ACT Accelerator Diagnostics Pillar

Member State Briefing

17 June 2021

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Multi-faceted approach by ACT-A Dx working groups has contributed to declining prices of dx tools

R&D Investments

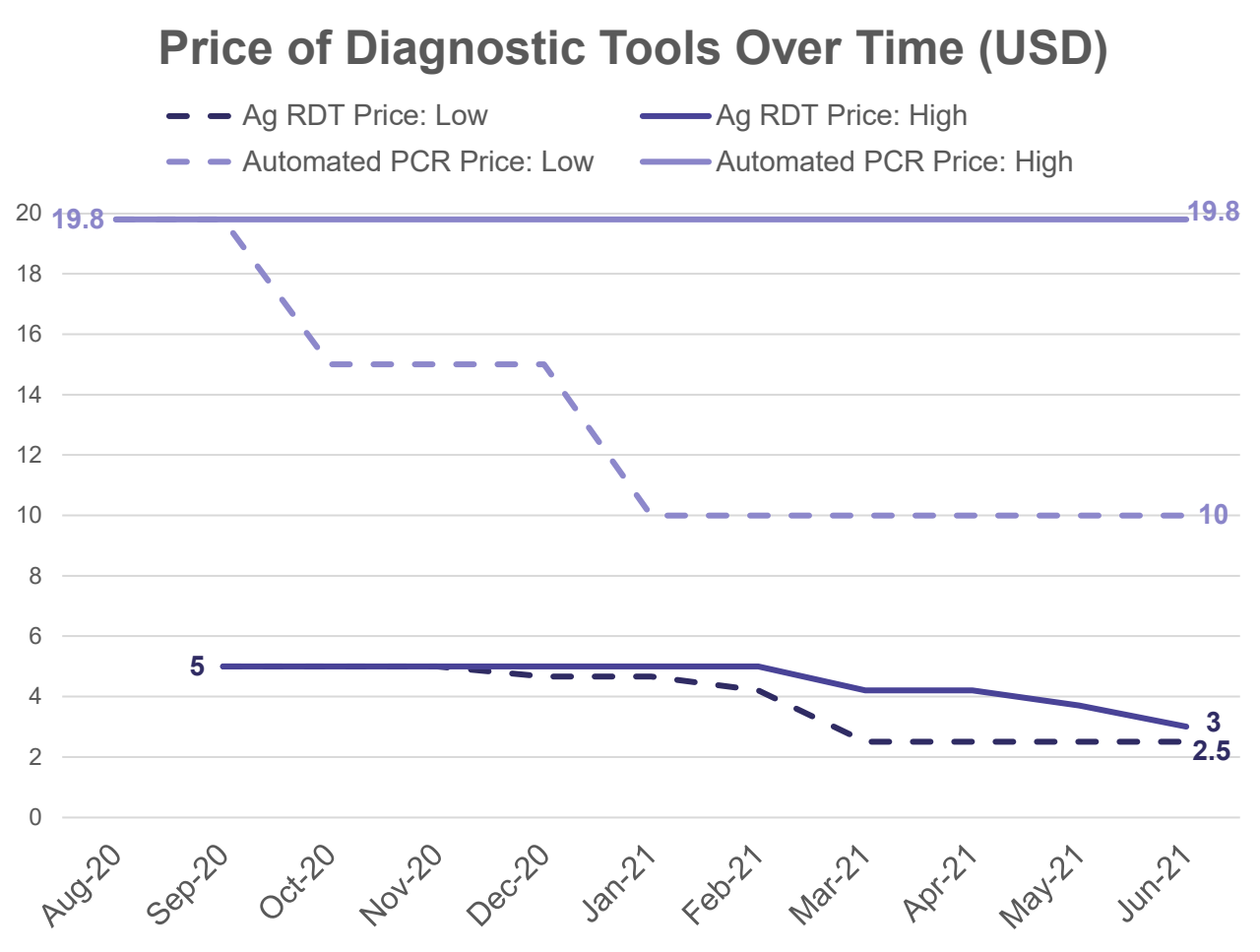
- Encouraging and guiding rapid development of Ag RDTs
- Investments in local manufacturing and increased efficiency to scale capacity

Market Shaping Interventions

- Coordinate negotiations across procurement organizations
- Invest in key suppliers and provide support for regulatory processes
- Increase number of high-quality suppliers in the market

Policy guidance and development

- Support to generate new policy guidance and rapid uptake of products to ensure adequate pull in the market



Source: Diagnostics Consortium for COVID data as May 31, 2021, Manufacturer pricing

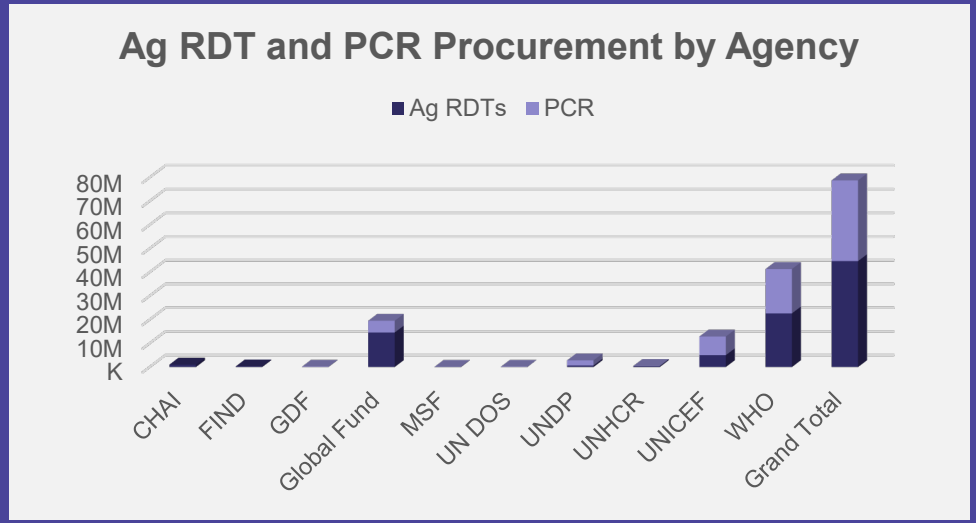
Dx Consortium supported procurement of over 80M tests to date[1]...

Diagnostics Consortium for COVID has **supported access to 80M diagnostic products across 175 countries and 6 regions** to date

Globally, 36M molecular tests procured to date, with an additional demand of 2M reported..

…44.5M Ag RDT tests procured to date, with an additional 20.5M of demand reported

...opportunity to increase volumes with additional support



Source: Diagnostics Consortium for COVID data as 15 June 2021

Diagnostics Consortium for COVID

BMGF, CDC, CHAI, FIND, Global Fund, GDF, MSF, PAHO, UN-DOS, UNDP, UNHCR, UNICEF, Unitaid, USAID, WHO

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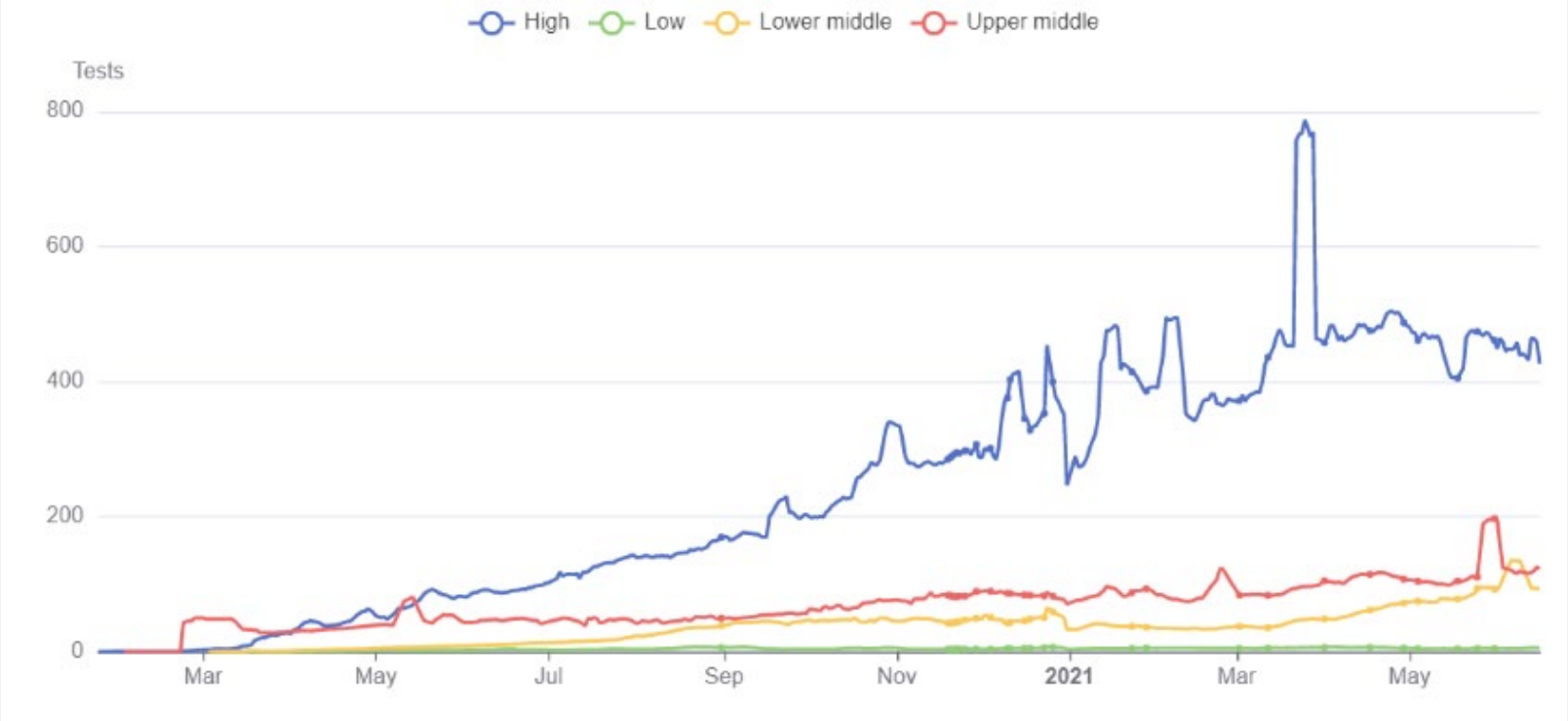
1 **Source:** Diagnostics Consortium for COVID data as 15 June 2021

Despite significant progress, equity gap remains

Daily tests/ 100k population by country income group[1]



1. Due to data inconsistencies, we show a moving 7-day average.
2. Most recent rolling 7-day averages per 100,000 population. Source: FIND test tracker (as of 16 June 2021)

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CORONAVIRUS GLOBAL RESPONSE

LMICs still testing at a fraction of HICs

Daily tests/ 100k population[2]

~x3 to x77 lower depending on income group

5 - 123

LICs, LMICs, UMICs (excl. China)

427

HICs

Efforts to understand and support member states needs expanded

Forums to understand needs and enable knowledge sharing and training:

- WHO Public Health Labs knowledge sharing webinars
- Country and regional roundtables
- Regional workshops for digital tools

WHO EUL and novel international standards:

- Ag RDTs and PoC NAT prioritized for WHO EUL
- WHO facilitated procedure introduced for streamlining in-country authorization/registration
- Development of 1st international standards for antigen tests

Practical support for capability building:

- Training & TA efforts
- Revised Essential Supplies Forecasting Tool to enable planning
- Prioritized efforts to enhance genomic surveillance and sequencing capabilities
- WHO External Quality Assessment: 3,300 panels distributed to 1809 laboratories from 101 countries

Guidance and evidence generation to support decision-making:

- Refreshed policy guidance for Ag RDTs
- Operational guidance and country checklist for RDTs

Expanded access to resources:

- Catalytic procurement to 175 countries
- Expanded access to funding through ACT-A fundraising efforts, including Global Fund's C-19RM

Regional forums to understand country needs and enable knowledge sharing

WHO Public Health Labs knowledge sharing webinar series

- Share individual countries experiences, lessons learnt and best practices
- Provide an additional forum to disseminate the latest WHO guidance

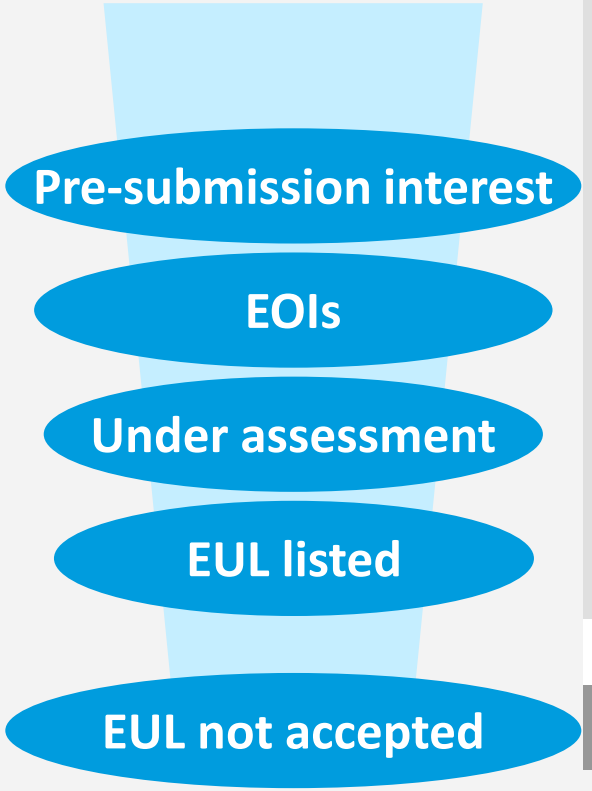
ACT-A Dx Country & Regional Roundtables

- Share relevant updates of what support ACT-A is offering to countries and how to access support
- Provide a listening forum for ACT-A to get feedback/input from countries on support needed, questions, challenges they are facing

ACT-A Regional Workshops on Digital Tools Matchmaking

- Support countries in the selection, implementation, and scale up of digital tools within their COVID-19 response by sharing knowledge and guiding development of an implementation plan.
- Provide a forum for countries to share best practices, challenges, and support needed for digital tools uptake and implementation.

WHO EUL pipeline for IVDs



	Total	Test types		
		Nucleic acid	Antibodies	Antigen
Pre-submission interest	>200	*(split not available)*		
EOIs	145	64	41	40
Under assessment	71	17	28	26
EUL listed	28	23	1	4
EUL not accepted	40	24	9	7

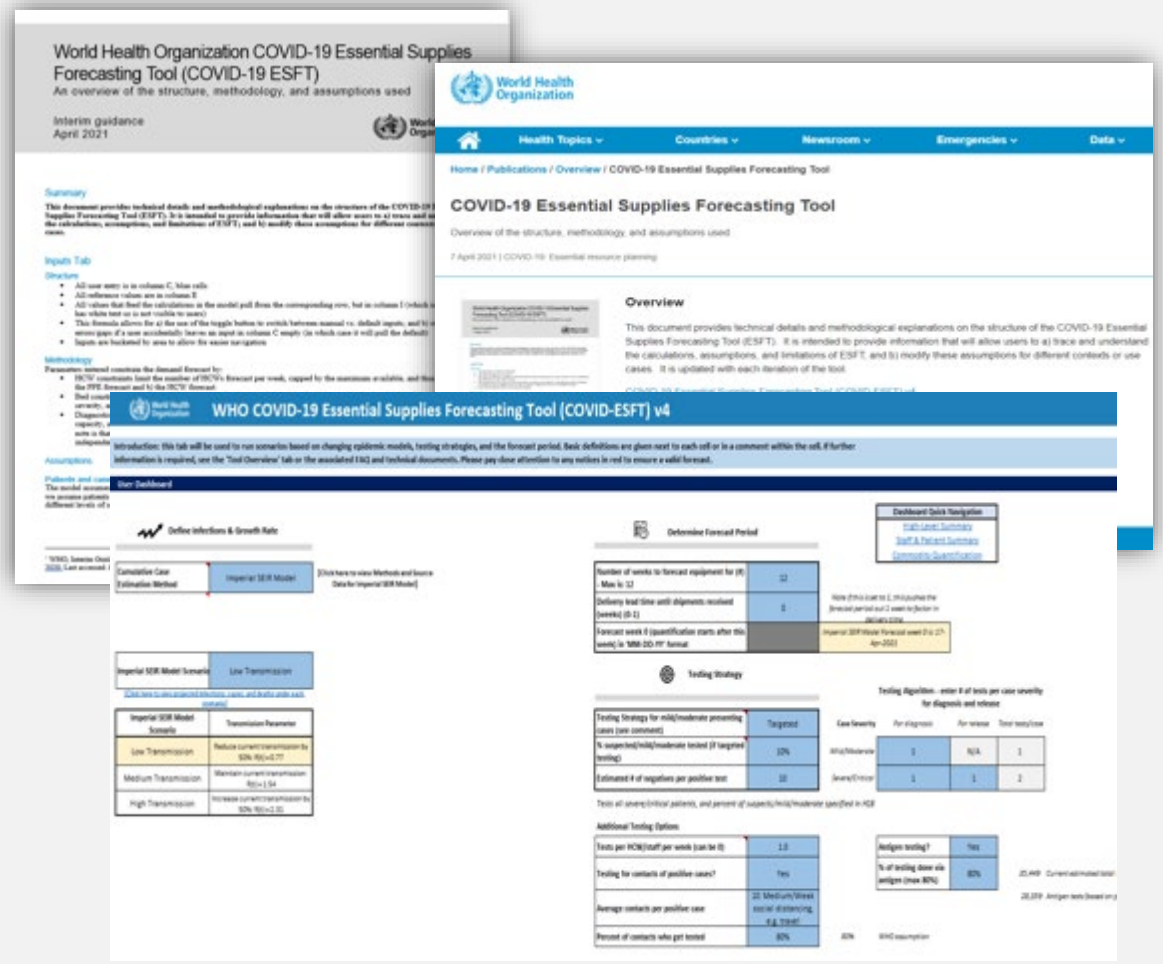
WHO's Essential Supplies Forecasting Tool, version 4 (ESFT v4) can support country procurement planning & needs

- The WHO COVID-19 Essential Supplies Forecasting Tool (ESFT) assists governments, partners, and other stakeholders to forecast the necessary volume of:
  - personal protective equipment,
  - diagnostic equipment,
  - consumable medical supplies,
  - biomedical equipment for case management,
  - essential drugs for supportive care and treatment of COVID-19.

- The tool provides the user with a choice among several epidemiological methods for forecasting COVID-19 cases.

- Version 4 offers several updates, including:
  - inclusion of a new pharmaceutical's module including corticosteroids and anticoagulants,
  - inclusion of antigen rapid diagnostic tests,
  - and a new case forecasting option using data from Imperial College

- A separate dashboard updated bi-weekly sharing aggregate forecast of the potential global demand over a 12-week period



To meet the challenge of new variants, ACT-A Dx is prioritizing sequencing and surveillance

World Health Organization

The ROCKEFELLER FOUNDATION

Launched in April 2021, the **ACT-A Dx Genomic Surveillance working group** is co-led by the WHO and the Rockefeller Foundation and focused on improving genomic surveillance to better control this pandemic and future major events.

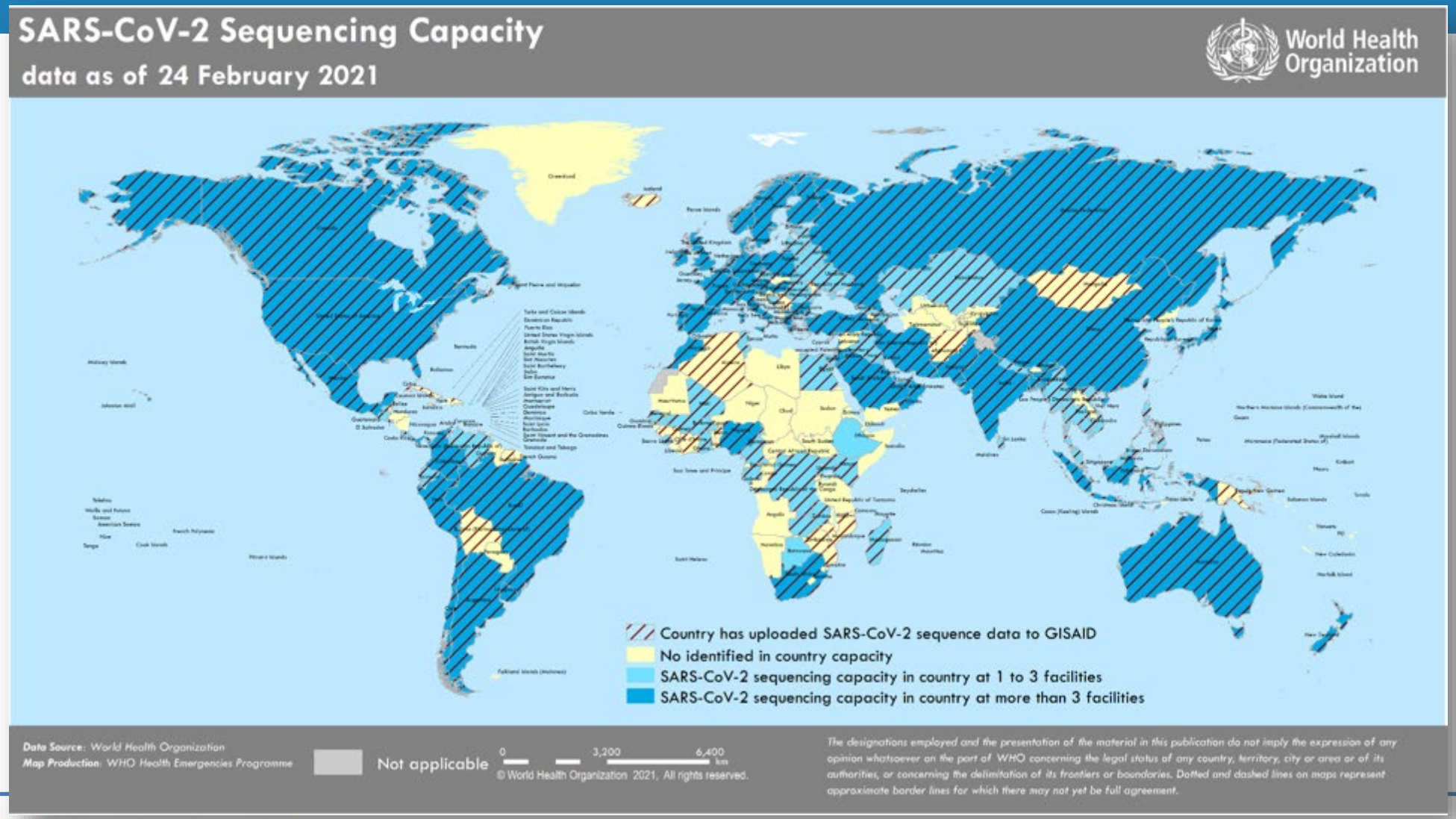
Country / regional objectives

- Sequencing and bioinformatics **capacity strengthening**
- Leveraging NGS capacity map to **identify gaps; tailor interventions** in priority countries

Global objectives

- Availability of **integrated bioinformatics**; data systems and tools
- **R&D/ innovation** for rapid and automated data analysis and sharing
- **Market shaping and supply chain** management interventions

Our current understanding of global capacity



World Health Organization

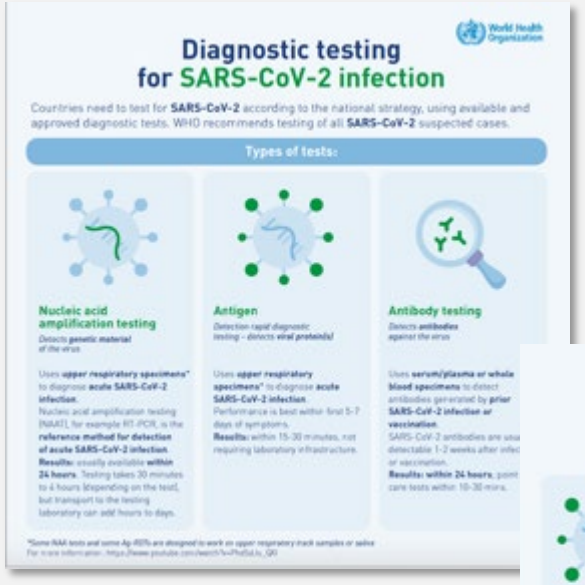
HEALTH EMERGENCIES programme

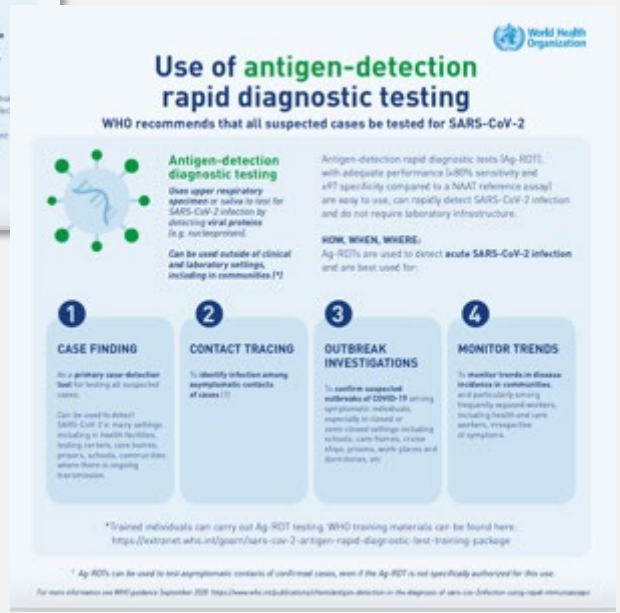
Updates in progress from WHO on technical and operational guidance on Ag RDTs

Interim guidance: Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays
WHO (currently under revision)

SARS-CoV-2 Antigen Rapid Detection Rapid Diagnostic Testing - Training package
WHO-FIND

SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide, including readiness checklist
WHO/FIND



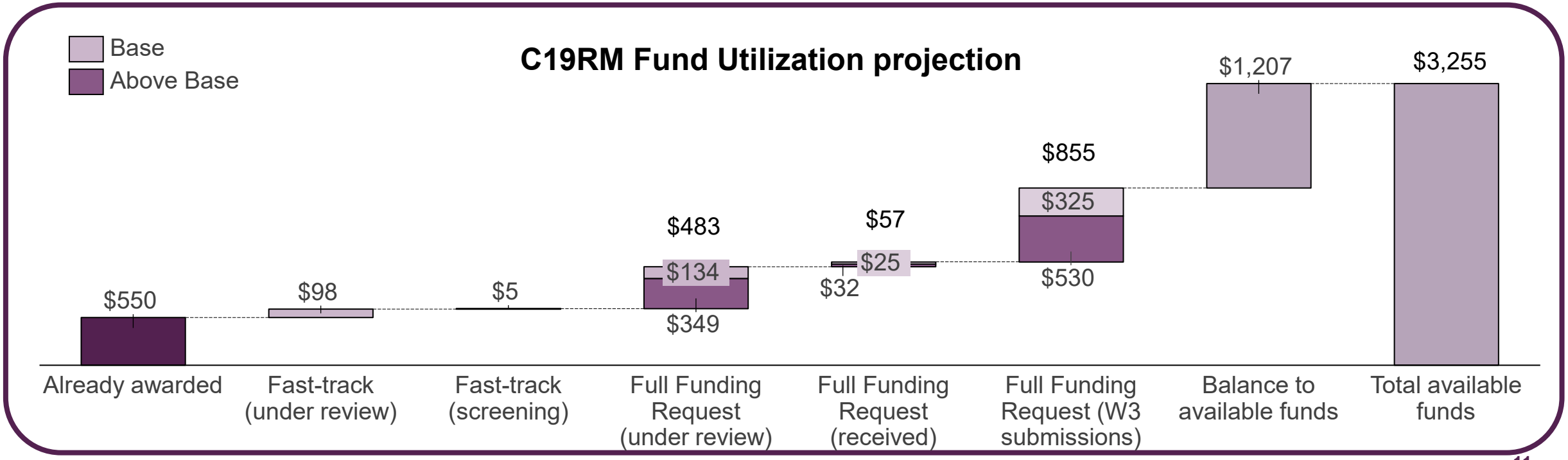


(as of June 16)

C19RM Status of Awards Submissions and Pipeline

<u>17% or US$550 million of C19RM 2021 funding is awarded to 27 countries and 1 multicountry for a portfolio average of 8.3% of HTM allocation.</u>

US $134 million was awarded for 2 Full Funding requests (1 is pending board approval before its confirmed).
US $416 million was awarded via Fast-track Funding Requests.
In addition, **20% or US$643 million is submitted or under review** for potential C19RM 2021 funding (**US$103** million under Fast-track; **US$159 million Base** and **US$381 million Above Base** under Full Funding Request).
In addition, for Window 3 we have just received 24 funding requests for **US$325 million Base** and **US$530 million Above Base**. This means that over US$1.5 billion is currently in the pipeline.



All values in the charts are in US$ million and rounded

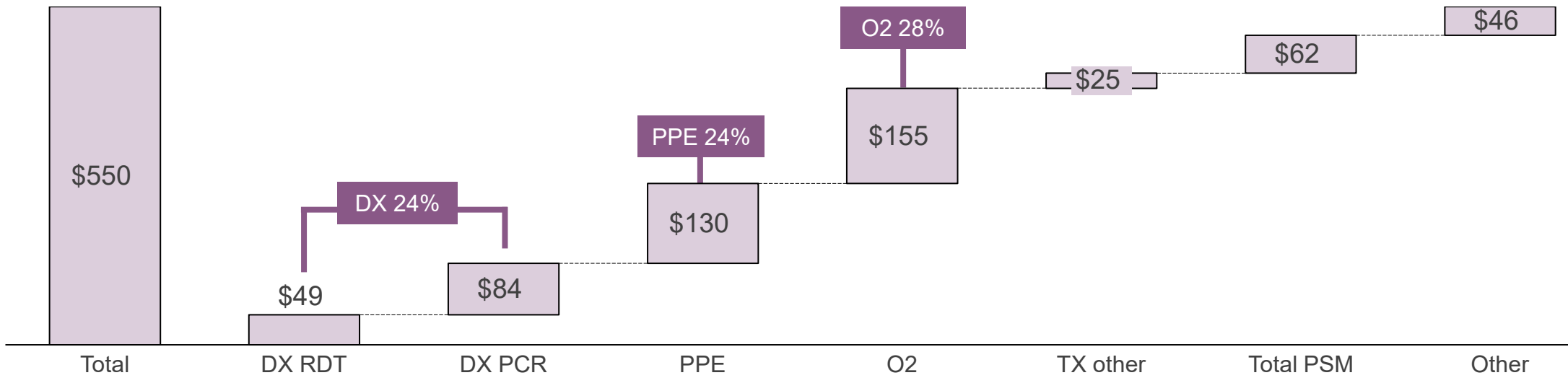
C19RM Award by Health Products

(as of June 16)

Health product **investments are more equally balanced across the key Health Products**

Over **50% of awards to date** are expected to come **via Wambo**.

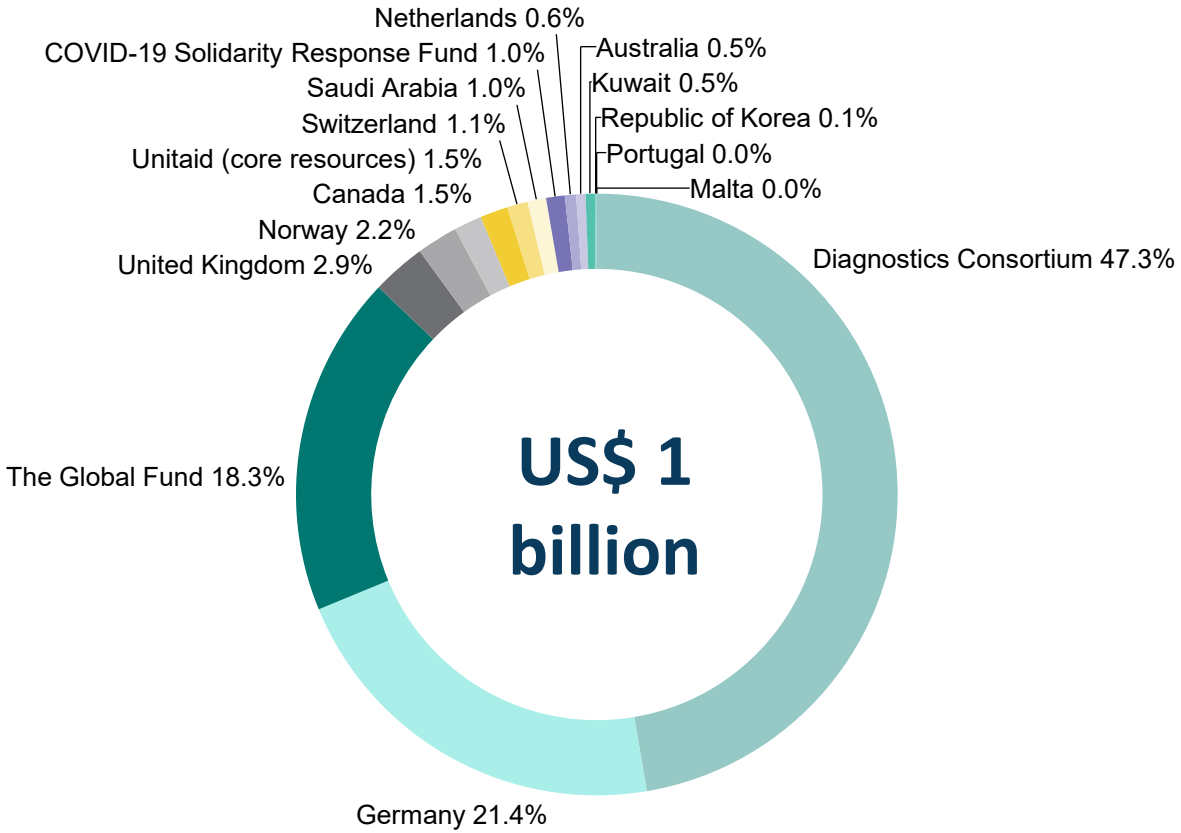
C19RM Awards by type



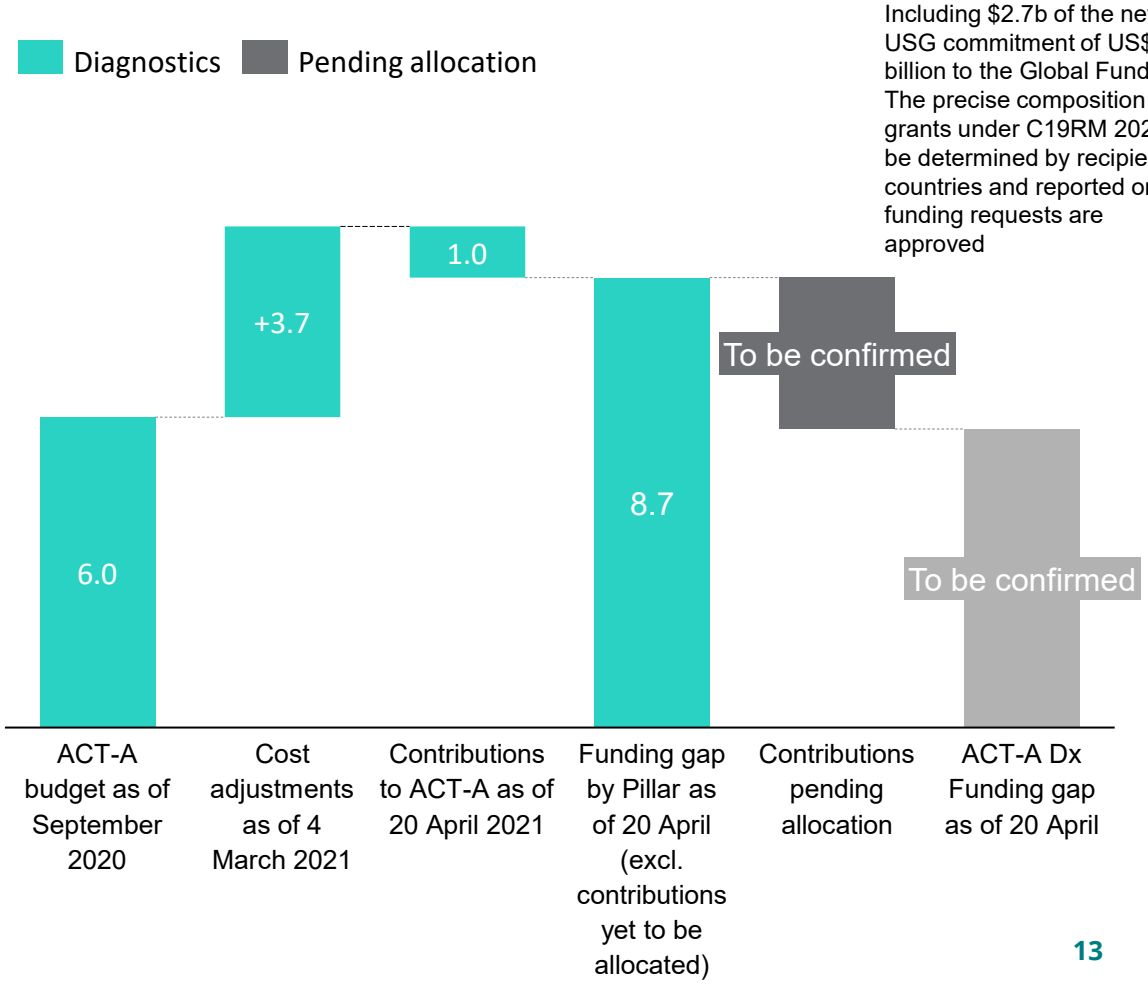
** All values in the charts are in US$ million and rounded*

US$1 BILLION FUNDED FOR DX PILLAR SO FAR, BRINGING THE FUNDING GAP TO US$ 8.7 BILLION FOR 2021

ACT-A Dx contributors as of 20 April 2021



ACT-A Dx funding gap for 2021 as of 20 April 2021



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Appendix: EUL facilitated procedure and IS for Ag RDTs

WHO EUL facilitated procedure

New risk-based approach mechanism for WHO EUL in vitro diagnostics similar to the WHO Collaborative Registration Procedure (CRP) - i*.e., Participants, sameness of product and confidentiality of information*

Aim: to **provide a convenient means for NRAs wishing to enhance listing/authorization of IVDs** by taking advantage of WHO EUL assessment outcome

Differences with CRP:

Information to be shared with the NRAs; under the EUL-FP the **dossier and QMS (desk review) assessment reports are shared**

Timelines are shortened i.e., **5 days instead of 30 days for sharing reports and 15 days of regulatory decision instead of 90 days**

Scope of products: **limited to SARS-CoV2 IVDs**

Roll out from 15 June 2021: Information to the Regional Advisors was shared on 31 May 2021 for wider dissemination to key stakeholders, webinar for manufacturers was conducted on 1 June and webinar for NRAs is planned on 15 June 2021.

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction

Developing 1st international standards for SARS-CoV-2 Antigen Tests

World Health Organization

Background

- More than **200 SARS-CoV-2 Ag tests commercially available** or in development[1].
- More than **100 regulatory approved** SARS-CoV-2 Ag tests worldwide

Intended use of the IS

- **Comparative evaluation** of SARS-CoV-2 antigen tests
- **Evaluation of analytical sensitivity** (determining LOD in IU)
- **Calibration of secondary references** for SARS-CoV-2 antigen
- **Other regulatory and QA activities** (post-market surveillance, EQA)

Project timelines

- **Proposal endorsed by ECBS in Dec 2020**
- Sourcing and characterizing materials during Jan-Apr 2021
- Feasibility study evaluating different SARS-CoV-2 antigen preparations as potential candidates: Apr-Jun 2021
- **Interim working standard available** (via NIBSC catalogue): **July/Aug 2021**
- Main collaborative **study to evaluate candidate IS in Q4 2021**
- **Final report submitted to ECBS in Q4 2021** for establishment of the IS

1 Source: FIND SARS-CoV-2 Diagnostic Pipeline: https://www.finddx.org/covid-19/pipeline

Appendix: ACT-A Dx Pillar priorities for 2021

ACT-A Dx refreshed priorities and goals for 2021

	Dx Pillar Priorities	Objectives & deliverables (Jan 2021)
1	Secure equitable access to tests	**Procure and deploy 900 M tests**, including molecular tests, AgRDTs, and expansion of sequencing capabilities
2	Stimulate rapid & effective country uptake	Deploy novel products, **generate operational research, and support testing strategies**
		Strengthen testing infrastructure and sequencing capacity
		Build capabilities and **provide technical assistance and training** for healthcare and community workers
3	Drive development and at-scale availability of affordable, digitally-integrated tests	**Support market entry**, product registration, and EUL process
		Develop 2 **rapid, $1 tests for professional and self-testing,** including expanded use settings
		Develop **multi-pathogen platforms and sequencing solutions** to detect novel variants
		Develop **non-proprietary test reader app** and **interoperability solution**
		Establish buyers' consortium and distribution network