

# **Diagnostics development pipeline**

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Partnering for better diagnosis for all

# **Importance of diagnostics**



- Individual health
- Public health



Surveillance to sustain elimination

### **Diagnostics development pipeline**



market surveillance and impact assessment

# **FIND's partnership strategy**



#### From concept to scale-up



Partnerships vary and level of involvement changes with stage of development



# **Partnerships in Feasibility**



Development of diagnostics for sleeping sickness

Test	Academic	Industry	Endemic country
Rapid test	Antigens and know- how from 10 universities and Labs	Antigen screen by Microcoat gmBH	Serum samples from 3 endemic countries
Molecular test based of LAMP Proof of concept by Murdoch, Obihiro & Makerere Universities,		None	Kenya, Uganda & Tanzania
	Funders, WHO (global policy), MOH (national policy)		

#### **Rapid diagnostic test for HAT**





### **Partnerships in Development**



Development of diagnostics for sleeping sickness

Test	Academic	Industry	Endemic country
Rapid test	Testing prototypes on stored samples by 2 universities and 3 research Labs.	Standard Diagnostics	Clinical evaluation of prototypes in Angola, DRC & CAR
Molecular cest based of LAMPTesting prototypes and optimization of sample preparation by Makerere University		Eiken Chemical Co	Clinical evaluation at sites in Uganda and DRC
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Funders, WHO (global policy), MOH (national policy)

# **Development of HAT LAMP kit**





Comparison of LAMP reagents before and after drying

# **Optimization of sample preparation**

#### foundation for innovative new diagnostics

#### **Makerere University**

# Methods tested on infected blood:

- Fresh whole blood
- Total lysis of blood using SDS
- Spotting blood or buffy coat on Whatman filter papers





## **Evaluation of HAT LAMP in Uganda**



# **Exploiting diagnostic platforms**





# LED fluorescence microscopy





Advantages over standard bright field microscopy

- ✓ More sensitive
- ✓ Faster
- ✓ Less tiring (dark background)
- ✓ Cheap and long-life LEDs (>10,000 hr)
- $\checkmark$  Can be solar/battery powered
- ✓ Dual-purpose: easy switching between

bright field and fluorescence



**Transport box** 

The Primo Star iLED originally co-developed by Carl Zeiss and FIND for tuberculosis

#### A technology plaftform for various applications:

Trypananosomes



Plasmodium



Courtesy IPR

Leishmania



Courtesy IPR

#### M. tuberculosis



#### **Identification of New Diseases**





#### **Decision-Making Criteria for Disease Selection**



Unmet need*	Importance	Feasibility*	Importance
Need for innovative / improved diagnostic tests positively impacting patient care (increased recovery chance thanks to well- adapted therapy, decreased usage of toxic treatments, etc.)	25%	How feasible are technical solutions to address unmet needs? (reasonable time for product development, cost- effectiveness of diagnostic, etc.)	40%
Need for innovative / improved diagnostic tests positively impacting community health (socio-economic impact, contribution to transmission prevention, chance for disease elimination / eradication, reduction of strain resistance, surveillance improvement, etc.)	25%	What is the availability of funds? (long term commitment of a specific donor, existing or potential advocacy required to release funds, etc.)	40%
Disease burden and expected development (incidence, mortality, DALYs, etc.)	25%	Can FIND address unmet needs better	
<b>Disease severity</b> ( <i>impact on patient health, resulting handicap,</i> <i>morbidity rate, etc.</i> )	25%	than other stakeholders? (comparative advantage in the competitive landscape, recognized expertise, etc.)	20%

Four criteria for unmet need and three criteria for feasibility identified and weighted

#### **Ranking based on Unmet Need**



	Diseases	Need for innovative / improved diagnostic tests <u>positively</u> <u>impacting community</u> <u>health</u>	Need for innovative / improved diagnostic tests <u>positively</u> impacting patient care	Disease burden and expected development	Disease severity	Weighted average
Irrent	ТВ	5	4	5	5	4.8
	Malaria	5	5	3	4	4.3
	HAT	5	4	2	4	3.8
ບັ	Chagas disease	4	4	2	4	3.5
	Visceral leishmaniasis	3	5	3	4	3.8
	HIV	5	4	5	5	4.8
	Hepatitis B	4	5	4	4	4.3
	Hepatitis C	5	3	5	4	4.3
	Buruli ulcer	5	5	2	5	4.3
	Schistosomiasis	3	5	3	5	4.0
	Cervical cancer	4	4	3	5	4.0
al	Pneumonia	4	5	5	2	4.0
nti	Influenza	5	1	4	1	2.8
ote	Typhoid	3	3	2	3	2.8
ď	Leprosy	4	2	1	4	2.8
	Onchocerciasis	2	2	2	4	2.5
	Diabetes	2	1	5	2	2.5
	Lymphatic filariasis	2	2	3	2	2.3
	Syphilis	2	1	4	2	2.3
	Dengue	3	1	3	1	2.0
	Rotavirus	1	2	3	1	1.8

#### **Ranking based on Feasibility**



	Diseases	How feasible are technical solutions to address unmet needs?	What is the availability of funds?	Can FIND address unmet needs better than other stakeholders?	Weighted average
	ТВ	3	4	5	3.8
nt	Malaria	5	4	5	4.6
ırre	HAT	5	3	5	4.2
บี	Chagas disease	4	3	4	3.6
	Visceral leishmaniasis	4	2	4	3.2
	Cervical cancer	4	5	2	4.0
	Hepatitis C	5	3	4	4.0
	Hepatitis B	5	3	3	3.8
	Influenza	4	5	1	3.8
	Diabetes	4	5	1	3.8
	HIV	3	5	1	3.4
le	Pneumonia	4	3	3	3.4
ntia	Schistosomiasis	4	2	4	3.3
ote	Syphilis	4	3	1	3.0
Ъ	Lymphatic filariasis	3	2	4	2.8
	Onchocerciasis	3	2	4	2.8
	Typhoid	3	2	4	2.8
	Rotavirus	3	1	3	2.2
	Buruli ulcer	3	1	5	2.6
	Dengue	3	3	1	2.6
	Leprosy	3	2	3	2.6

### **Prioritizing Diseases**





Notes:

(\*) Need for innovative/improved diagnostic tests, disease burden and disease severity;

(\*\*) Technical feasibility, availability of funds and ability of FIND to address unmet needs.

Sources: interviews, FIND, Advention BP

#### 'work in progress'



# Thank you