Facilitation Council Preparation

19 March 2021

#UnitedAgainstCoronavirus
#StrongerTogether | #GlobalResponse

Contents

- Therapeutics
- Diagnostics
- Funding Required

Since its inception, the Tx Pillar has been able to achieve several goals through its donors and partners

1

Tracked > 300 actionable trials across products (mAbs, novel antivirals and repurposed therapeutics)

2

Supported 2 large randomized controlled platform trials and identification of the first life-saving therapy dexamethasone, and provided global guidance on its use

3

Catalyzed and supported the use of dexamethasone, securing 2.9 million treatment courses

4

Identified US$ 90 million immediate funding needs for medical oxygen in up to 20 LMICs

5

Formed COVID-19 Oxygen Emergency Taskforce to assess and address COVID-19 surges in oxygen demand and cut preventable deaths

6

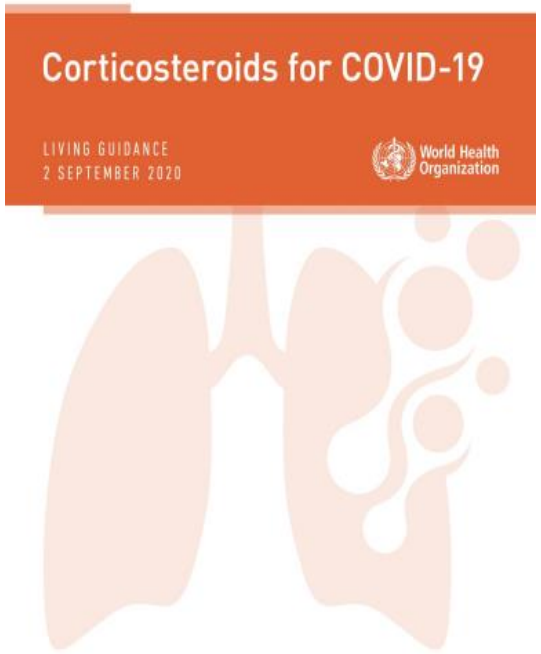
Immediate contribution of up to US$ 20 million to kick off the emergency response

Therapeutics will continue to play a critical role in the broader Covid-19 response

Estimated that up to 70M people in LMICs may contract Covid-19, despite Vx roll-out

Safe and effective Tx essential for a broad population including non-high-risk populations and those not yet vaccinated, where 80% of cases are expected

Reminder | Only recommended Tx today are corticosteroids in combination with oxygen



Systemic corticosteroids recommended for the treatment of patients with **severe and critical COVID-19**

Assumed that these patients would be treated in hospitals **and receive respiratory support in the form of oxygen[1];** non-invasive or invasive ventilation if these options were available

Looking ahead, promising therapeutics specifically for mild/ moderate use cases are advancing swiftly along clinical pipeline

Based on latest knowledge ACT-A Tx revised the 2021 strategy

1. WHO guidelines recommend immediate administration of supplemental oxygen therapy to any patient with SpO_2 < 90%

Strategy | Tx priorities for 2021

Deploy what we have

Ensure successful uptake of existing Tx for up to 12M patients

- Bridge gaps in use of existing products and apply key learnings to future Tx
- Provide visibility on country demand & mobilize resources to support rollout
- Support clear policy & regulatory guidance to accelerate Tx availability

Prepare for what's coming

Introduce new Tx for up to 100M treatment courses

- Support market interventions (incl. licensing & tech transfer)
- Initiate operational research to support optimized clinical care and test-&-treat
- Support procurement and country allocation for scaled deployment

Enrich research pipeline

Accelerate and intensify R&D to expand the Tx clinical pipeline

- Support existing candidates in ongoing phase 2/3 trials
- Accelerate repurposed Tx with meta-analyses of platform trials
- Expand portfolio of Tx tools to include additional compounds and combo Tx

Deploy what we have - Rapid action to support Dexa & O_2 access

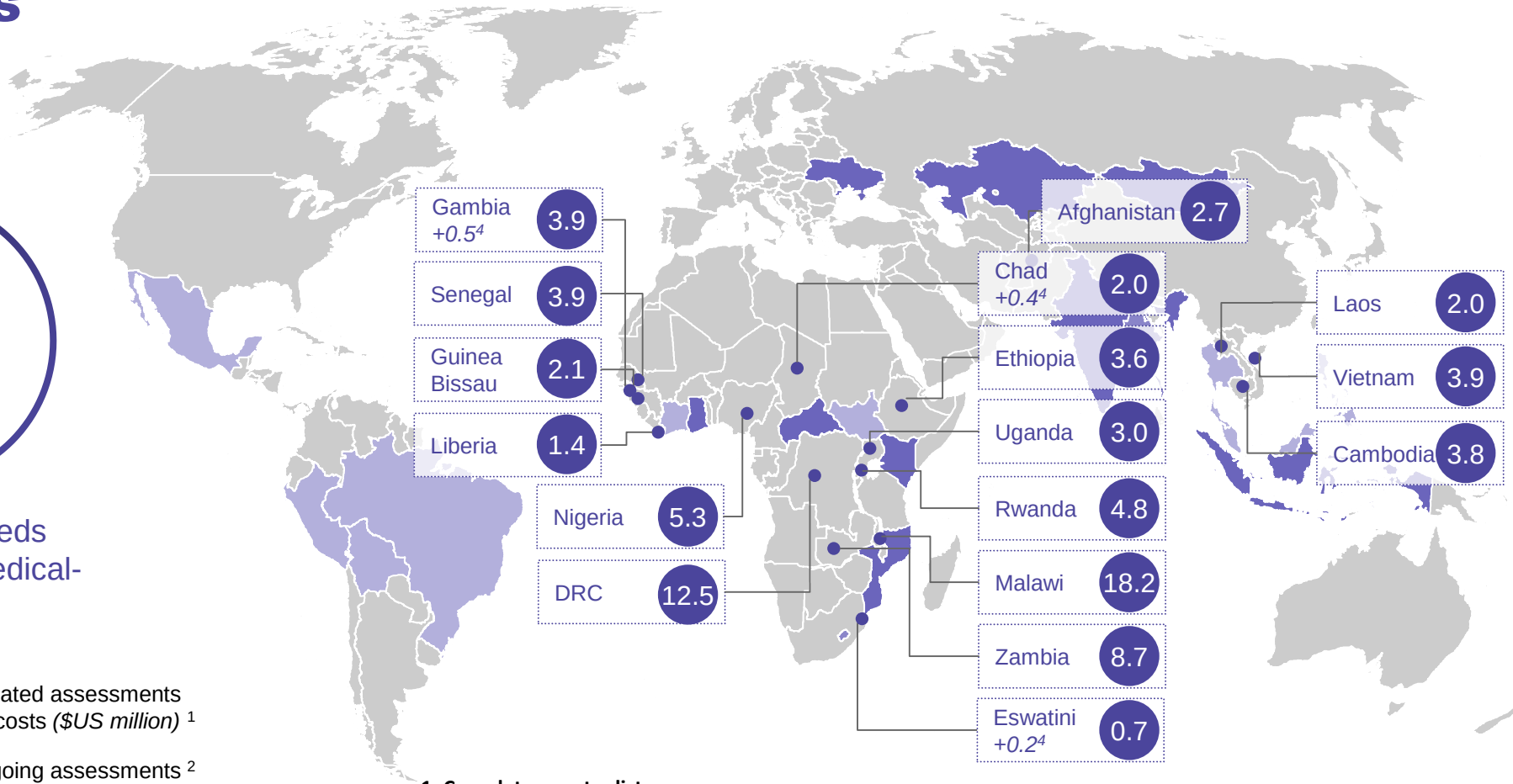
- ☑ Survey launched in 31 countries[1] via CHAI – 20 in Africa, 6 in Asia, 5 in LATAM – to baseline local Tx situation and identify associated challenges / needs
- ☑ Emergency oxygen response partnership established
- ☑ 82+ mUSD of actionable funding requests gathered and vetted
- ☑ 10 mUSD unlocked by Unitaid / Wellcome to act as catalytic investment on medical oxygen
- ☑ Overview of available funds across partners developed
- ☑ Advocacy approach structured and launched

1. Complete country list:
Africa: Burkina Faso, Cameroon, DRC, Ethiopia, Eswatini, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Uganda, Zambia, Zimbabwe
Asia: Cambodia, Indonesia, Lao PDR, Myanmar, PNG, Vietnam
Latin America: Dominican Republic, Guatemala, Haiti, Honduras, Panama

OVERVIEW | $82m LMICs validated oxygen needs , covering 17 countries

$82m
+1.1m vs. last week[4]

Total oxygen needs validated by Biomedical-consortium[1]



Gambia 3.4 — Validated assessments and costs *($US million)* [1]

On going assessments [2]

Acute needs [3]

1. Complete country list:
Africa: Burkina Faso, Cameroon, DRC, Ethiopia, Eswatini, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Uganda, Zambia, Zimbabwe
Asia: Cambodia, Indonesia, Lao PDR, Myanmar, PNG, Vietnam
Latin America: Dominican Republic, Guatemala, Haiti, Honduras, Panama

1. Total for one quarter; Source: Biomed Consortium 25feb 2021; 2. Assessments in the PATH-CHAI "current investment" or in the GF pipeline, 3. Countries in the "hotspots" of the PATH covid-19 oxygen need tracker, as of 12 Feb 2021; 4. Delta to last week due to service Agreements, previously not counted for Gambia, Chad and Eswatini

Prepare for what's coming - Our priority products subject to evidence

Current summary of potential products - does not reflect endorsement
Subject to evidence (pending) and review

High potential *for broad applications*

Potential *for targeted applications*

Assets	Use case(s)	What we know
Molnupiravir	Mild, moderate (early severe)	• **Positive preliminary results**, no safety signals identified with full results due soon • Actionable data **late Q2**
Ivermectin	Mild, moderate, severe	• **Preliminary results indicate reduced time to viral clearance**, variable availability in LMICs, low cost and oral • **Ongoing data quality challenges**
Colchicine	Mild	• Demonstrated significant **reduction in hospitalizations** for mild OP, widely available in LMICs, ease of scalability (oral) • **Negative results from RECOVERY trial** in severe – critical use case
Tocilizumab	Severe, critical	• Demonstrated **additional reduction in mortality** when **added to current standard of care with O2, corticosteroids** • **High cost & access requirements** (IV, cold chain)

New oral products for mild / moderate patients could change the course of the pandemic and test & treat paradigm

Cut down transmission

Prevent severe / critical Covid-19 forms

Offer a cost-effective way to treat early

Enrich Research Pipeline | Revised strategy to expand portfolio

Significant changes to R&D landscape at start of 2021

- Emerging variants have put wave 1 mAb efficacy under greater scrutiny, with more validation needed across whole asset class
- Delayed vaccine rollout and impact of variants has increased the time window for Tx demand

Revised R&D strategy

1. **Shift mAb focus** towards **combinations** and **targets less likely to be impacted** by variants
2. **Pro-actively accelerate repurposed therapies** with **targeted support for evidence generation** where needed
3. **Support NAV efforts further upstream** to build up the currently thin pipeline
4. Across all asset classes, **promote combination therapies** and other strategies to hedge against new variants

Current WS1 focus to deliver the new strategy

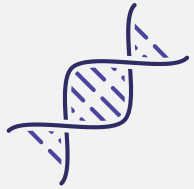
Comprehensive re-review of overall R&D landscape to determine promising assets / approaches to prioritize with additional ACT-A attention and investment

Ongoing horizon scanning to support prioritization and ACT-A activities

If these priorities are achieved, ACT-A Tx will have…

Supported countries in utilizing efficacious products available to date

Reduced the burden on health systems through a jointly implemented test-and-treat approach with Dx Pillar



Bolstered the arsenal of tools available to treat existing and future Covid variants

Contents

Therapeutics

Diagnostics

Funding Required

Widespread testing remains essential component of global COVID response

Testing queue – Kerala State, Dec 2020

Testing queue – Nairobi, May 2020

Gradual roll-out of vaccines and continued threat of novel variants mean that widespread, affordable, and accurate diagnostic tools remain critical to global COVID response

- To break chains of transmission
- To enable targeted public health interventions and treatment
- To inform epidemiological surveillance
- To detect novel variants

Source: Hindustan Times Accessed 18 March 2021; https://www.hindustantimes.com/india-news/covid-19-18-uk-returnees-to-kerala-test-positive-samples-sent-to-niv-pune-for-studying-variant/story-VKLbF2zxyXK3lH02bnhYWP.html; The East African Accessed 18 March 2021; https://www.theeastafrican.co.ke/tea/news/east-africa/kenya-could-be-flattening-the-covid-19-curve-shows-data-3245178

Looking back on 2020, we've accomplished a great deal with support from donors and partners across the globe

1. Launched antigen RDT scale-up package including 120m volume guarantee for LMICs (Oct 2020 - March 2021)
2. Executed 4 priority investments to bring lower-cost antigen RDTs with regionalized manufacturing in 2021
3. Refreshed R&D product pipeline for molecular tests, antigen RDTs, decentralized & at-home self-tests
4. Procured over 34m molecular tests & 31m antigen RDTs via the Supply Consortium
5. Assessed impact of digital tools for screening & diagnosis to strengthen the COVID-19 response in countries
6. Finalized data governance framework to guide ownership & management of Dx data
7. Set up & accelerated in-country deployment support activities: policy mapping, operational research, catalytic funding
8. Published antigen RDT implementation guide & modular training package

Speed of COVID Ag RDTs introduction has been unprecedented compared to any other RDTs

- Dec 2019: Cluster of "pneumonia of unknown cause" identified in Wuhan
- Early Jan 2020: **Genetic sequencing** shared
- July: **FIND/ Unitaid issue EOI** to bring lower cost Ag RDTs with regionalized manufacturing to LMICs
- Mid Sep: WHO releases **interim guidance** on the use of rapid antigen tests
- End Sep: **WHO issues EUL: first** rapid point-of-care reader-free Ag test[1]
- **120m volume guarantee** for LMICs announced under ACT-A
- Oct: **Countries start using** rapid antigen tests in healthcare settings and beyond, together with PCR
- Nov: **WHO issues EUL: first** rapid point-of-care reader-free Ag test **with easier sample collection** (nasal)[2]
- Jan 2021: **FIND/ Unitaid announce first EOI agreement:** with PMC, bringing Ag RDTs price down to **US$2.50 per test**

Within 6 months of EUL-listing: **over 30 million Ag RDTs have been procured** across Dx Supply Consortium partners only[3]

Example: malaria RDT timeline

- **Early 1990's** — Emergence of malaria RDTs into largely unregulated markets and with uncertain performance
- **1999** — WHO first meeting on rapid diagnostic testing
- **Early 2000's** — Rapid expansion in number of products
- **2002** — Development of coordinated effort to quality control RDTs pre & post purchase
- **2018** — WHO requirement for RDTs to be pre-qualified

1. SD Biosensor STANDARD Q COVID-19 Ag Test. 2. Abbott Panbio COVID-19 Ag Rapid Test Device (NASAL) 3. Global Fund, GDF/StopTB, PAHO, UNDP, Unicef, WHO
Source: WHO EUL, Malaria Journal (all accessed 15 March 2021)

ACT-A Dx progress on increasing the supply of lower-cost Ag RDTs…

R&D/ Market shaping

- **Reduced cost of Ag RDT LMICs**
- **Negotiated regionalized manufacturing**

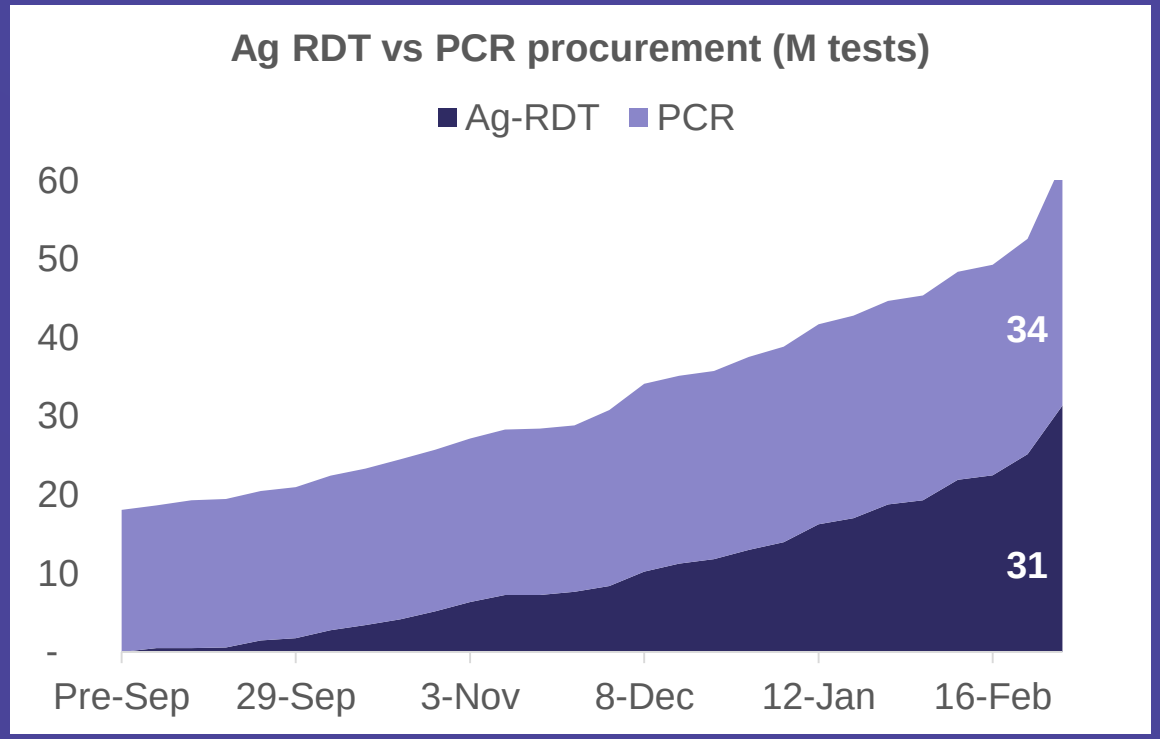
Procurement

- **Secured volume guarantee of 120M AgRDTs for LMICs** for 6 months
- **Procured 65 million tests** through the Diagnostics Consortium for COVID

Country uptake

- **Developed policy & implementation guidance**
- **Deployed catalytic funding** for 20+ governments to accelerate implementation

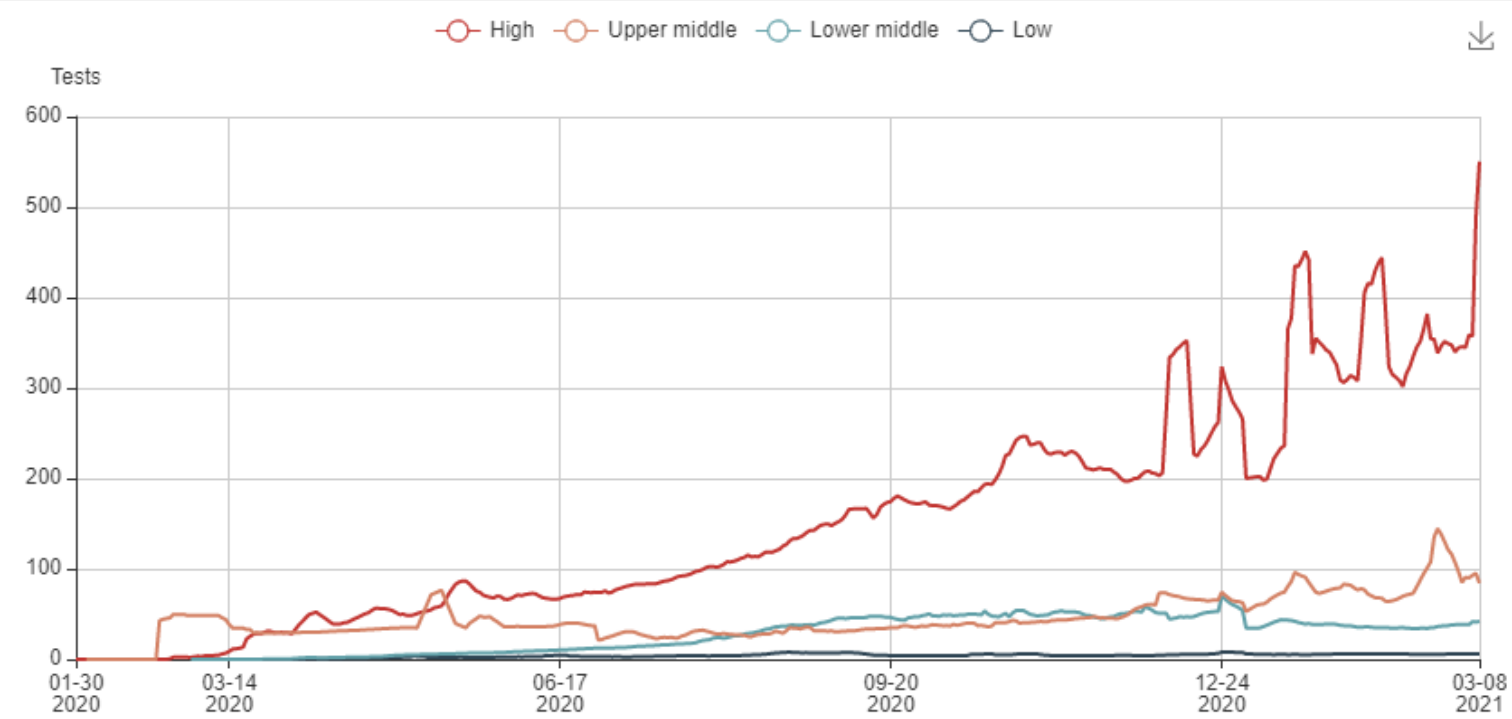
… has contributed to increasing uptake over past several months



Source: Diagnostics Consortium for COVID data as of 8 March 2021

Increasing Dx uptake in LMICs, but significant gap remains relative to HICs testing rates

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

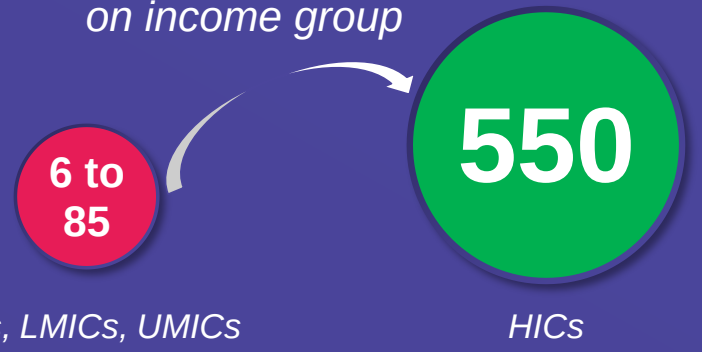


1. Due to data inconsistencies, we show a moving 7-day average.
2. Most recent rolling 7-day averages per 100,000 population. Source: FIND test tracker (as of 8 March 2021)

LMICs still testing at a fraction of HICs

Daily tests/ 100k population[2]

x6 to x90 lower depending on income group



LICs, LMICs, UMICs (excl. China)

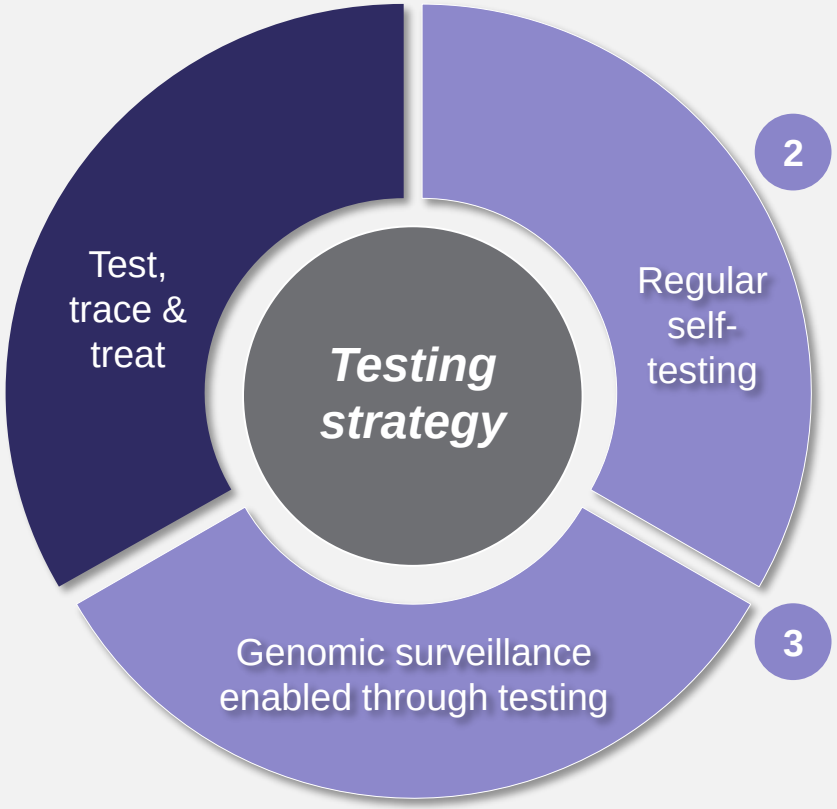
HICs

Looking forward, Act-A Dx is working to support equitable access to a holistic dx toolkit

Optimizing access and use of existing tools → **Preparation for and expanded access to innovative products**

1 Test, trace & treat

- **Molecular PCR & rapid antigen tests** to enable effective containment of hotspots and appropriately deploy therapeutics and other resources



Illustrative visual – does not indicate relative priority of each testing strategy component

2 Regular self-testing

- Fit-for-purpose **low-cost self-tests** to support social & economic activities (e.g., schools, workplaces, mass gatherings)

3 Genomic surveillance

- **Genomic sequencing technology** for early detection and tracking of novel variants

1

Drive uptake and expand access to existing tools in order to scale test, trace, and treat capabilities

A joint session of the Country Preparedness and Market Readiness working groups considered the **main challenges to uptake** and **prioritized solutions to support demand and increase uptake of AgRDTs in LMICs**

Challenge to uptake	Priority solutions
Policy & testing strategies	• Generate evidence & support data-driven advocacy with policymakers • Organize webinars on expanded use cases
Regulatory and access	• Engage procuring & non-procuring countries to understand rationale • Tailor support to context by learning from country experiences
Funding	• Explore additional sources and engage private sector
Procurement & supply management	• Where forecasting is challenging, assist countries on supply issues

Working group members are collaborating to produce a roadmap and country engagement approach to operationalize these solutions

2

Support the development and early introduction of affordable self-testing for LMICs

Technology Development + **Policy Development** + **Market Shaping**

RFP to **accelerate the availability of low-cost, digitally enabled self-testing solutions** for SARS-CoV-2 in LMICs expected to launch by end of March 2021

Note: Proposals are anticipated to build on advances made in AgRDTs manufacturing

Work underway to **refine use cases and support evidence generation** for policy evolution and catalytic market introduction

Plan in place to launch **a needs assessment to identify key customer segments, enablers to uptake, and prioritize go-to-market models** and distribution pathways across public and private channels

Expanded testing will lay groundwork to enable expanded genomic surveillance capabilities

Short term

- Understand the effect of novel variants on **performance of currently used Dx, Tx & Vx**
- Inform **real-time outbreak response** (hotspots, contact tracing, inform travel restrictions, containment measures & patient management)

Long term

- Strengthen diagnostic surveillance via **sustainable early warning & response systems** to contain outbreaks & improve pandemic preparedness beyond COVID

Support a global genomic surveillance system to monitor for the emergence, evolution and spread of virus variants

- In close coordination with global, regional & country partners and linked to efforts to strengthen monitoring of respiratory pathogens
- Supporting planning & decision-making to target effective responses from emerging COVID variants & other respiratory pathogens

Optimizing the impact of our priorities requires regular bi-lateral engagement with country stakeholders

What?

- **Regular ACT-A Dx "Country Roundtables" to hear from stakeholders on what is most needed from ACT-A, hold open Q&A, and offer peer-to-peer learning** about successful implementation and scaling of diagnostic tools and programme

When?

- Active planning ongoing with **goal to hold our first, pilot session in the coming weeks**
- Goal for a **series of 60-90 minutes sessions** occurring at regular (i.e., every 2-3 month) cadence

Why?

Partner feedback and reflection on existing operating model has revealed need for:

- **Increased engagement** with country stakeholders
- **Bilateral collaboration**
- **Renewed focus on activities considered most relevant** for country stakeholders

Who?

- **Pilot session to be co-chaired** by *Chikwe Ihekweazu (Director NCDC) & Dr. Sydney Yee (CEO DXD Hub, ASTAR)*
- Working with partner network to compile an invite list with **objective to target leaders in diagnostics policy setting in countries** (e.g., MOH, members of advisory committees and key opinion leaders, civil society representatives)

Contents

Therapeutics

Diagnostics

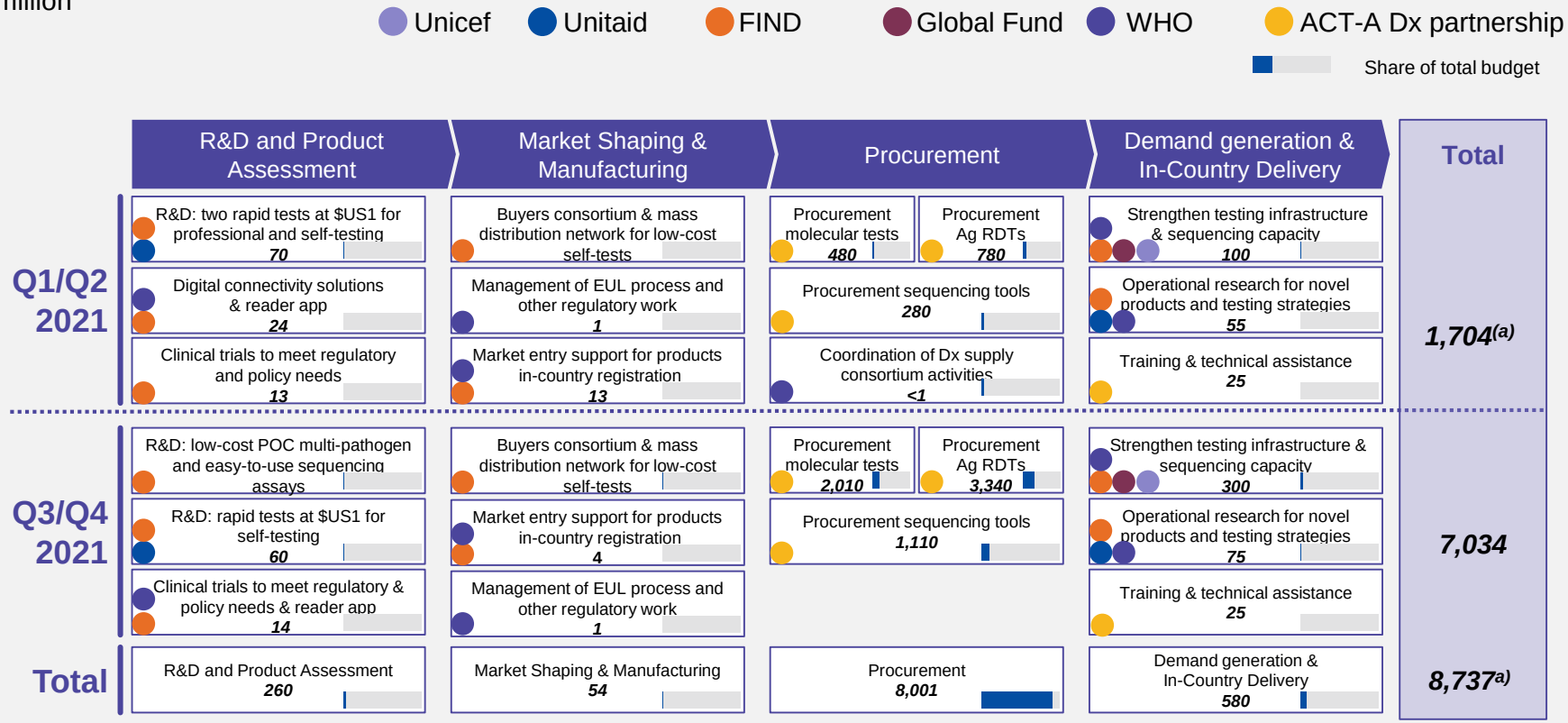
Funding Required

Data as of 3 March 2021

Delivering on these priorities will require investment across the value chain

by deliverable package

Diagnostics funding gap by period and deliverable package, in USD million



Diagnostics Pillar convenes many stakeholders who play multiple roles across the workstreams due to the evolution of the pandemic, changing needs of countries and the dynamic multifaceted collaboration. Workstreams are coordinated by FIND, Global Fund and WHO and funding flows directly to multiple partners depending on their role and country needs. For further details, please reach out to ACTADiagnostics@finddx.org, gf_acta@theglobalfund.org or actdiagnostics@who.int

a. Additional contributions of USD 158 million reduce Diagnostics funding gap: Including an additional recent contribution of USD 18 million allocated to WHO, USD 61 million allocated to FIND and USD 79 million allocated to Global Fund, yet to be approved through the Global Fund COVID-19 Response Mechanism. While they are not yet operationalized in specific work packages, they will reduce the funding gap of WHO, FIND and Global Fund work packages.

Therapeutics | Funding gap for 2021 is $US 3.2 b

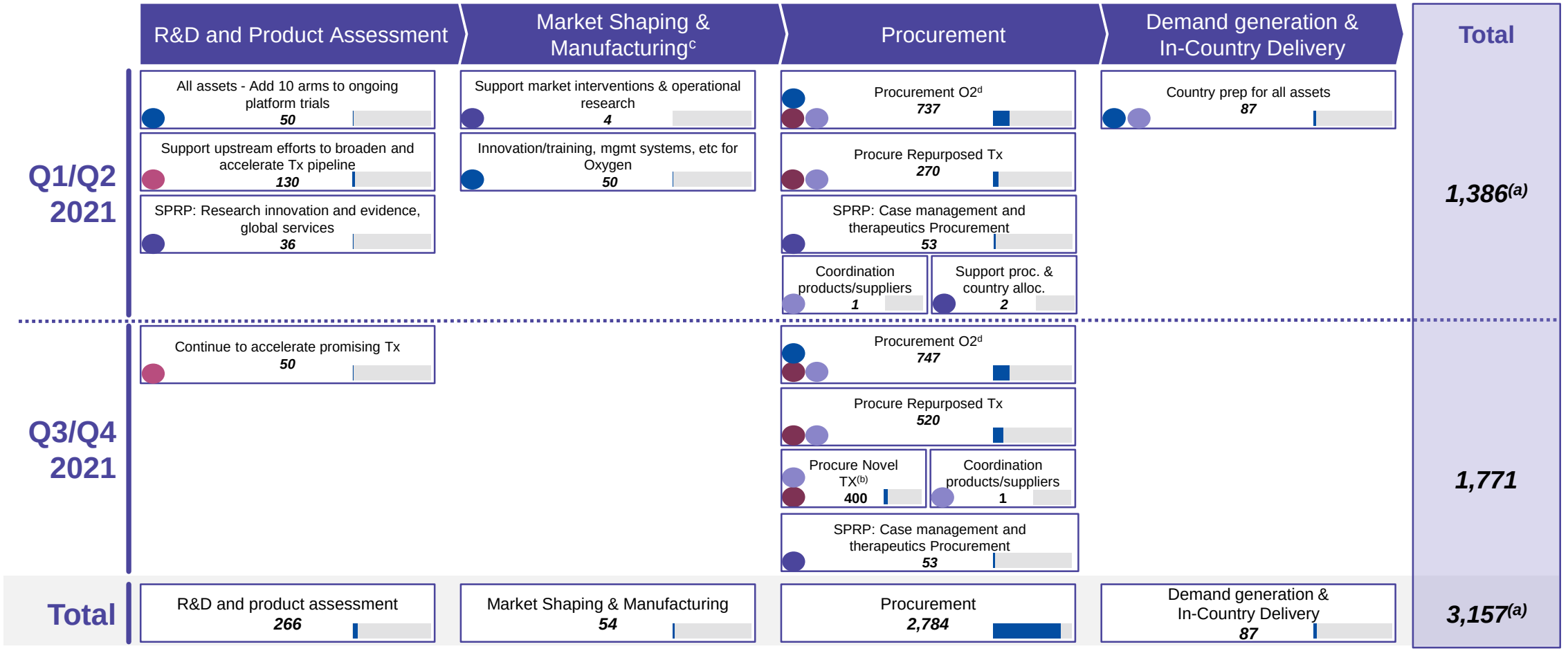
Therapeutics funding gap by period & deliverable package,
in USD million

Last update: 13 Mar 2021

by deliverable package

WHO Wellcome Unitaid Unicef Global Fund

Share of total budget



a. Additional contributions of USD 33 million reduce Therapeutics funding gap: Including an additional recent contribution of USD 6 million allocated to WHO that is decreasing the funding gap, and USD 27 million allocated to Global Fund yet to be approved through the Global Fund COVID-19 Response Mechanism. While they are not yet operationalized in specific work packages, they will reduce the funding gap of WHO and Global Fund work packages b. Canada has pledged a contribution of CAD 230 million to procure COVID-19 treatments for developing countries (recipient: UNICEF). To be evaluated in light of evolving clinical information. c. Market-shaping activities may leverage funding embedded in country preparedness or procurement line items for Therapeutics (e.g. for advanced purchase arrangements or other price-volume agreements, reserved volumes for operational research and/or early adopter countries). d. Funding requirements for medical oxygen are subject to review as the scope of the COVID-19 Oxygen Emergency Taskforce is developed, and a better understanding of country-specific needs is available.

Q&A: Council Members & Member States