Diagnostics for epidemic preparedness: disrupt to deliver

Dr Cassandra Kelly-Cirino, Director of Emerging Threats
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FIND is a global non-profit driving diagnostic innovation to combat major diseases affecting the world’s poorest populations

- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member
- ISO-certified quality management system for IVD clinical trials

We address market failure by partnering to develop and deliver diagnostic solutions to LMICs

<table>
<thead>
<tr>
<th>ANTIMICROBIAL RESISTANCE</th>
<th>HEPATITIS C &amp; HIV</th>
<th>MALARIA &amp; FEVER</th>
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<tbody>
<tr>
<td>NEGLECTED TROPICAL DISEASES</td>
<td>PANDEMIC PREPAREDNESS</td>
<td>TUBERCULOSIS</td>
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Geneva (HQ)

South Africa

India

Kenya

Viet Nam
Outbreak markets are inherently failure markets

We are unable to predict

- Size and rate of expansion
- Geography and potential for spread – where will it happen? Where will it go?
- Temporal distribution – when will it happen next?

Markets cannot be sustained by countries for dozens of different diagnostics for events that rarely occur
A lot of effort, little long-term reward: Ebola example

- New diagnostics on the market by 2016: 75
- Platforms: 40
- Manufacturers:
- Requests for samples & testing: 10
- Emergency Use Authorized (EUA/L) diagnostics by 2018: 10
- FDA-cleared diagnostics (as of Nov 2019): 2

Prioritization to ensure rapid development and roll out

Samples & trials

Approvals

Implementation
What have we learned from Lassa testing network expansion in Nigeria?

- Centralized testing capacity in 2 highly capable sites

- Need to expand testing network to sites with more limited infrastructure and resource availability to ensure adequate response

- Altona manual PCR assay is gold standard but challenging to implement in new network laboratories

Fully automated systems with open-access assay design with assured criteria (cost, appropriateness)

Allow countries and researchers to rapidly develop novel assays on an established automated platform
Simplified automated systems already exist

**BD Max™**
- Fully integrated, automated platform
- Nucleic acid extraction and real-time PCR
- Results for up to 24 samples across multiple syndromes in <3 hours

**cobas® Liat® System**
- PCR system designed for on-demand testing in POC settings
- Fully automated
- Single sample results in <20 mins

Assays are locked; new assays require strong business cases for development and sustained offering
Simplified automated platform & open access assay design in development

- Open-access development platform
- Customizable diagnostic toolset to support diverse test menu
- Generic disposable cartridges with integrated sample preparation processes and reagents
- Flexible multiplexing is facilitated by a new type of reagent that combines multiple roles into one self-contained unit

**PRODUCT PLATFORM**
An integrated Product Development and Test Platform
- Hardware: BLINK One Analyzer, BLINK One Cartridge
- Software: BLINK Toolbox
- Reagents: BLINK Reactor Beads

**BUSINESS MODEL**
An Open-Access Development and Business Model
- Non-exclusive development license
- Remuneration for platform use
- Transparent cost structure
Innovation in manufacturing is critically needed

Current challenges in mobilizing manufacturing in HIC to address small or unclear diagnostic needs in rest of world

- Ramp up for cleared Ebola tests took months
- Yellow fever diagnostic needs remain a bottleneck to outbreak identification and management
- Low prioritization of R&D innovation for meningitis, cholera, Lassa fever, Nipah, CCHF
Matching local demand with local production for greater impact

- Small volumes not a deterrent
- Lower manufacturing costs can translate into affordable diagnostics
- Highest quality assurances with certified manufacturing facilities
- Diagnostic pipeline that caters to the needs of endemic and episodic outbreaks

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<tr>
<th>Test indication</th>
<th>Purchasing Partner</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
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<tbody>
<tr>
<td>Yellow fever test co-developed by IDI &amp; MetLogic</td>
<td>NGO</td>
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<tr>
<td>Measles test developed by MetLogic</td>
<td>NGO</td>
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<td>Meningococcal meningitis test developed by IMACCES</td>
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<td>HBsAg test developed by biolMenseur</td>
<td>Government</td>
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<tr>
<td>Human African Trypanosomiasis test developed by INT &amp; RID</td>
<td>NGO &amp; PH5</td>
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Transformations in R&D and logistical/health system preparedness

R&D:

- Comprehensive diagnostic platforms that can rapidly adopt new assays
- Diagnostics with limited sample preparation and training needs
- Market incentives / sustainable business models to offset losses during non-outbreak years
- Specimen banks for easily accessible samples

Logistical & health system preparedness:

- Preselected suppliers to ensure appropriate capacity for outbreak situations
- Established, local manufacturing lines for diagnostic production during outbreaks
- Reinforced surveillance capacities at national and international levels
Thank you