Laboratory Board laying claim to the Regulation)

◆ Lack of regulation harmonization of diagnostics in Africa resulting in slow and expensive registrations in each country

◆ Lacks of adequate capacity to evaluate more recent diagnostic technologies e.g. some molecular and electronic based diagnostics

◆ Lack of adequate funds for taking the diagnostics through the process of WHO prequalification

◆ Competitions with superior technologies from developed countries and failure to get funds for continuous technology improvement (KEMRI Hepcell became obsolete few year after the end of development cycle)

◆ Limited numbers of diagnostic manufacturing facilities in Africa from whom KEMRI get more technology knowledge or platform in development of new products or improvement of the existing products
Role of ANDI through this project critical in addressing challenges

◆ ANDI could work with its global partners to help the member countries formulate a clear policy for regulation of the diagnostics.

◆ ANDI could also work with WHO and other global partners to harmonize regulation of diagnostics in Africa (*something similar to the concept of Common Technical Documents, CTD, that is currently being rolled out for registration of Medicines*)

◆ ANDI could work with WHO to support the African countries that are seeking WHO prequalification of their products

◆ ANDI could be the enabler of sharing of technology, knowledge or platform for development and evaluation of new products among the African countries.
Tech transfer and capacity building opportunities

◆ Tech Transfer holds a key role in building the capacity of developing countries in manufacturing of quality diagnostics locally and at lower prices.

◆ As an example of Tech Transfer the KEMRI Production facility is currently engaged in a Tech Transfer Agreement with CDC Tech transfer office in establishment of manufacturing line for HIV Incidence Testing kits. The facility is also considering entering into Contract Manufacturing Agreement with a multinational company in production of the culture media for the regional market.

Thank you
Summary of deliverables, conclusions & next steps

Solomon NWAKA.
Director, ANDI.
Highlight of innovative aspects

- **Delinkage of cost of R&D from price of final product**
  - Combination of pre-competitive & open source approaches
  - Project publicly funded, will not recover R&D cost
  - No royalties applied to public sector licensure

- **Open source & innovation**
  - Open platform for sharing R&D results, collaborative & networked approach

- **Licensing for access**
  - Ensure public access to data, manufacture & unhindered access to final product
Highlight of innovative aspects cont

- **Financing**
  - Interlinked R&D and access approaches
  - Pooled funding (for R&D grants & targeted prizes)
  - Leverage funding or co-funding from partners, e.g. EDCTP

- **Coordination**
  - Inclusive coordination, advisory committees involving all regions
  - Coordinated networks, partnerships & consortia through ANDI

- **Capacity building**
  - Integral to project – based in Africa
  - Engages LMIC – South South & North South collaboration
  - Tech transfer for R&D and local manufacture
### Illustration of innovative aspects of the project

<table>
<thead>
<tr>
<th>Product Value Chain</th>
<th>Research &amp; Development</th>
<th>Evaluation/optimization</th>
<th>Manufacture, Registration &amp; Access</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partnership model</strong></td>
<td>Open, network, PPP and other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Funding model** | 1) Pooled fund for grants & prizes  
2) co-financing, bilateral agreements  
3) Other | | | |
| **Key partners** | PPP partners, donors | | | |
| **Portfolio/Program Management** | Inclusive governance involving global partners, Advisory committees, coordination by ANDI Secretariat | | | |
| **IP management & licensing** | Licensing for access | | | |

**Project transition phase**

- PPP, Tech transfer, Partnership, procurement
- 1) Pooled fund for catalytic grant/prizes  
2) Social/Joint venture or equity funding  
3) Other

- Partners for access  
Regulators  
Other stakeholders (communities, donors)

- Inclusive governance, Product Access Committee
- Licensing for access
Proposed ANDI R&D & open knowledge database
Project aligns existing open source approaches
Project will build capacity through ANDI CoEs

National Institute for Pharmaceutical Research and Development
University of Ibadan
University of Lagos
University of Bamako
Kumasi Center for Collaborative Research
LaGray Chemical Co. Ltd
Noguchi Memorial Institute for Medical Research
University of Buea
Institut de recherches médicales et d'études des plantes médicinales
African Institute of Biomedical Science and Technology
Stellenbosch University (2)
The Biovac Institute
University of Cape Town (3)
IThemba Labs
South African Medical Research Council
Institut Pasteur de Tunis
Theodor Bilharz Research Institute
Vacsera (2)
Vacsera Manufacturing
National Center for Research
Joint Clinical Research Center
Makerere University
KEMRI Production Unit
Institute of Primate Research
Kenya Medical Research Institute
Kenya Agricultural Research Institute
Kilimanjaro School of Pharmacy
University of Zambia
University of Mauritius
Botswana Vaccine Institute
Council for Scientific and Industrial Research
IThemba Pharma
University of Witwatersrand (2)
Ithemba Labs
Project coordination & governance

- Global technical committee of ANDI, NIPD & partners
- Global access committee will also be established
- Overall coordination will be through ANDI Secretariat and Board

ANDI governance structure

NIPD governance structure
Integrated platforms

- Research/Design
- Develop/Validate
- Approve/Recommend
- Introduce/ Optimize
- Manufacture/Locally

Screening, development & evaluation platform

Access platform

ANDI CoEs

ANDI

Health Innovation for Development
Key project deliverables

- 4 diagnostic kits meeting current control/elimination needs
- 1 product prequalified for use in Africa

- 2 technology transfer initiatives for R&D or manufacture through South South, North South or Academia-industry
- 30 individuals trained
- 5 institutions strengthened as part of this project
Key milestones, timeframes and budget

Total USD 19 Million (Coordination including staffing cost USD 3 million & Administration USD 1 million)

USD 9 Million (Implementation of platform II mainly catalytic activities III)

USD 9 Million (Initiate implementation of platform I & III)

Activities

2014 (June - Dec)
- Funding secured, project initiation & logistics
- Initiate implementation of platform I & III
  - Sample collection & Biomarkers discovery
  - Networking

2015 (Jan - Dec)
- Implementation of platform I & III
  - Reactive antigens identified
  - Networking
  - Capacity building
  - IP mgment
  - Tech transfer

2016 (Jan - Dec)
- Implementation of platform I & III
  - Rapid diagnostic & Molecular test development
  - Development/evaluation of immunostrips

2017 (Jan - Dec)
- Implementation of platform I, II & III
  - Field evaluation, validation & production
  - Specification definition and manufacture of immunostrips
  - Initiate WHO prequalification & registration of the products

2018 (Jan - Dec)
- Implementation platform I, II & III
  - WHO prequalification & registration of products
  - Development of remote/mobile control system with data transfer
  - Development of appropriate m/e Health platform and advocacy

2019 (Jan - Dec)
Next steps

• Secure funding for project
• Agree implementation, capacity building & tech transfer modalities
• M&E framework & reporting
• Engage new partners
• Develop/implement advocacy & fundraising strategy
Thank you