3rd Health Working Group Meeting

Side Event

on

Strengthening Global Collaboration on Research and Development in MCMs (Diagnostics, Vaccines, and Therapeutics)

Date: 5th June 2023
Panel 1
Global Collaboration in Diagnostics: Challenges, R&D, and Regional Capacity Building

Dr Bill Rodriguez, CEO

FIND
Diagnosis for all
COVID-19 was a watershed for diagnostic testing

More than 50 organizations support the Dx Pillar on strategy, product development, policy, and implementation across the Dx value chain

- COVID tests procured: 190 M
- Tests listed through WHO EUL: 40
- Decrease in the price of tests: –50%
- Test capacity for LMICs produced by local manufacturing sites: 1.15 B
- Sites for local manufacturing and tech transfer: 14
- Member States with genomic sequencing capabilities: 77%
WHO declares Public Health Emergency of International Concern (PHEIC)

2020

30 January
WHO declares PHEIC

3 April
WHO reports 1 million confirmed COVID-19 cases

4 April
WHO EUL

9 May
100 days

64 days:
First real-time PCR test granted WHO EUL

65 days:
WHO reports 1 million confirmed COVID-19 cases

2 September
216 days:
WHO approves dexamethasone as the first COVID-19 therapeutic

22 September
236 days:
First rapid diagnostic test granted WHO EUL

25 November
300 days

31 December
336 days
WHO issued its first EUL for a COVID-19 vaccine

Accurate and approved molecular tests and RDTs
An initial regimen of therapeutics
Vaccines ready to be produced at scale

Critical need for a quicker diagnostic response

G7 100 Days Mission to respond to future pandemic threats.
Hospitals sound alarm at failings in privately run virus test centre

Tests for key workers
Government under fire

Exclusively...
Critical need for a quicker diagnostic response

- **WHO declares Public Health Emergency of International Concern (PHEIC)**
- **2020**
  - **30 January**: WHO declares PHEIC
  - **3 April**: WHO reports 64 days: First real-time PCR test granted WHO EUL
  - **4 April**: 65 days: WHO reports 1 million confirmed COVID-19 cases
  - **9 May**: 100 days
  - **2 September**: 216 days: WHO approves dexamethasone as the first COVID-19 therapeutic
  - **22 September**: 236 days: First rapid diagnostic test granted WHO EUL
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- **Accurate and approved molecular tests and RDTs**
- **An initial regimen of therapeutics**
- **Vaccines ready to be produced at scale**

Critical need for a quicker diagnostic response

COVID-19 tests per 1’000 people per day, G20 Countries

First 100 Days

Sources: Our World in Data and FIND Test Tracker
Critical need for a quicker diagnostic response

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Day 1

June 2020

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Day 60 Scaled regional manufacturing

2020

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22 September

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2020

100 days

100 Days Mission to respond to future pandemic threats.
# What needs to happen?

## Diagnostic R&D Agenda

<table>
<thead>
<tr>
<th>Day:</th>
<th>Pre-Pandemic</th>
<th>Validate, Produce, and Distribute</th>
<th>Scale</th>
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<tbody>
<tr>
<td>&lt;0</td>
<td>• Development of prototype diagnostic libraries for molecular tests and RDTs</td>
<td>• Analytical validation of tests in real time</td>
<td>• Collaborative registration process across SRAs and regional and national regulatory agencies</td>
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<td>• Sharing of pathogen material through global biobanking and material transfer agreements</td>
<td>• Evidence generation in relevant populations supported by pre-established clinical trial frameworks and global trial network</td>
<td>• Activation of strategic contracting vehicles with reliable mechanisms to ensure equitable access</td>
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<td>• Validation and routine use of pathogen tests in surveillance of regional priority pathogens</td>
<td>• Rapid and transparent sharing of test data with public and private sector decision makers to enable targeted pandemic response</td>
<td>• Scaled, regional manufacturing</td>
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<td>60</td>
<td>• Continuous pathogen surveillance, reporting, and insight generation via regional surveillance hubs</td>
<td>• Rapid regional production at established regional manufacturing hubs on a global basis</td>
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<tr>
<td>100</td>
<td>• Genomic surveillance of pathogen evolution / variants</td>
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What needs to happen?
Diagnostic R&D Agenda – Pre-Pandemic

1. Multiplex molecular diagnostic platforms
2. Prototype diagnostic libraries for 10 pathogens
3. Clinical reference standards
4. Global virtual biobanking network
5. Global clinical trial and product evaluation network
6. Harmonized EUL/ regulatory pathway to enable global product registration
7. Active global surveillance networks with new tests...
8. ...linked to primary care testing programs
   - Pandemic/endemic disease panels
   - AMR
   - HPV
   - Respiratory panels, including TB
9. Regional manufacturing hubs
10. Defined procurement mechanisms

Total cost: $40-80M/year x 5 years
G20 Priority: Strengthening VTD R&D and Manufacturing Networks

FIND and Unitaid convened >20 diagnostics manufacturers during the 2nd G20 Health Working Group meeting:

13th-14th April 2023
BUILDING FOR SUSTAINABILITY: Accelerating Distributed Manufacturing For Diagnostics
Leveraging ACT-Accelerator Regional Manufacturing Investments

To support the COVID response, FIND and Unitaid partnered to accelerate the availability and affordability of quality-assured Ag RDTs for SARS-CoV-2 in LMICs through local manufacturing.

- Funding to support capacity expansion in exchange for access pricing and volume
- Technical assistance for manufacturing tech, regulatory & market entry
- Technology transfer partnership matchmaking

Technology Partners:
- DCN
- BIONOTE
- Wondfo
- Premier Medical Corporation Private Limited
- DIATROPIX

Manufacturing Expansions:
- DCN: Manufacturing expanded at 144 Mio tests/year + Technical assistance
- BIONOTE: Manufacturing expanded at 120 Mio tests/year + Technical assistance
- Wondfo: Manufacturing expanded at up to 50 Mio tests/year + Technical assistance
- Premier Medical Corporation Private Limited: Manufacturing expanded at 120 Mio tests/year + Technical assistance
- DIATROPIX: Manufacturing expanded at up to 50 Mio tests/year + Technical assistance
Reliable Diagnostics Supply: producing tests close to where people need them

Global manufacturers
- Realize benefits of economies of scale
- Benefits for LMICs can be leveraged through access terms & volume commitments
- Extend benefits of skilled personnel and access to capital through partnerships

Local manufacturers
- Reduce reliance on import of finished products from small number of suppliers
- Reduce transportation costs
- Suitable products and supply channels that meet priority health needs
- Reinforce local ownership

End users

Customs
(export)

Customs
(import)

Regional distributors

Local buyers
(hospitals, pharmacies, clinics, people)
South-South Collaboration on the diagnostics R&D agenda for PPR

Initiative within 100 Days Mission will improve pandemic preparedness for approximately one-quarter of the world’s population

- Create **diagnostic libraries** to detect outbreak-prone diseases of regional and global importance
- Enhance country health system capability to integrate new **diagnostic tools** into existing health settings, laboratories, and surveillance programmes
- Verify/validate in six countries to demonstrate **global scalability and impact**
- Help develop **sustainable R&D capacity** of the country partners

**Consortium to enhance South–South collaboration**

- Country partners
- Global multilateral organizations
- Delivery partners

Institut Pasteur de Dakar
FOCRUZ Fundação Oswaldo Cruz
PASTEUR NETWORK
## R&D diagnostic priorities for PPR

### Developers and manufacturers
- Establish partnerships between manufacturers in low, middle- and high-income countries to facilitate the transfer of know-how and technologies
- Maintain a balanced portfolio of products prioritizing developing and manufacturing products that meet global and regional public health needs

### G20 countries and donors (including investment banks)
- Invest in different business models to support the full value-chain of diagnostics, including infrastructure development, tech-transfer, training, and capacity building
- Facilitate access to early investments and financing support for small and medium size enterprises

### Multilateral organizations
- Continue to support and promote technology transfer of diagnostics, building on the successes of the ACT-Accelerator
- Continue and expand seed funding support
- Provide visibility of public health priorities to guide R&D priority investments

### National governments
- Promote industrial parks and facilitate business registrations, which can help attract investments, stimulate innovation, and overcome infrastructure and transport barriers
- Develop and publicly share national diagnostic strategies to guide R&D priorities, and with concrete budget allocations earmarked for sourcing of regional manufactured

### Important factors
- Manufacturing capacity
- Financing and procurement mechanisms
- Regulatory barriers
Request to G20 Member States

- Enabling policy environment
- Anchor in UHC
- Funding
- Champion the VTD R&D and Manufacturing networks

Thank You