



## Is Xpert MTB/RIF a breakthrough for people living with HIV?

CROI  
HIV/TB Research Frontier meeting  
February 27, 2011  
*Catharina Boehme*

*Partnering for better diagnosis for all*

## Conflict of interest

- ❖ FIND is a non-profit foundation devoted to developing and rolling out diagnostic tools for poverty-related diseases.
- ❖ In this role, FIND has development partnerships with industry.
- ❖ Xpert MTB/RIF has been developed through a partnership between Cepheid, FIND and UMDNJ with support from BMGF and NIH.
- ❖ FIND has no financial beneficial participation in any form.

# A multi-disease platform



Xpert  
MTB/RIF

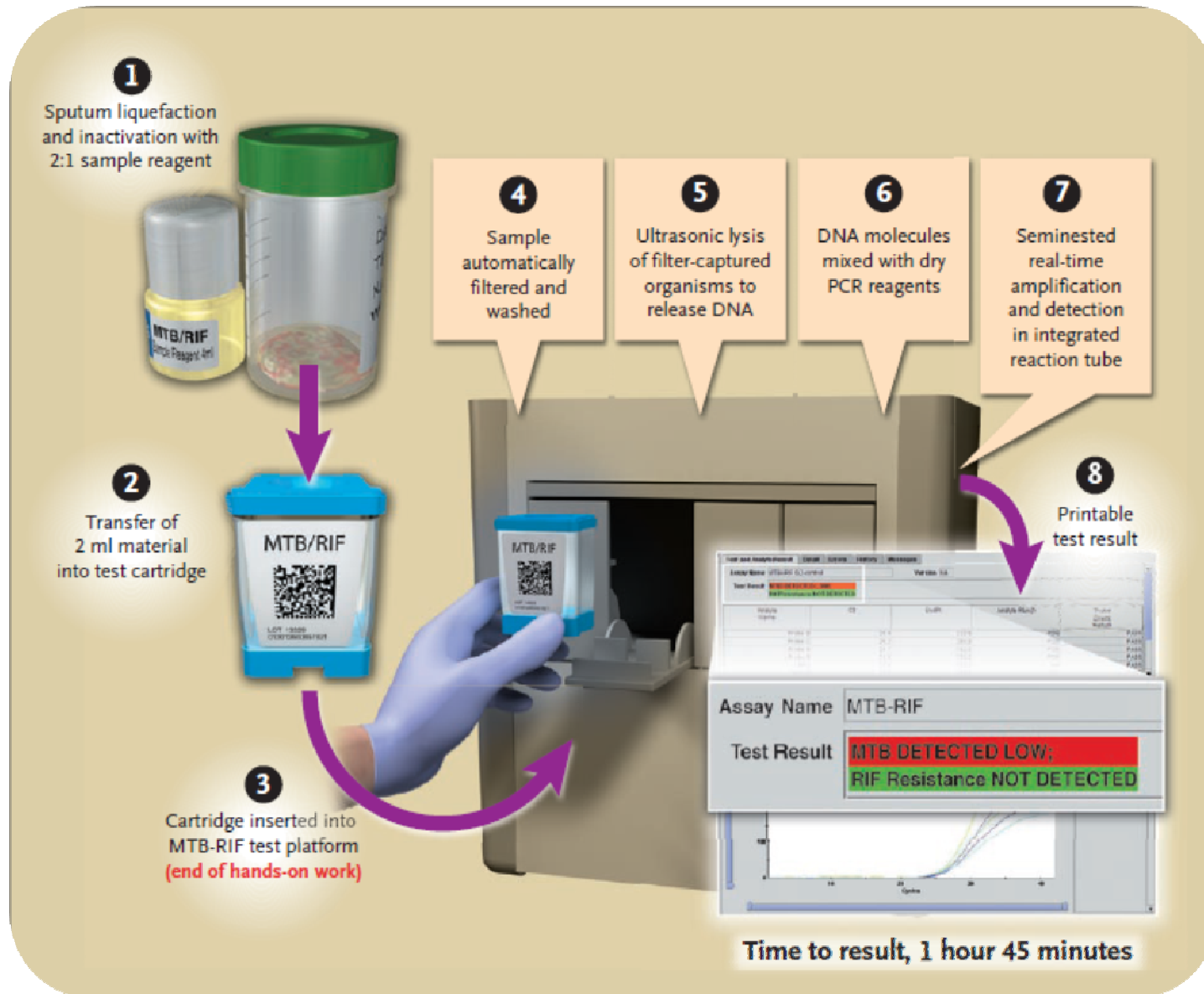


GeneXpert



5      20      80      Samples per shift      500-1000

# Assay principles and procedure



# Multi-center implementation studies

- ❖ 9 settings of intended use in 6 countries
  - ❖ (Sub)-District (3), microscopy centers (3), MDR screening / ER (3)
- ❖ **Diverse** laboratory conditions (temp up to 40C, space, staff background)
- ❖ **6648** TB or MDR-TB suspected patients screened from diverse populations
- ❖ **1255** known HIV+ (313 C+), **1884** known HIV- (441 C+), **3509** HIV unknown (774 C+)



Lima	Peru
HIV	3%
TB (C+)	17%
MDR TB	8%

Kampala	Uganda
HIV	80%
TB (C+)	42%
MDR TB	2%



Baku	Azerbaijan
HIV	6%
TB (C+)	47%
MDR TB	22%



Vellore	India
HIV	<1%
TB (C+)	10%
MDR TB	7%



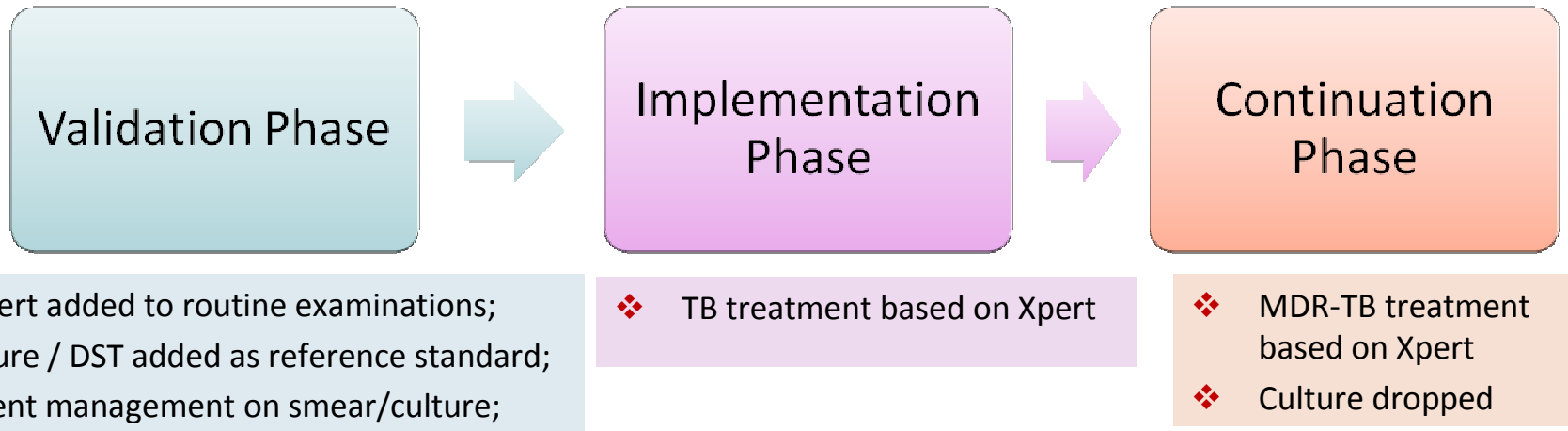
Cape Town	South Africa
HIV	77% (K), 30% (P)
TB (C+)	26%
MDR TB	4%



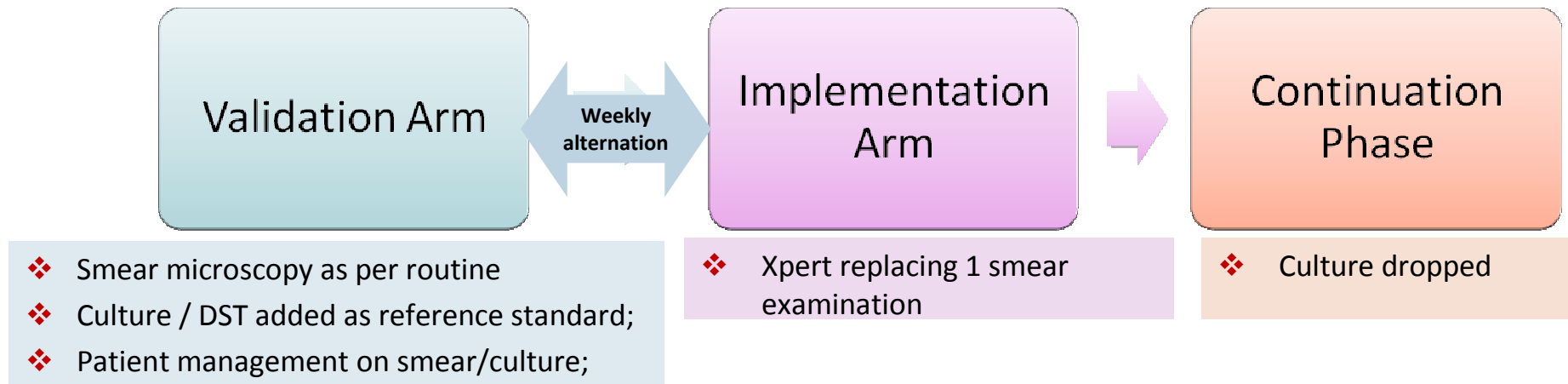
Manila	Philippines
HIV	<1%
TB (C+)	20%
MDR TB	54%

# Study design

## Peru, Uganda, Azerbaijan, India, Philippines



## South Africa



## Considerations for implementation

Variable	Performance / outcome
Preventive maintenance	Annual calibration (logistics and costs).
Storage, operating temperature	2-28 °C storage; 15-30 °C operation. High lab temperature = no effect on performance. (Error message at >40 °C)
Electrical supply and back-up power	Uninterruptable power supply with UPS (400 VA) for 20 min. Serial car batteries tested.
Biosafety requirements	Same as smear microscopy*.
Waste management	As for sputum containers; additional waste volume compared to smear microscopy.

\*Banada PP., et al. Containment of bioaerosol infection risk by the Xpert MTB/RIF assay and its applicability to point-of-care settings. J Clin Microbiol 2010; 48 (10): 3551-7



## A breakthrough for people living with HIV?

- ❖ Significantly increases pTB or MDR-TB case detection rates compared to current routine practice? *Yes*
- ❖ Robust enough to be implemented near point-of treatment? *Important considerations for implementation*
- ❖ Ex-pTB? Pediatric TB? *Promising preliminary data*
- ❖ Shortens diagnostic delays, but also time to treatment? *Yes*
- ❖ Decreases drop out rates? *Promising preliminary data, but treatment programs need to be strengthened*
- ❖ Decreases morbidity and mortality? *Promising preliminary data* Increases cure rates? *No data*
- ❖ Decreases transmission rates (TB or MDR)? *No data*
- ❖ Is a cost-effective intervention? *ICER < GDP per capita; resource mobilization critical*
- ❖ Multi-disease platform? *Yes, HIV VL and STD of particular relevance*
- ❖ Being rolled-out and scaled up? (without weakening other TB control efforts). *WHO surveillance program.*



Thank you to all partners and patients who participated in this demonstration study



### Lima, Peru

- ❖ INS
- ❖ NTP / DISA IV Lima Este
- ❖ Instituto A. v. Humboldt
- ❖ UPCH

### Manila, Philippines

- ❖ Lung Institute
- ❖ TDF
- ❖ CDC

### Cape Town, South Africa

- ❖ MOH / NTP
- ❖ NHLS
- ❖ MSF
- ❖ UCT

### Newark, US

- ❖ D. Alland team at UMDNJ

### Geneva, Switzerland

- ❖ FIND

### Vellore, India

- ❖ Central TB Division
- ❖ Community Health Dep.
- ❖ Christian Medical College
- ❖ FIND, India

### Kampala, Uganda

- ❖ NRL
- ❖ Makerere University
- ❖ Mulago Hospital
- ❖ University of California
- ❖ FIND, Uganda

### Baku, Azerbaijan

- ❖ MOH
- ❖ MOJ
- ❖ STI/Main Medical Dep.

### Sunnyvale, US

- ❖ Cepheid

## Glance inside the cartridge

