1st Health Working Group
18th - 20th January 2023
Session 2
Strengthening Cooperation in Pharmaceutical Sector with Focus on Availability & Access to Safe, Effective, Quality and Affordable Medical Countermeasures (MCMs) — VTDs (Vaccine, Therapeutics & Diagnostics)

Bill Rodriguez, FIND
Key addressable issues drive the inequity in availability of diagnostic tests
Global Dx production capacity has grown dramatically but remains highly centralized.

60% of production limited to ONLY 3 countries with needs of LICs/LMICs not met adequately.

Source: Confidential manufacturer interviews n=17, April 2021.
COVID-19 enabled technology transfer for regional manufacturing of diagnostics

<table>
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<tr>
<th>Supported by ACT-A Diagnostics Pillar</th>
<th>Products</th>
<th>Total Capacity For LMICs</th>
<th>Locations</th>
<th>Priority Markets</th>
<th>Pricing / Savings</th>
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<tr>
<td>▪ Late-stage R&amp;D</td>
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<td>Increase in capacity from 128 to 314 mill test per year through ACT-A</td>
<td>Senegal</td>
<td>LMICs</td>
<td>Decreased prices from $5 to $1.50 per test</td>
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<td>▪ Clinical validation</td>
<td></td>
<td></td>
<td>India</td>
<td></td>
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<td>▪ Regulatory support</td>
<td></td>
<td></td>
<td>China</td>
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<td>▪ Technology transfers</td>
<td></td>
<td></td>
<td>Brazil</td>
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<td>▪ Improving fragile supply chains through strengthening local capacity</td>
<td>4 manufacturers</td>
<td>COVID-19 Antigen RDTs</td>
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<td>▪ Decreasing prices</td>
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COVID-19 accelerated R&D, manufacturing, and launch of affordable diagnostic tests

- Funding to support capacity expansion in exchange for access pricing
- Building and expanding local manufacturing capacity in LMICs through technology transfer agreements between diagnostic developers and local manufacturers
- Technical assistance for manufacturing, regulatory procedures, and market entry
- Ensuring high-volume commitment and distribution to LMICs through manufacturing capacity expansion

Map showing collaborations:
- USA
- UK
- India
- South Korea
- Brazil
- Senegal

- Up to 50 Mio tests/year x200%
- Up to 30 Mio tests/year x3,000%
- Up to 120 Mio tests/year x 400%

Tech transfer & local capacity building
Capacity expansion for global distribution
Sustained, secure global supply of affordable diagnostic tests will require a coordinated network

**Technical & business innovation**
- Support for the development of transformative diagnostics
- Identify innovative business models built for sustainability

**Partner matchmaking & tech transfer**
- Establish a network of developers and manufacturers to foster win/win partnerships
- Use the Center of Excellence approach to facilitate tech transfer

**Technical assistance & guidance**
- Support in building the test portfolio and identifying skilled personnel
- Perform independent evaluations to help local manufacturers choose the best tests to transfer

**Market entry & regulatory support**
- Perform and share market intelligence and demand assessment reports
- Support regulatory and market access strategies

**Advocacy with local authorities and buyers**
- Demonstrate long-term cost effectiveness and impact on supply security and broader economic benefits
Collaborative global network of DX R&D and Manufacturing Hubs

Potential sites for future DX R&D and manufacturing hubs

- Align agendas with regional and global health priorities
- Explore disease areas that are underserved by global manufacturers but are aligned with country priorities
- Link procurement to questions of improving fragile supply security & broader economic benefits
- Link manufacturing development efforts to address access gaps in regional health systems

Numbers of site and location per region of interest will be determined with a Diagnostic Manufacturing Network Optimization (Q1 2023)
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Setting up a DX R&D and Manufacturing network

1. Sustainable Market Demand
2. Regional priorities/Public Health priorities/gaps
3. Tech Transfer Donor Interests
4. Tech Transfer Recipients – Existing Regional Manufacturers

- Gather market intelligence
- Conversations within regions

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