



3rd Health Working Group Meeting

Side Event
on

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

वशुधेव कुटुम्बकम् | ONE EARTH • ONE FAMILY • ONE FUTURE

Date: 5th June 2023

Panel 1

Global Collaboration in Diagnostics: Challenges, R&D, and Regional Capacity Building







Dr Bill Rodriguez, CEO



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

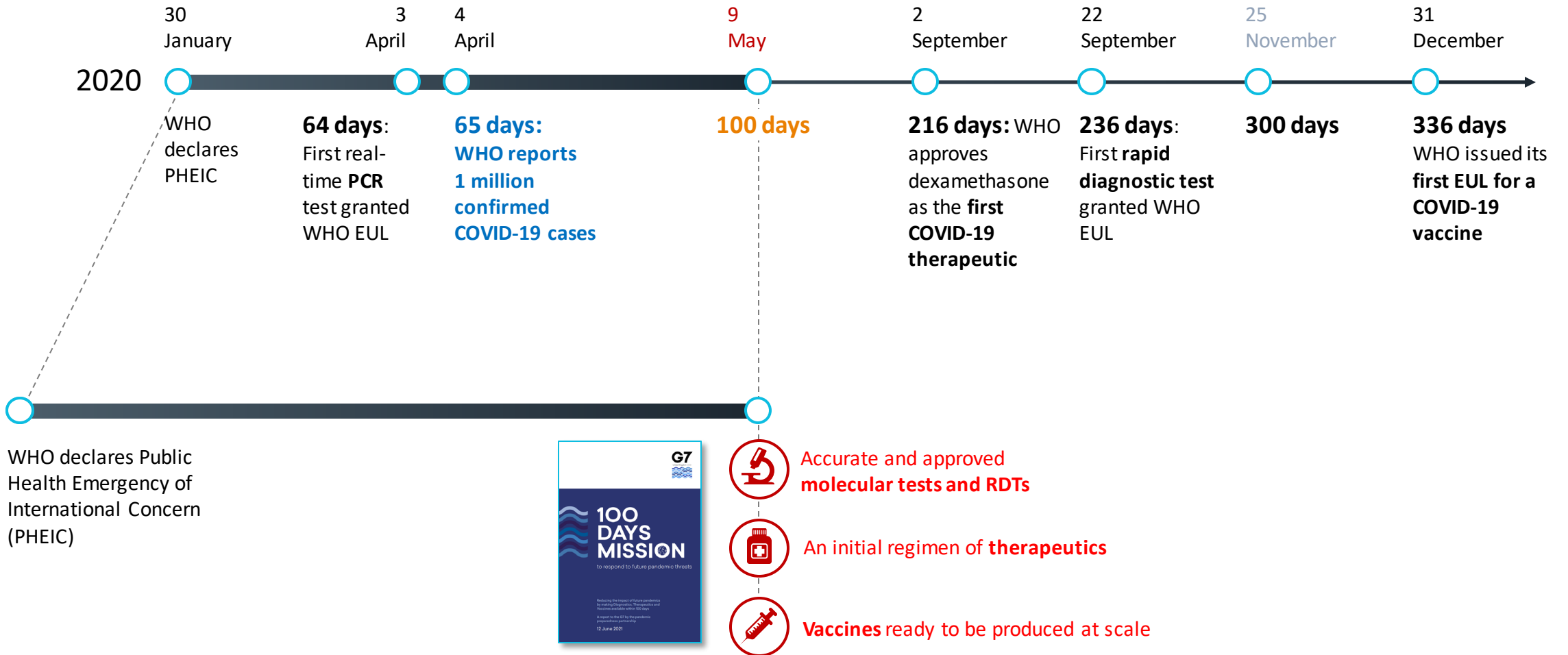


-  **190 M** COVID tests procured
-  **40** Tests listed through WHO EUL
-  **-50%** Decrease in the price of tests
-  **1.15 B** Test capacity for LMICs produced by local manufacturing sites
-  **14** Sites for local manufacturing and tech transfer
-  **77%** Member States with genomic sequencing capabilities

ACTaccelerator
ACCESS TO COVID-19 TOOLS



Critical need for a quicker diagnostic response





Gaga songs ranked!

Friday
24 April 2020
£2.20 | £2.70
From £1.75 for subscribers

The Guardian

Hospitals sound alarm at failings in privately run virus test centre

Exclusive

Juliette Garside

The drive-through centre, at Chessington World of Adventures in Surrey, was among the first in what will be a network of about 50 regional facilities, trumpeted by the health secretary, Matt Hancock, as key to delivering on his promise of 100,000 tests a day by

be handling logistics across a number of the sites, working alongside other private firms such as Serco and Boots. Deloitte says it does not run or manage the testing centres, but rather supports the Department of Health. In revelations that raise concerns

Tests for key workers
Government unveils plans

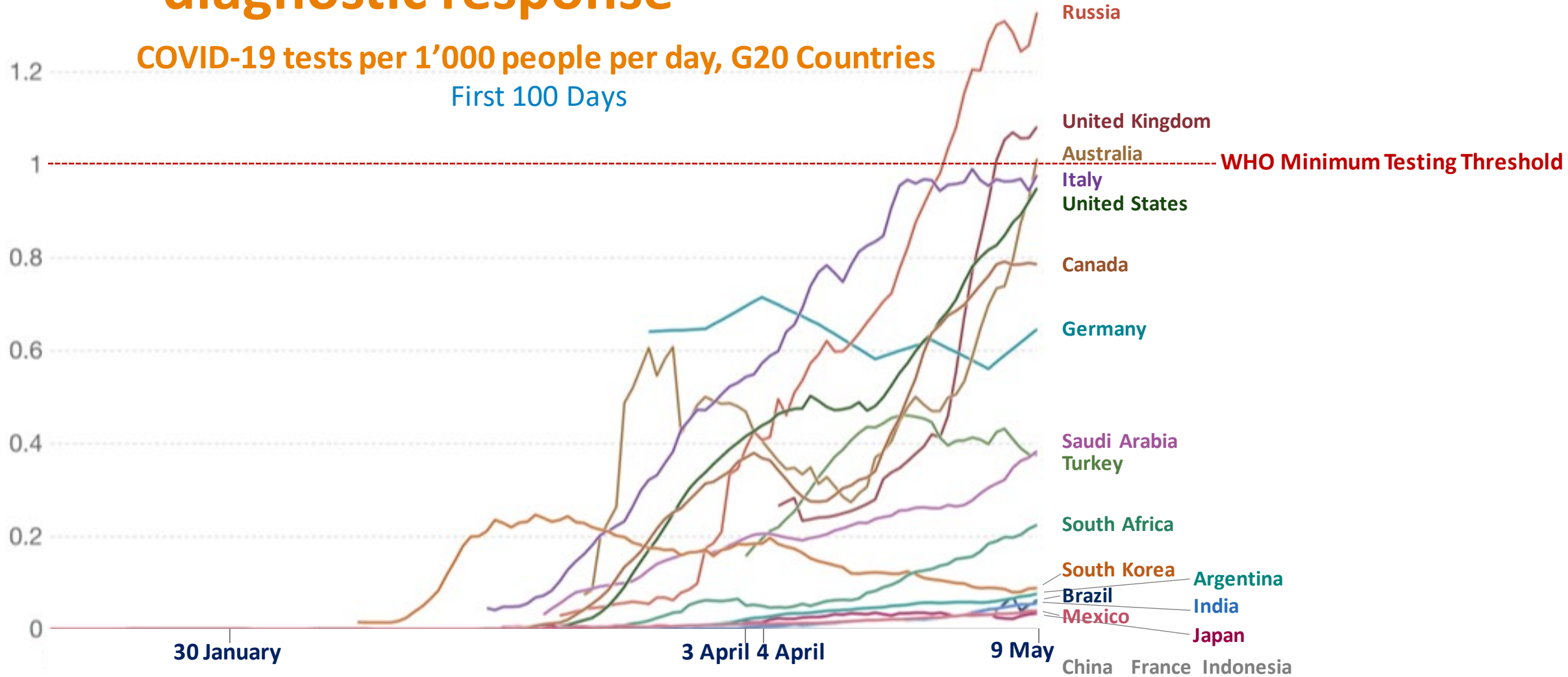
been sent someone else's results. In other cases, the test centre could not ring with a result because of a failure to record the correct phone number. In an email written in early April, seen by the Guardian, the chief executive of Fraser Hospital said: "The centre



Critical need for a quicker diagnostic response



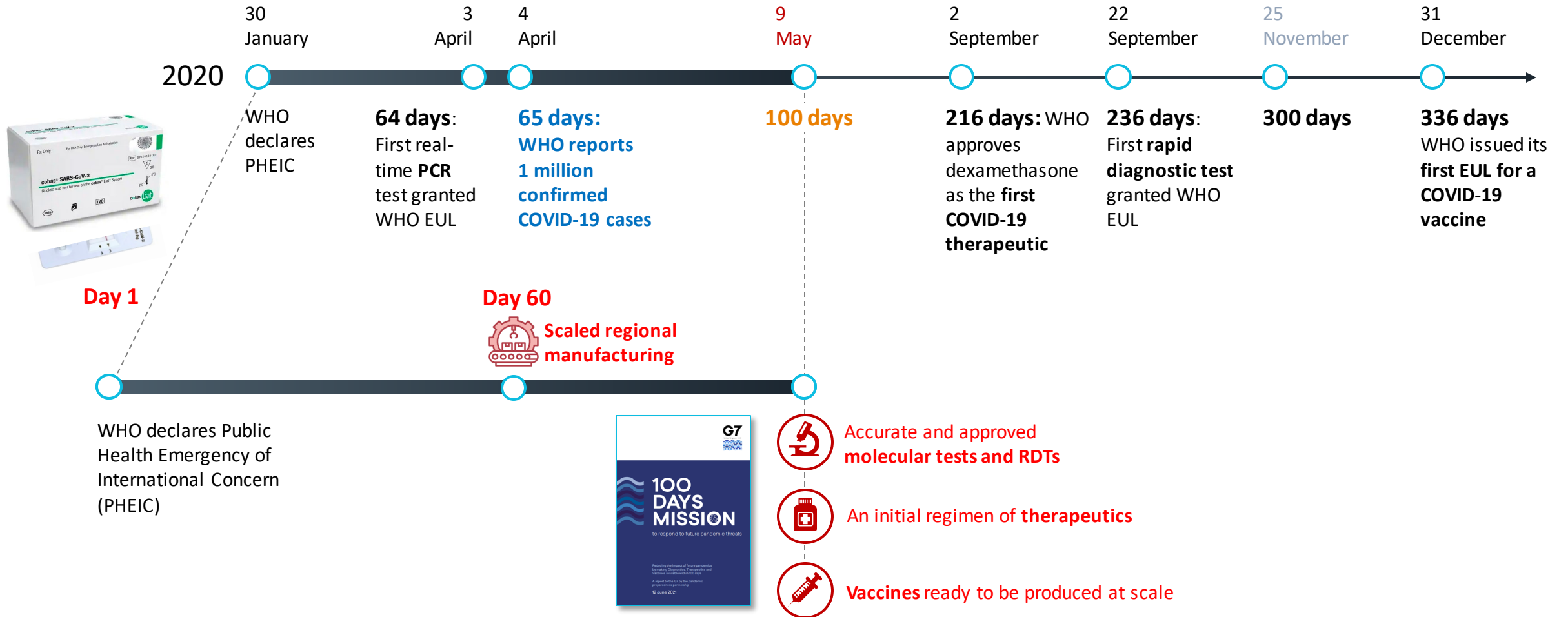
Critical need for a quicker diagnostic response



Critical need for a quicker diagnostic response



Critical need for a quicker diagnostic response



What needs to happen? Diagnostic R&D Agenda

Day:

<0

60

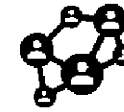
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Pre-Pandemic



- **Development of prototype diagnostic libraries** for molecular tests and RDTs
- **Sharing of pathogen material** through global biobanking and material transfer agreements
- **Validation and routine use of pathogen tests in surveillance** of regional priority pathogens

Validate, Produce, and Distribute



- **Analytical validation of tests** in real time
- **Evidence generation** in relevant populations supported by pre-established clinical trial frameworks and global trial network
- **Rapid and transparent sharing of test data** with public and private sector decision makers to enable targeted pandemic response
- **Rapid regional production** at established regional manufacturing hubs on a global basis
- **Genomic surveillance** of pathogen evolution / variants

Scale







- **Collaborative registration process** across SRAs and regional and national regulatory agencies
- **Activation of strategic contracting vehicles** with reliable mechanisms to ensure **equitable access**
- **Scaled, regional manufacturing**

- **Continuous pathogen surveillance**, reporting, and insight generation via regional surveillance hubs



What needs to happen?

Diagnostic R&D Agenda – Pre-Pandemic

	R&D	Regulatory pathway	Surveillance	Scalable Regional Manufacturing
Near Patient POC  < \$10 	1 Multiplex molecular diagnostic platforms	4 Global virtual biobanking network	7 Active global surveillance networks with new tests...	9 Regional manufacturing hubs
True POC < \$5 	2 Prototype diagnostic libraries for 10 pathogens	5 Global clinical trial and product evaluation network	8 ...linked to primary care testing programs <ul style="list-style-type: none"> • Pandemic/endemic disease panels • AMR • HPV • Respiratory panels, including TB 	10 Defined procurement mechanisms
Self-Test < \$2 	3 Clinical reference standards	6 Harmonized EUL / regulatory pathway to enable global product registration		

Total cost: \$40-80M/year x 5 years



G20 Priority: Strengthening VTD R&D and Manufacturing Networks

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

13th-14th April 2023



BUILDING FOR SUSTAINABILITY:

**Accelerating Distributed Manufacturing For
Diagnostics**



FIND ➡➡
Diagnosis for all

Unitaid
Innovation in Global Health

 Global diagnostic manufacturer
 Regional diagnostic manufacturer



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

DCN^D
Center of Excellence to facilitate Tech Transfer

Training and transfer
COVID-19 Ag RDT



Manufacturing expanded at up to 50 Mio tests/year

+
Technical assistance



Training and transfer
COVID-19 Ag RDT



Manufacturing expanded at up to 50 Mio tests/year +
Technical assistance

Training and transfer
COVID-19 Ag RDT



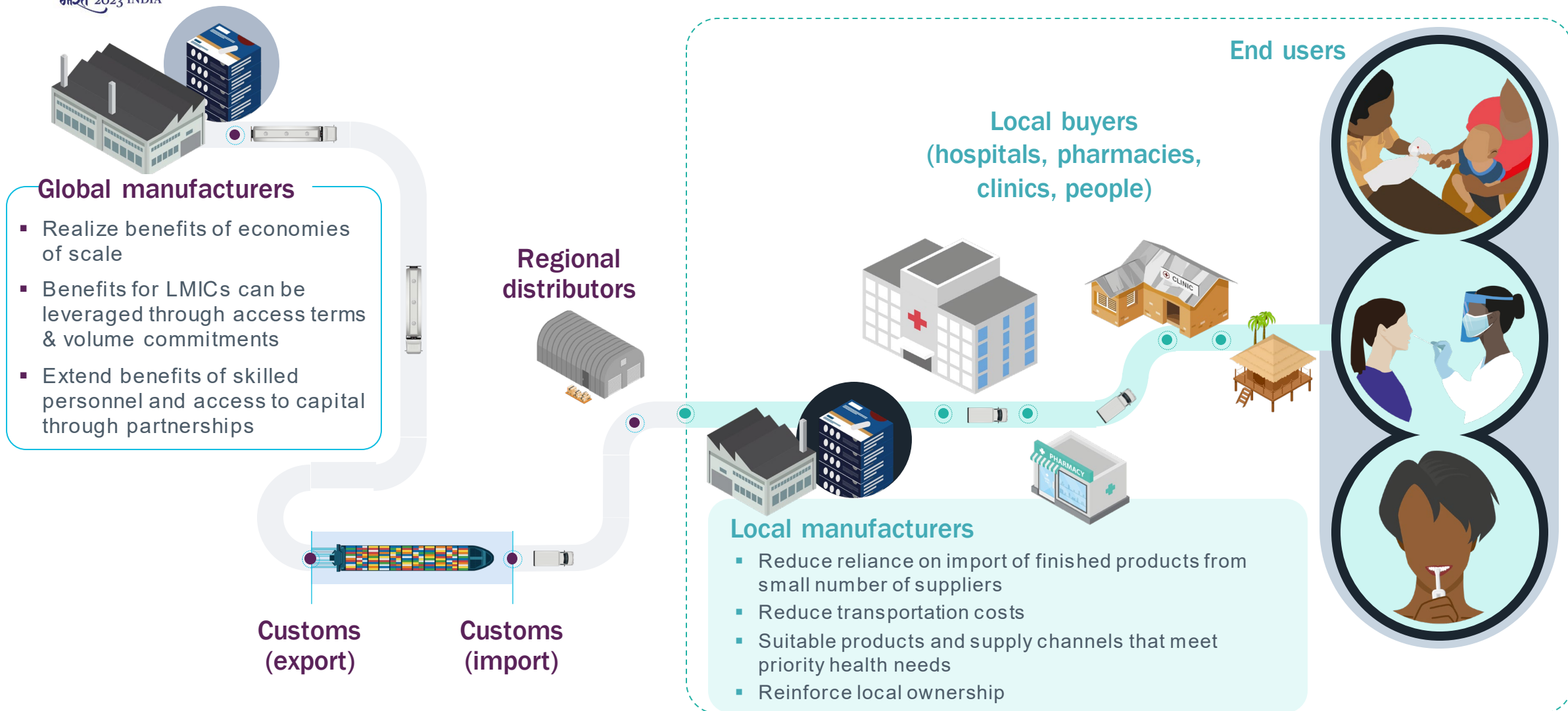
Manufacturing expanded at 144 Mio tests/year
+
Technical assistance



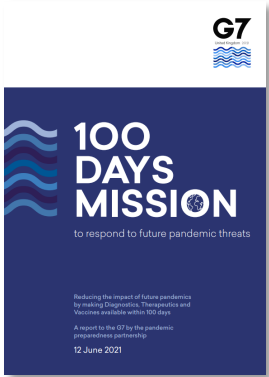
Premier Medical
Corporation Private Limited

Manufacturing expanded at 120 Mio tests/year
+
Technical assistance

Reliable Diagnostics Supply: producing tests close to where people need them



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



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



Manufacturing capacity

Financing and procurement mechanisms

Regulatory barriers



Request to G20 Member States

Enabling policy
environment

Funding



Anchor in UHC

Champion the VTD R&D and
Manufacturing networks

Thank You

