ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

Update on Monitoring Vaccination, Testing, Treatment and PPE Targets for COVID-19

ACT-A Council Working Group on Tracking & Accelerating Progress

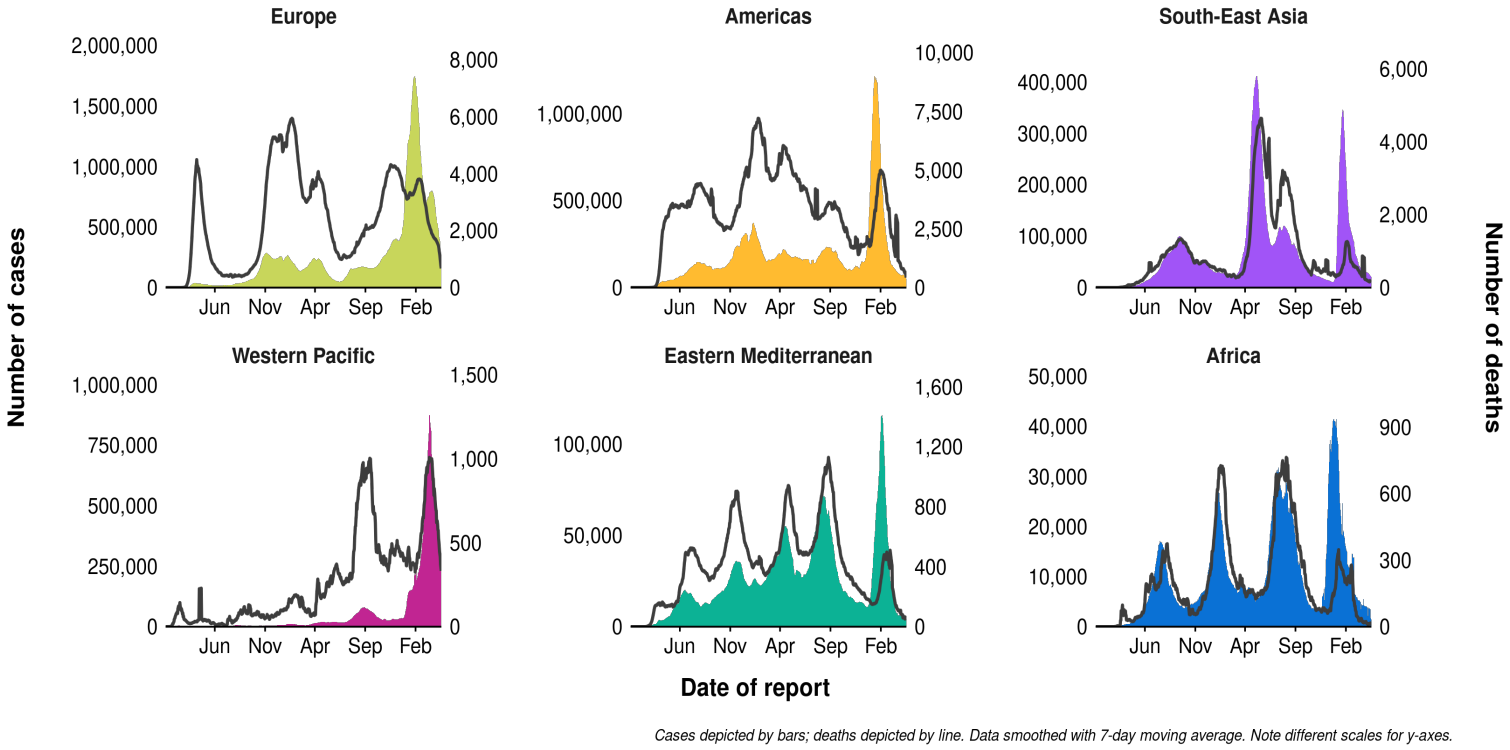
10TH ACT-ACCELERATOR FACILITATION COUNCIL MEETING

26 APRIL 2022

ACT now, ACT together to accelerate the end of the COVID-19 crisis

Evolving context | The COVID-19 pandemic has entered a new phase with new challenges

COVID-19 caseload declining from a record high in many regions



Cases depicted by bars; deaths depicted by line. Data smoothed with 7-day moving average. Note different scales for y-axes.

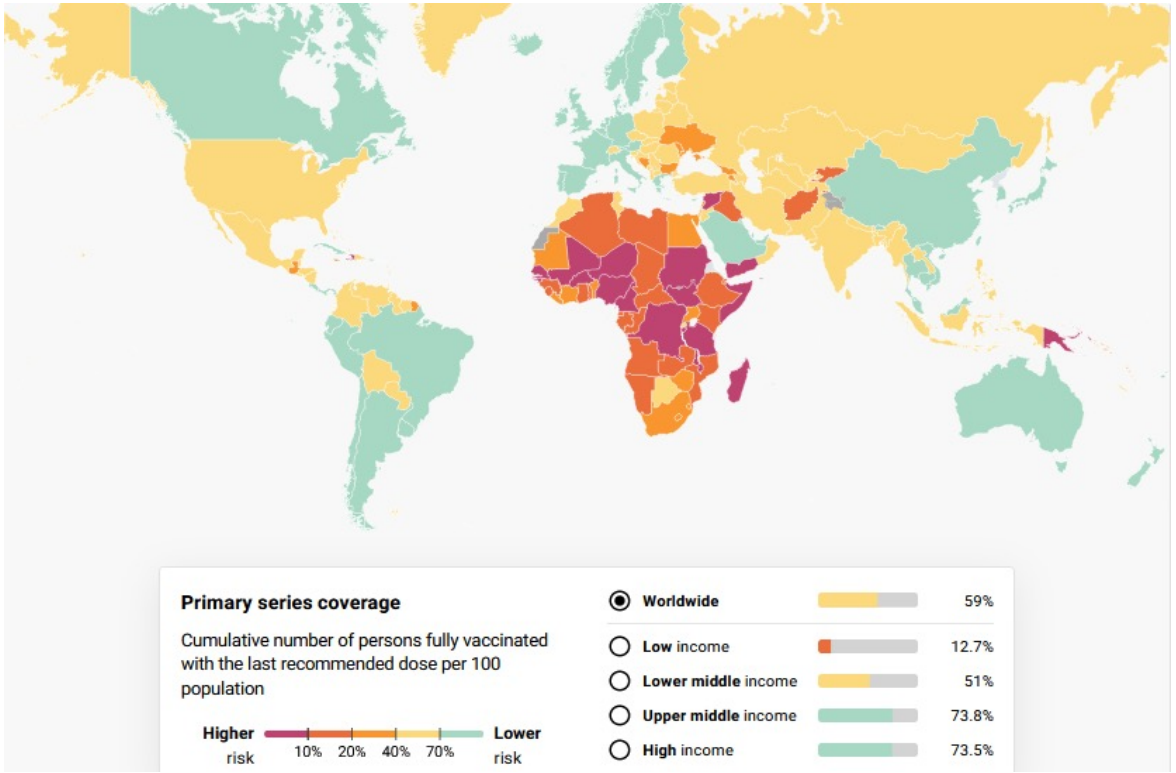
Key updates since the last meeting

- **Easing of restriction is creating a false perception** that the pandemic is over
- **Need to balance the COVID-19 response** with other health priorities
- The **geopolitical crisis is diverting much needed political attention** and resources

COVID-19 vaccines | Coverage in LICs & LMICs still inadequate

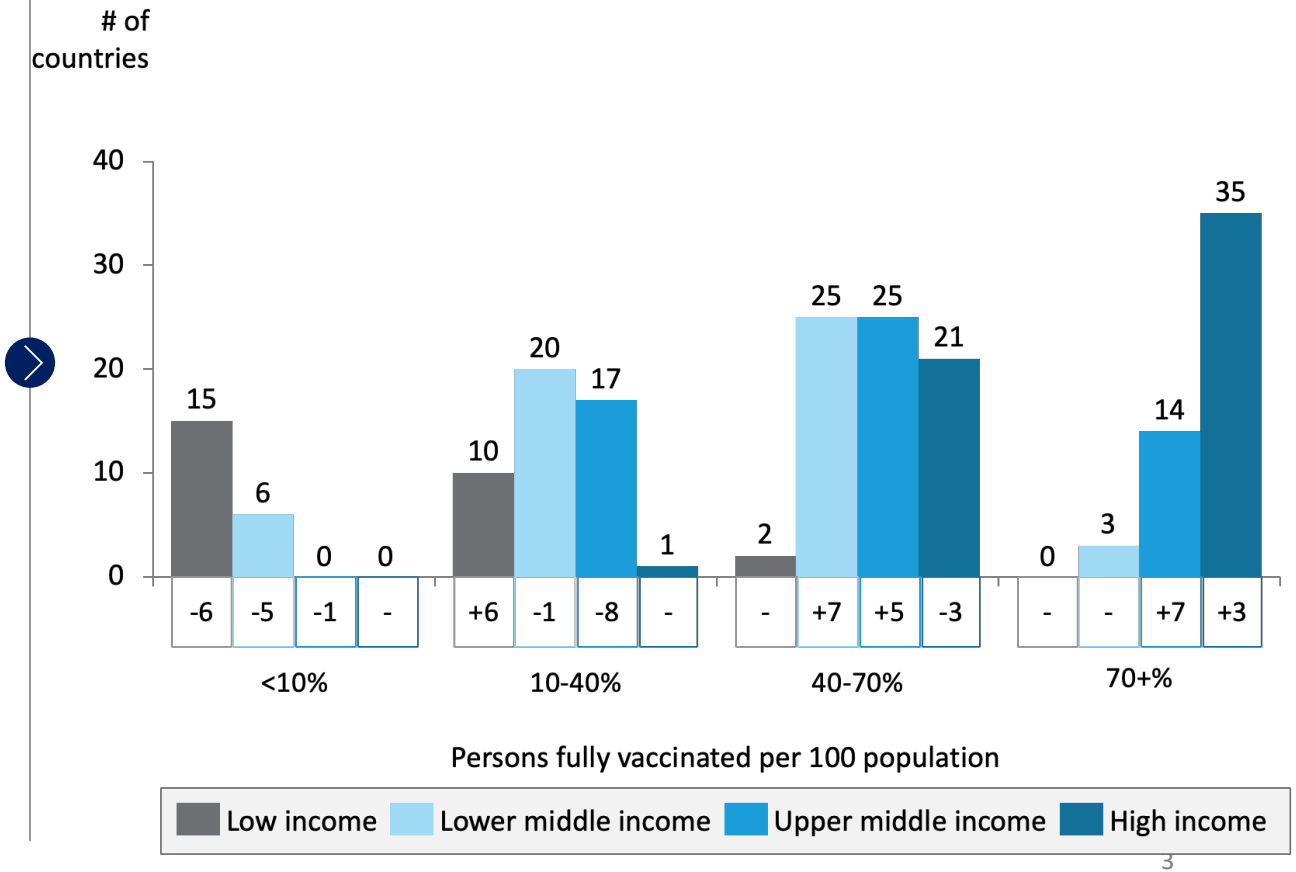
Only 12% of the population in LICs are fully vaccinated[1]

Source: GCAT as of 20 April 2022



1. %-share of persons fully vaccinated with the last recommended dose by country

21 countries still below 10% coverage & 69 countries still below 40% coverage

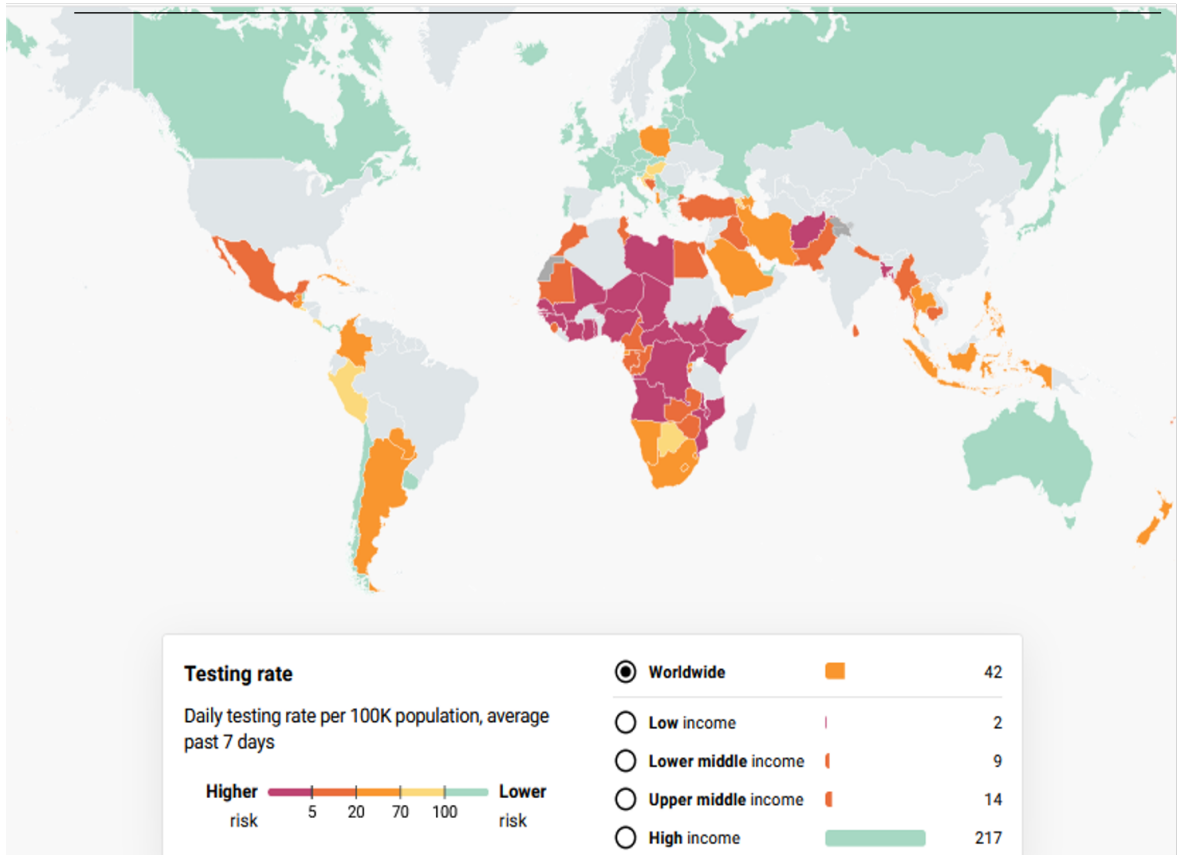


Source: WHO COVID-19 Dashboard, at 20 April 2022

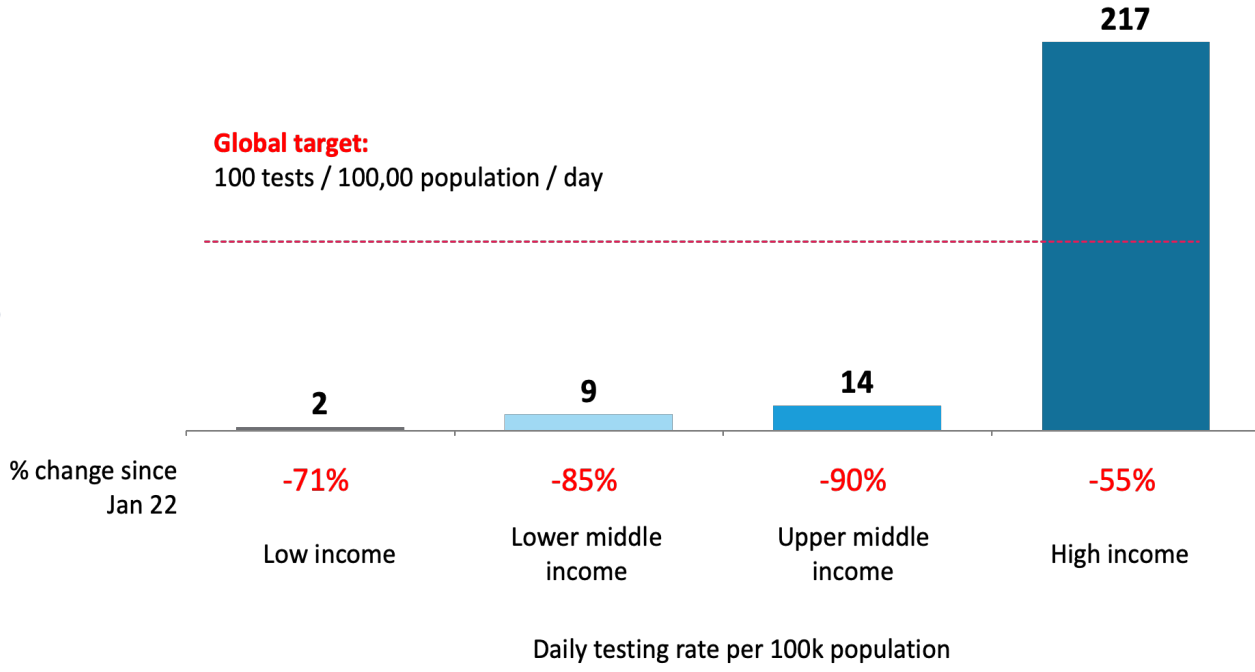
COVID-19 diagnostics | Worrying reduction in testing rates

Increasing disparities in testing rates[1] & sequencing

Source: GCAT as of 20 April 2022



Testing rates significantly reduced and are below target everywhere outside HICs



1. Daily testing rate per 100K population, average past 7 days

COVID-19 therapeutics | We are at the cusp of a paradigm shift

New oral antivirals

offering a pathway for decentralized, outpatient treatments that can be implemented at scale

- **WHO recommended molnupiravir & paxlovid,** the first two oral antiviral for mild-to-moderate COVID-19 cases
- **four more therapeutic options currently under assessment** by WHO
- **Continued efforts to increase access to O2, corticosteroids &** other therapeutics

6 asks to the ACT-Council | The ACT-A Council can help accelerate the equitable scale-up of COVID-19 tools globally

Highlight that the COVID-19 is not over

Prioritize financing for in-country delivery, Dx & Tx

Support the Vaccine Delivery Partnership

Make commitments during the 2nd Global COVID-19 Summit

Promote data collection/sharing, esp for Tx & HSRC targets

Support TAP Working Group effort to accelerate uptake of tools

Oral antiviral therapies for COVID-19

April 2022

Clive Ondari, Director, WHO Department of Health Products Policy and Standards

World Health Organization

WHO COVID-19 clinical care recommendations

Severe and critical patients

- Baricitinib
- IL-6 receptor blockers
- Systemic corticosteroids
- Seronegative: combination casirivimab and imdevimab

Non-severe patients, at risk*

- Sotrovimab
- Casirivimab and imdevimab
- Molnupiravir
- Nirmatrelvir and ritonavir
- Remdesivir (c)

* those who are unvaccinated, older people, and those with immunosuppression or chronic diseases such as diabetes

World Health Organization

Molnupiravir overview

- For patients with non-severe COVID-19 at highest risk of hospitalization (excluding pregnant and breastfeeding women, and children)
- Licences:
  - 8 Indian manufacturers
  - Medicines Patent Pool signed agreement with MSD
- WHO prequalification: several dossiers are under assessment including generics
- Allocation: an expression of interest from countries for access is currently open

Nimaltrivir/ritonavir overview

For patients with non-severe COVID-19 at highest risk of hospitalization

- Licences:
  - Medicines Patent Pool signed agreement with Pfizer
- WHO prequalification: Dossier from Pfizer is under assessment
- Allocation: algorithm is under development and will be integrated into the partners platform
- Manufacturer engagement: ACT-A partners working on access terms

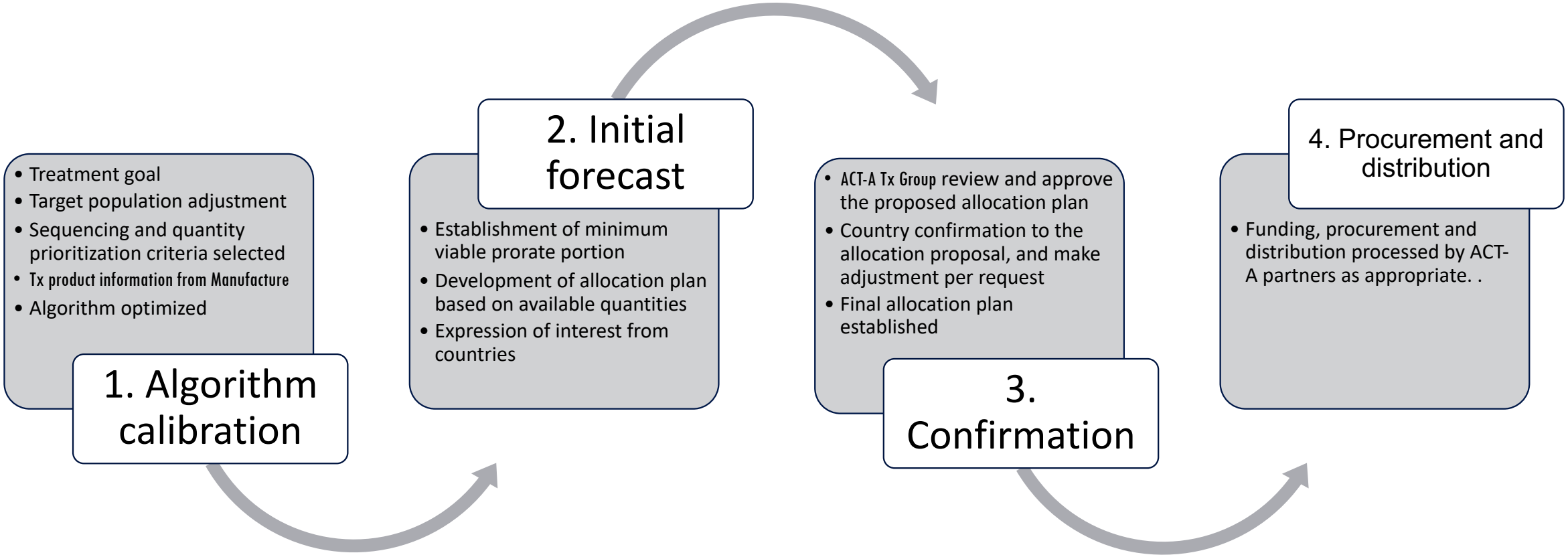
World Health Organization

Allocation of COVID-19 therapeutics
Principles for equitable access

- Selection of therapeutics based on scientific evidence to address the public health need
- Relevant principles of equity to inform allocation strategies
- Countries prioritized based on severity and vulnerability
- Stewardship of products in limited supply to promote rapid use
- Flexible short- and long-term regulatory approaches to improve access
- Transparency to improve efficiency and accountability
- Collaboration across with relevant stakeholders to accelerate response

World Health Organization

ACT-A Tx Allocation Process



World Health Organization

Thank you

Living guidelines: www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.1

COVID-19 Clinical Care Pathway: www.who.int/tools/covid-19-clinical-care-pathway

Prequalification: https://extranet.who.int/pqweb/medicines

ACT-A: www.who.int/initiatives/act-accelerator

World Health Organization

MPP Licences on COVID-19 Antivirals: Progress and Timelines

Select Key terms of MPP licences on molnupiravir (Merck) and nirmatrelvir (Pfizer)

- Licences allow MPP to grant sub-licences to manufacturers anywhere in the world
- Include confidential know-how
- Royalty-free during the WHO Public Health Emergency of International Concern (PHEIC)
- Licensees can supply 105 or 95 countries respectively (approx. 4.1 billion people covered)
- Require approval by WHO PQ or Stringent Regulatory Authority, including emergency use authorizations. For MOL conditional waivers in some circumstances
- Licensee has right to terminate at any time
- Licences are fully transparent, available on MPP website

[In addition to MPP licences on molnupiravir, there are eight Indian manufacturers with bilateral licences directly with Merck]

NEWS & PRESS RELEASES » PRESS RELEASES

The Medicines Patent Pool (MPP) and MSD enter into licence agreement for molnupiravir, an investigational oral antiviral COVID-19 medicine, to increase broad access in low- and middle-income countries

27 October 2021

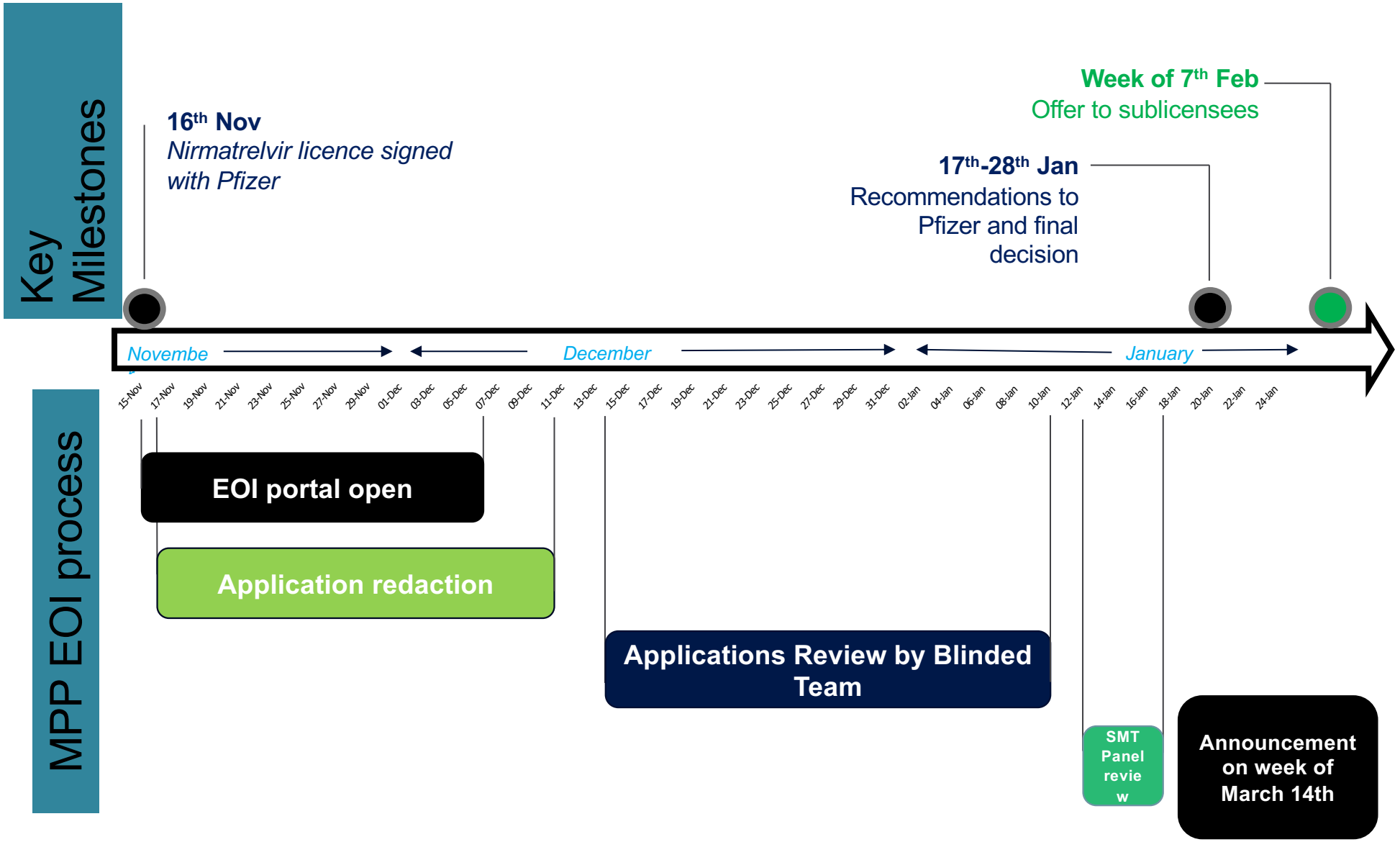
NEWS & PRESS RELEASES » PRESS RELEASES

Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries

16 November 2021

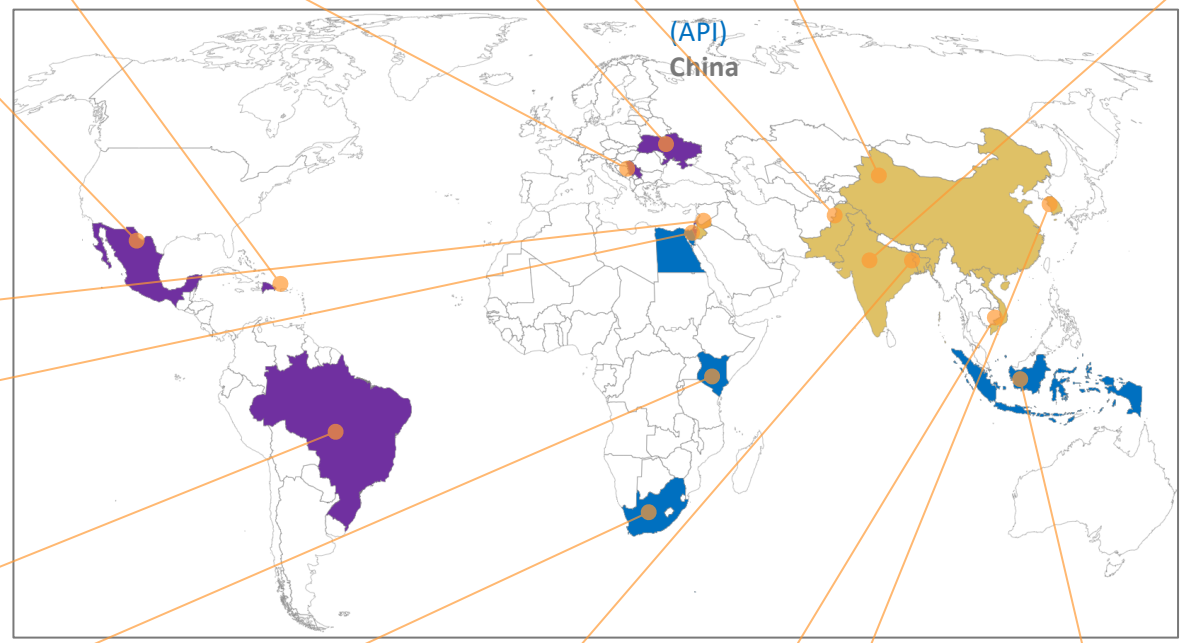
15

Nirmatrelvir: MPP Sublicensees selection process timeline



MPP licencees for Covid19 Tx

Nirmatrelvir licence only | **Molnupiravir licence only** | **Nirmatrelvir and Molnupiravir licences**



Laboratorios Magnachem (FDF)
Dominican Republic

FHI Zdravlje AD Leskovac (FDF)
Serbia

Remington (FDF)
Pakistan

Darnitsa (FDF)
Ukraine

Lonzeal

(VI)
BrightGene (VI)
Langhua

(API)
China

Apeloa (API)
Zhejiang Jiuzhou (API)
Zhejiang Huahai (VI)
Shanghai Desano (VI)
Shanghai Fosun (VI)

India
Arene (API)
SMS Pharma (API)
Strides (VI)
Lupin (VI)
MSN (VI)
Laurus (VI)
Biophore (VI)
BDR (VI)
Optimus Pharma (VI)
Natco (FDF)
Cipla (VI)
Emcure (VI)
Sun (VI)
Hetero (VI)
Divi's Labs (API)
Aurobindo (VI)
Amneal (VI)
Torrent (VI)
Cadila (VI)
Glenmark (VI)
Granules (VI)
Macleods (VI)
Biocon (VI)
Mylan (VI)

Grupo Neolpharma (FDF)
Mexico

Egypt /Jordan
Hikma (FDF)

Israel
Teva (VI)

Brazil
Nortec Química (API)

Kenya
Universal Corporation (FDF)

South Africa
Chemical Process Tech (API)
Aspen (FDF)

Bangladesh
Beximco

(F
DF)
Incepta

Vietnam
Stellapharm (FDF)

(F
DF)

South Korea
Dongbang (API)
Celltrion (FDF)
Hanmi (VI)

Indonesia
Kimia Farma (VI)

Nirmatrelvir/ritonavir: Tentative Development timelines scenarios

TENTATIVE AND CONFIDENTIAL

Activity	Baseline	Best Case	Conservative	Assumptions
API development (at least lab scale)	3 M	1 M	6 M	Formulation development to start with lab scale API. API developemnt , scale up, dossier batches run in parallel to formulation development. Best case : already have process developed. Baseline :Development started Conservative : completely new player
Formulation Development	6 M	3 M	9 M	Best case : Already started basic develoment of PF 07321332, have Ritonavir SRA approved product ready Baseline : Development started for poth the FDFs Conservative : Need to initiate development for both products No bottlenecks wrt sourcing, equipemnts, facility etc
Pilot BE	1 M	1M	3 M	2 analytes to be measured, same for all scenarios Baselline + best case : Pilot in first attempt Conservative : 2 pilots, considering two low solubility molecules
Scale up and Dossier Batches	1 M	0.5 M	1 M	API validation batches are assumed to be done before execution of EB batch for all the cases. No bottlenecks with respect to facility. Best Case : Less time since only 1 product to be manufactured
Stability Studies + Pivotal BE	3 M	3M	6M	Best case and baseline : EUA, with 3 M stability data Conservative : Normal filing : 6 M stability data
Dossier compilation and filing	0.5 M	0.5 M	0.5 M	Same for all scenarios.
Filing (WHO PQ)	**14.5 M approx**	**9 M approx**	**25.5 M approx**	Assuming EOI is in place.

* Does not include regulatory approval timelines

ACCELERATING ACCESS TO NEW ORAL THERAPEUTICS at

The 10th ACT-A Facilitation Council Meeting

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Presenter: Sehrish Aslam
Head of Corporate Compliance
& R&D Global Markets

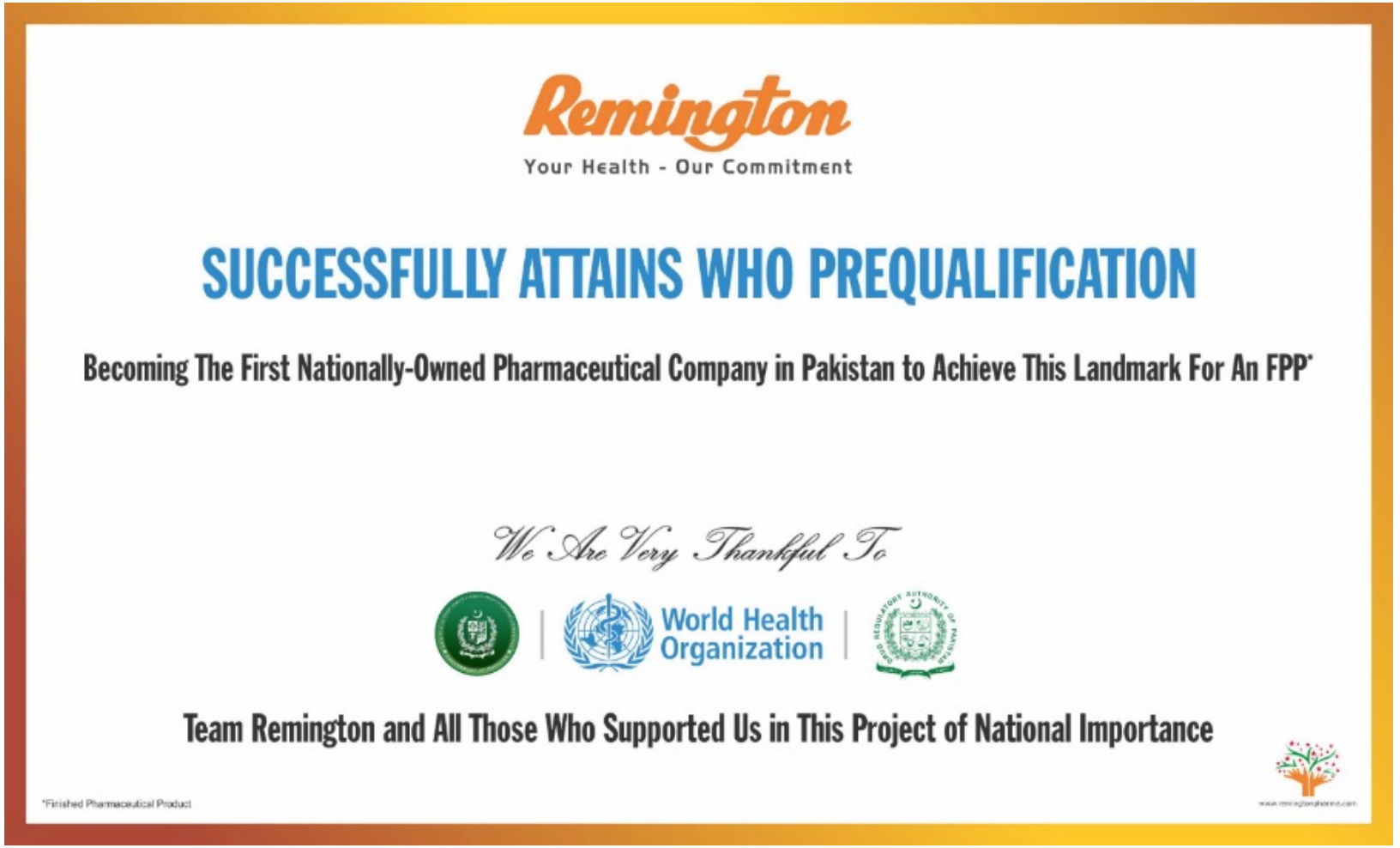
April 26, 2022

Remington
Your Health - Our Commitment

Disclaimer & Confidentiality

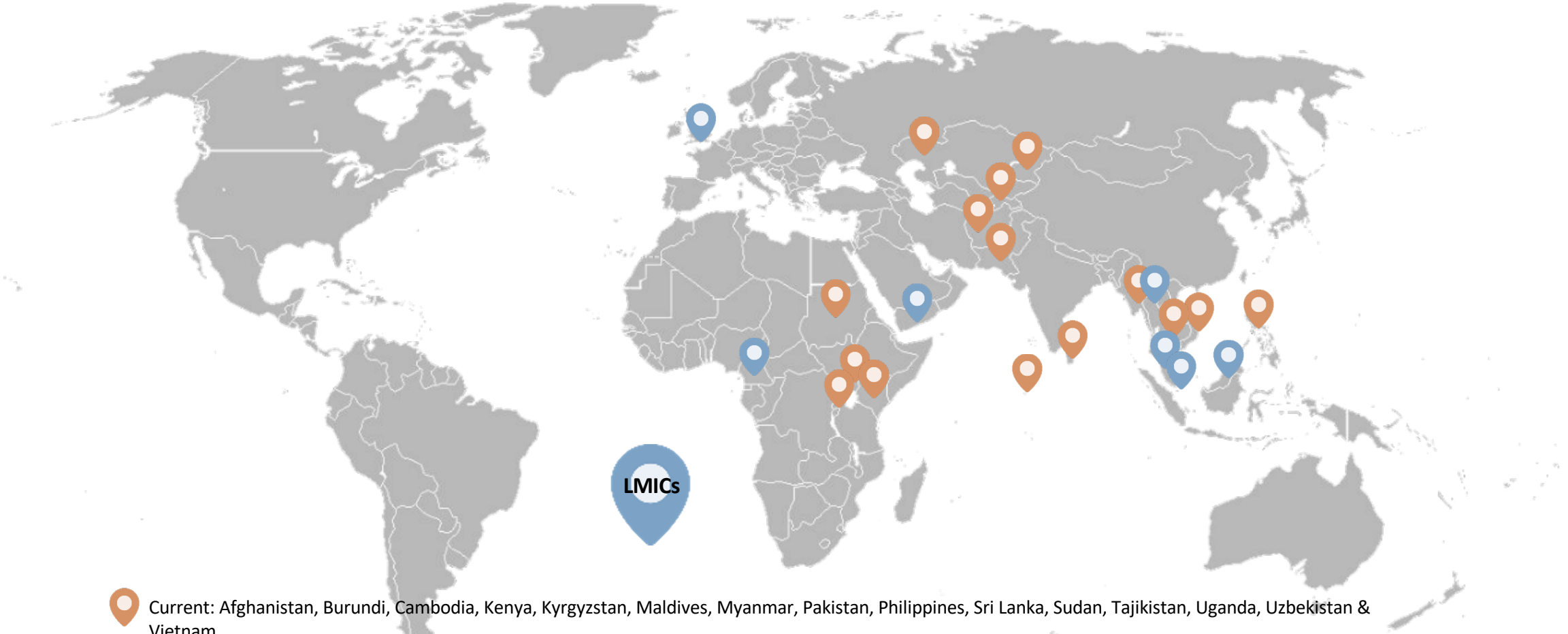
This presentation is confidential and for your information only and is not intended as an offer, or a solicitation of an offer, to buy or sell any investment or other specific product. Although all information and opinions expressed in this document were obtained from sources believed to be reliable and in good faith, no warranty, express or implied, is made as to its accuracy or completeness. All information and opinions as well as any prices indicated are subject to change without prior notice. Any information herein are not binding upon any party and cannot constitute any evidence in any court of law.

First National WHO Prequalified Pharmaceutical Company in Pakistan



Official Publication

Special Focus on the LMICs



Current: Afghanistan, Burundi, Cambodia, Kenya, Kyrgyzstan, Maldives, Myanmar, Pakistan, Philippines, Sri Lanka, Sudan, Tajikistan, Uganda, Uzbekistan & Vietnam

Under Process: Brunei, Cameroon, Malaysia, Singapore, Thailand, UK. Europe & LMIC

Ongoing Development Against the COVID–19 Infection

- In agreement with the Medicine Patent Pool (MPP) for developing, manufacturing and marketing Molnupiravir in 105 Countries & Nirmatrelvir/Ritonavir in 95 Countries.

Official Publication

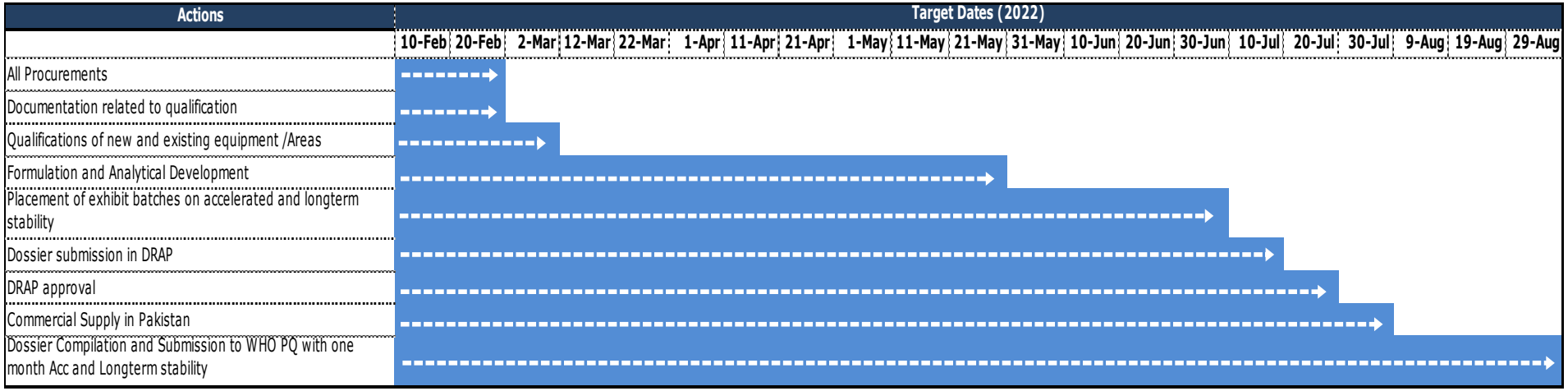
Fast Track Development of Molnupiravir to Ensure Availability in 105 LMICs

- Current status of our ongoing Development Against the treatment for COVID–19 Infection,

API & Pharmaceutical Excipients	Packaging	Art Work & Labelling	Regulatory
Molnupiravir available at premises. Sourced from Shanghai Desano.	Vendor selected for 20s and 40s HDPE bottles.	Unit Carton for Bottle & Blister Packaging selected.	Import license acquired, RLD to be received.
Excipients availability confirmed at premises.	Bottles with induction seals and child lock selected.		Export Only Registration for Remnovir.
Unprinted HPMC capsules available at premisis after evaluation.			

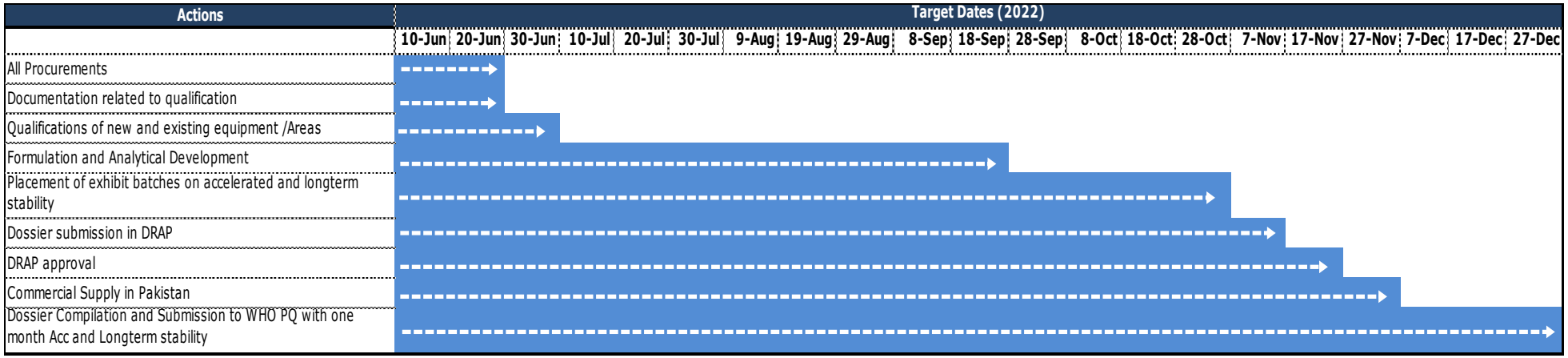
Commercialization Timelines

- Actively working on rolling out the distribution plan of Molnupiravir Capsules to ensure treatment access to patients in low resource settings.
- Dossier to be filed with **Drug Regulatory Authority of Pakistan (DRAP)** in July 2022.
- Dossier will be filed to **WHO PQ** by August 2022.



Commercialization Timelines

- Actively working on rolling out the distribution plan of Nirmatrelvir/Ritonavir to ensure treatment access to patients in low resource settings.
- Dossier will be filed to WHO PQ by December 2022.



Challenges for Generic Manufacturers of Oral COVID-19 Therapies

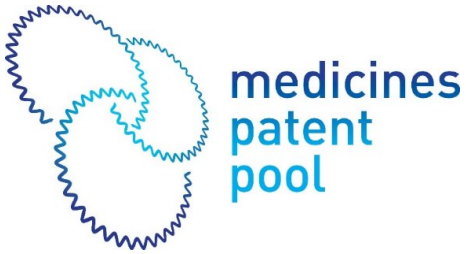
- We are working at full pace towards the development of Oral Covid-19 therapies and making huge investments in:
  - Capex
  - Product Development
  - Bioequivalence Studies
  - WHO Prequalification
  - Global Registrations
  - And much more…

HOWEVER, SIGNIFICANT CHALLENGES REMAIN…

Among many technical and supply chain challenges, the Biggest Impediment remains to be the **Lack of Commercial Visibility** and, most importantly, **No Guaranteed Up-Takers**.

Thank You To All the Stakeholders

ACT-A co-convening partners:



Thank You

USA

Sehrish Aslam, New Jersey, USA
E: saslam1@remingtonpharma.com
M: +1-609-686-9049

Dubai

Ayesha Hammad, Dubai, UAE
E: ahammad@remingtonpharma.com
M: +971-521 291750

REGIONAL

Hamza Salman, Lahore, Pakistan
E: hsalman@remingtonpharma.com
M: +92-313 4000002

Facilitation Council

Dx: Reversing the decline in diagnostics globally

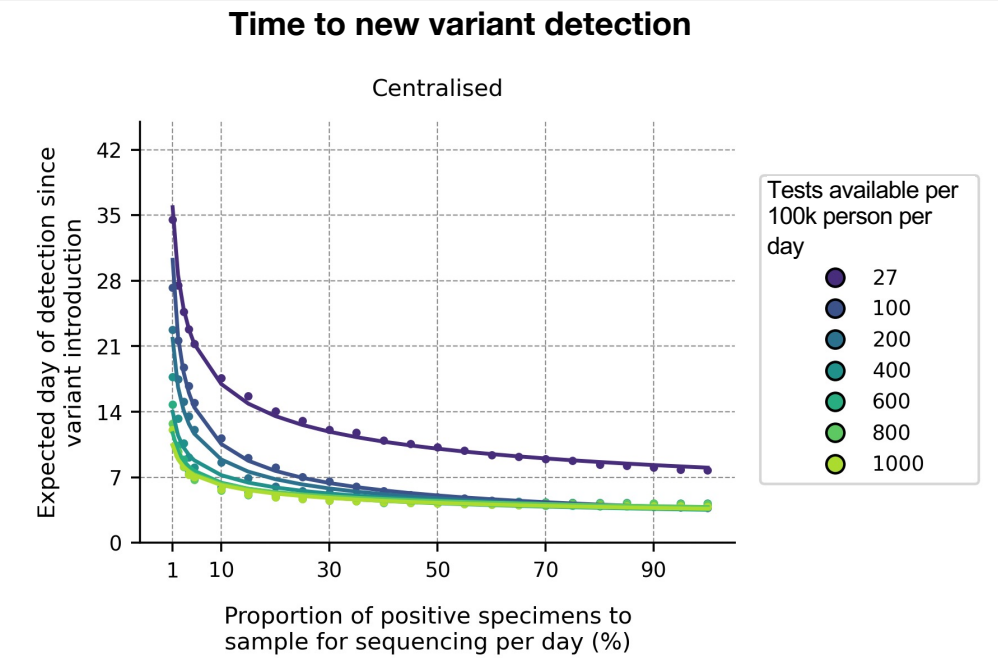
26th April 2022

#UnitedAgainstCoronavirus

#StrongerTogether | #GlobalResponse | #GlobalGoalUnite

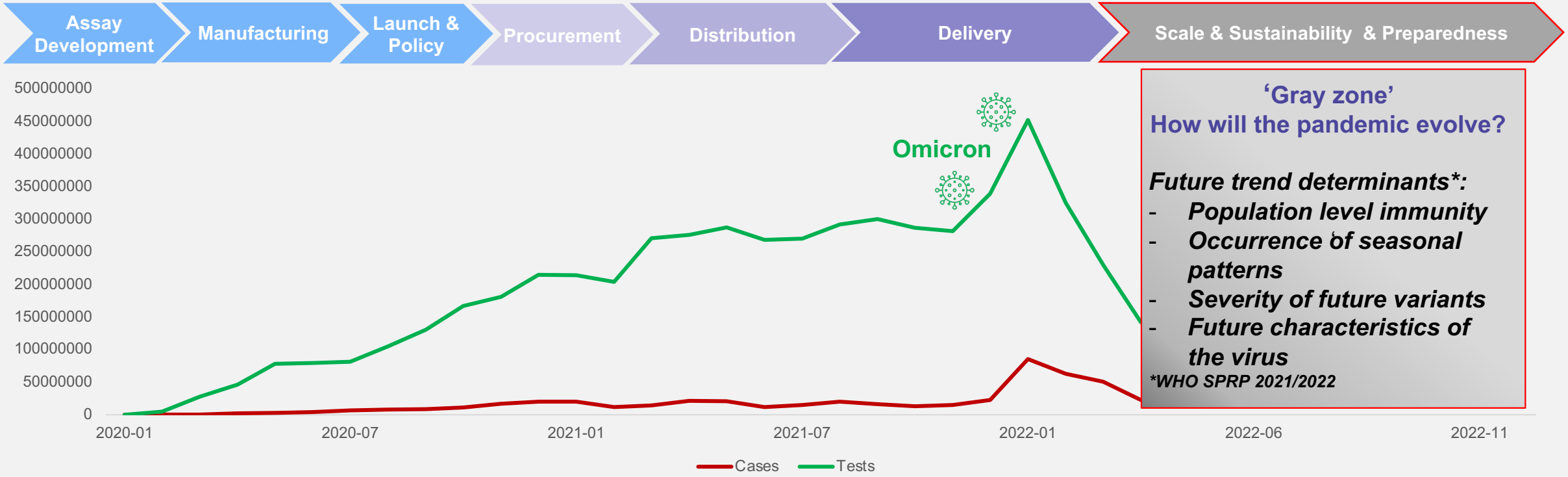
Testing remains an integral part of the COVID-19 pandemic response

Access to COVID-19 testing supports public health containment and swiftly **identify patients to link to early oxygen therapy and effective treatments** as they became available



Recent modelling efforts show that increasing access to healthcare-provided diagnostic testing at a **minimum rate of 100 tests / 100,000 people / day is essential for timely identification of variants**

Test usage has dropped globally, heightening challenges in the Dx space



- How do we **address current challenges** to ensure lab systems are strengthened and COVID Dx are scaled sustainably in 2022 and beyond?
- **How can we move from acute response to sustaining gains and preparing for future pandemics**?

Based on engagement with country partners, the Dx pillar advocates for strengthening lab systems

Decentralized testing models create an enabling environment for populations to more effectively access testing

A 6-country study in Sub-Saharan Africa* showed that regardless of healthcare setting, females are much less likely than males to receive testing; only 27% to 37% of females (vs 73% to 63% of males) accessed PCR tests while 42% to 47% females (vs 58% and 53% of males) accessed antigen tests

Scaling access through decentralised testing models and prioritizing vulnerable/hard to reach populations is part of the C-19 funding request

* *A Multi-Country Evaluation of the Delivery and Administration of SARS-CoV-2 Antigen Rapid Tests in Sub-Saharan Africa by CHAI with support from Unitaid and other partners, Data from Nov 2020 to July 2021*

The Dx pillar continues to prepare for the future by prioritizing local manufacturing and multiplex molecular platforms

Progress in local manufacturing

Local manufacturing and in country capacity is being prioritized to support fragile supply chain systems

Construction of a manufacturing facility in India*

Local production scaled up from 1 to 5 countries through ACT-A

Increasing in country capacity to support genomic sequencing and developing open PCR platforms to adapt protocol to regent availability and decrease dependency on single commercial provider

COVID has triggered innovation in molecular Dx

~ 56 novel point-of-care MDx tests launched (regulatory authorized) including 16 true POC (instrument-free home test)

Multiplexing capacity
4 targets/test
Sample processing
Fully integrated
Turnaround time
30 min
Technology
RT-PCR
Validated sample type
Nasal, MT swab

#GlobalGoalUnite

*Photo credit: Premier Medical Corporation (PMC) Pvt Ltd, India

Nigeria Centre for Disease Control

Protecting the health of Nigerians

Diagnostic Priorities in Achieving Decentralised COVID-19 Testing in Nigeria

10th Facilitation Council – COVID-19 Tools Accelerator (ACT-A)

Dr Chinwe Ochu
Director, Prevention Programmes and Knowledge Management
Nigeria Centre for Disease Control

26 April 2022

Testing Strategy

Genomic sequencing

PCR

- Routine surveillance
- HIV/TB/malaria
- Inpatients
- Travellers
- SARI/ILI surveillance
- Multiplex pathogen testing

Ag-RDT

- Healthcare workers
- Outpatients' triage
- RMNCH
- Travellers
- Congregate settings (NYSC, schools, sports, political rallies, workplace, religious events, etc)

Successes

- ❑ Policy & strategy documents
  - COVID-19 testing strategy
  - Guidance for the use of approved COVID-19 Ag-RDT in Nigeria
- ❑ Scaling of Ag-RDTs to 33 out of 36 states & FCT following successful regional ToT
  - Health Facilities
  - Schools, NYSC camps, prisons, office/workplace, land borders & seaports, airports, and other congregate settings.
- ❑ rRT-PCR
  - >157 molecular labs across all states in the country
- ❑ Improved capacity for Genomic Sequencing

Challenges

- Invasive procedure
- Misinformation
- Low risk perception & COVID fatigue

→ Poor uptake

- Self-testing not yet instituted
- Poor community-based surveillance

→ Poor Access

- Underutilisation of PCR labs
- Sample transportation challenges
- Inadequate Genomic surveillance

→ Inadequate capacity

Lessons Learned & Recommendations

- Ag-RDT scale up
  - State & community engagement
  - Demand creation (effective, affordable, convenient and accessible tests)
  - R&D into Ag-RDTs requiring less invasive sample collection method
  - Public access to Ag-RDTs for self-testing
- Quality Assurance with adequate regulatory control of influx of unvalidated RDTs into the country
- Integrated data management system that captures the whole spectrum of COVID-19 testing


Thank you

ACTaccelerator
ACCESS TO COVID-19 TOOLS

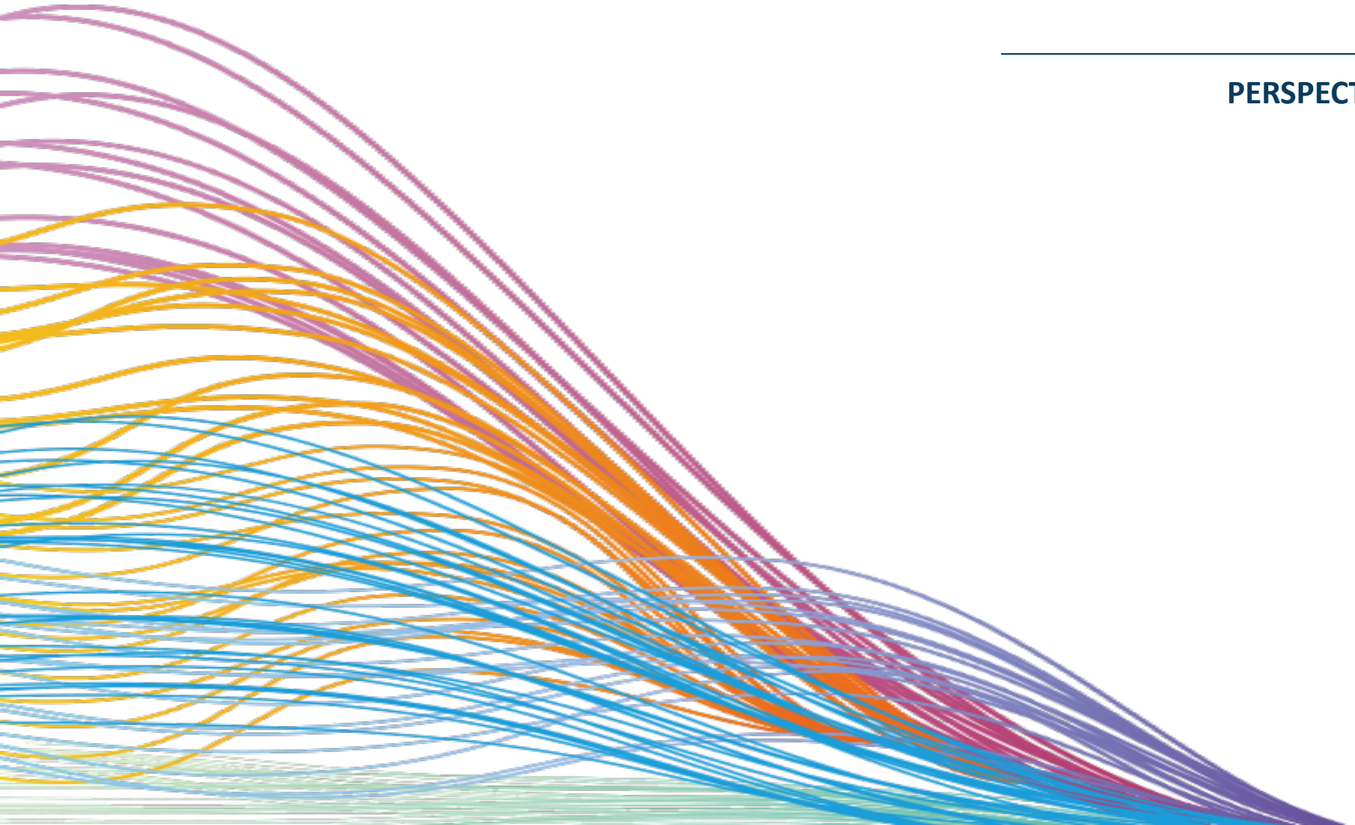
Hosted by World Health Organization

Financing our most urgent priorities

PERSPECTIVES FROM THE FACILITATION COUNCIL FINANCE AND RM WORKING GROUP

26 APRIL 2022

ACT now. ACT together to accelerate the end of the COVID-19 crisis.

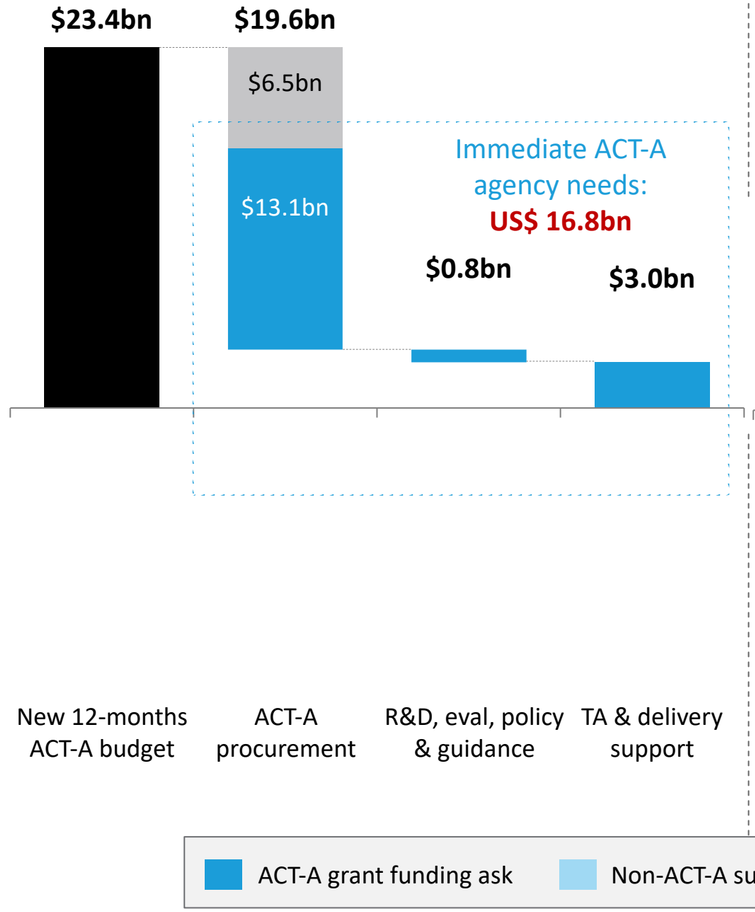


New ACT-A Financing Framework integrates crucial in-country delivery costs

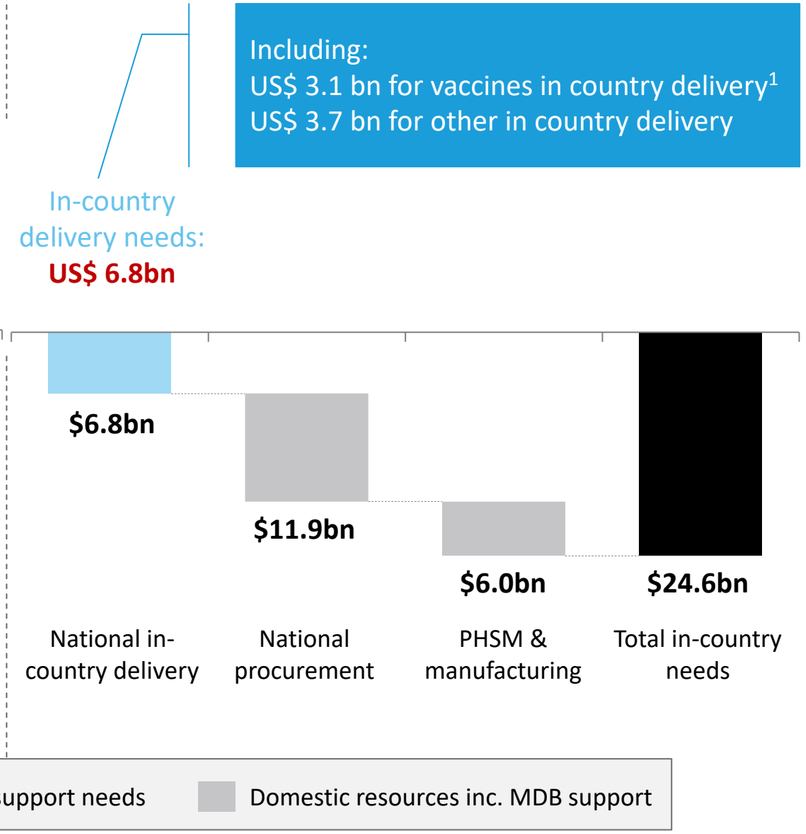
ACT-A Council Financing Framework

Includes a breakdown of each agency's needs

Prioritizes the ACT-A budget



Explains in-country delivery needs



1. Oct. 2021 estimation, updated in January 2022

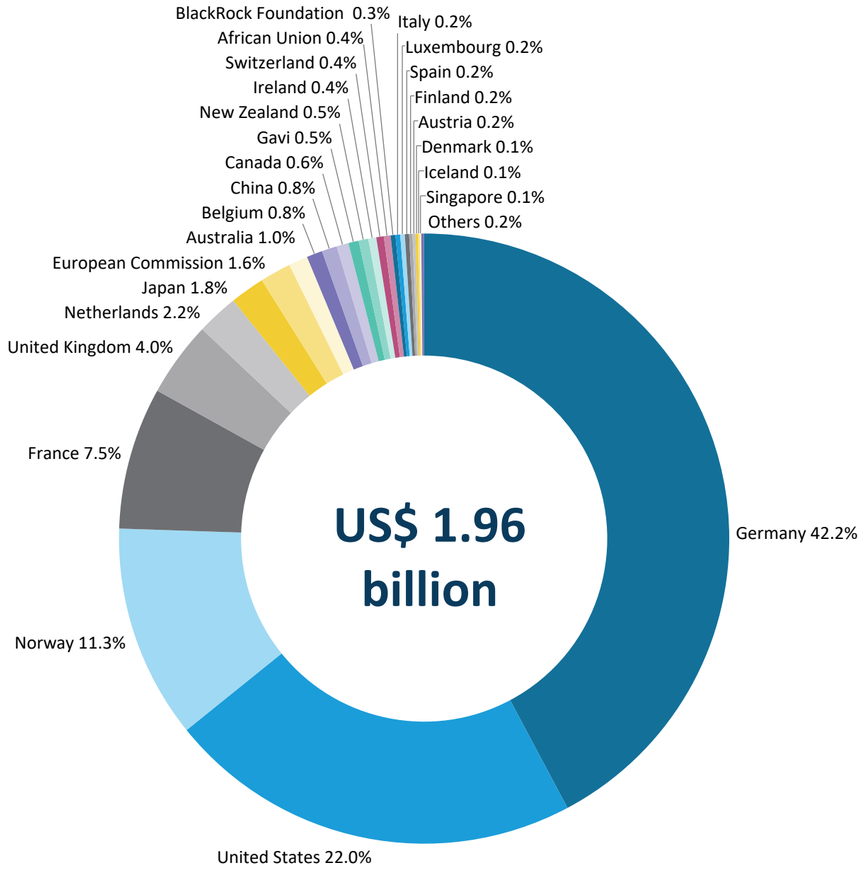
ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

ACT-A funding gap | As of 26th April, ACT-A's 21-22 funding gap remains at US$ 14.89bn

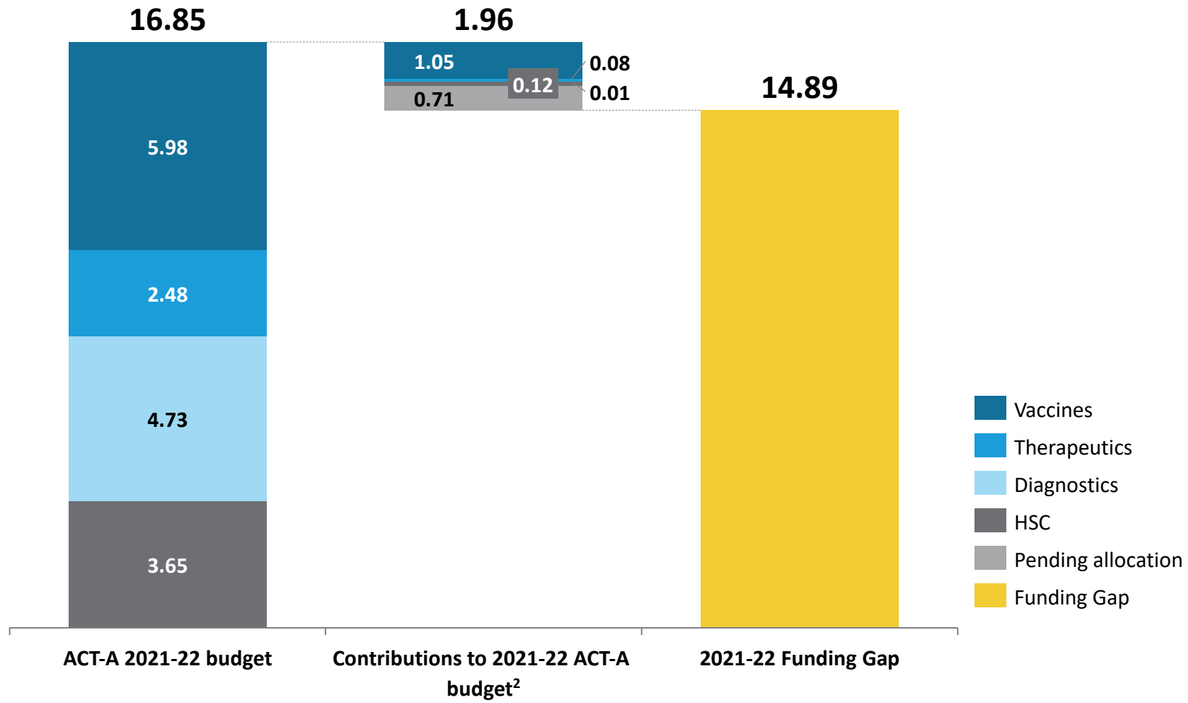
Based on Commitment Tracker Update - 21 April 2022.
Recent pledges are still under validation and therefore not included here, but could reduce the funding gap by US$ 1600m

ACT-A contributions[1] since October 29, 2021



ACT-A funding gap for 2021/22 since October 29, 2021

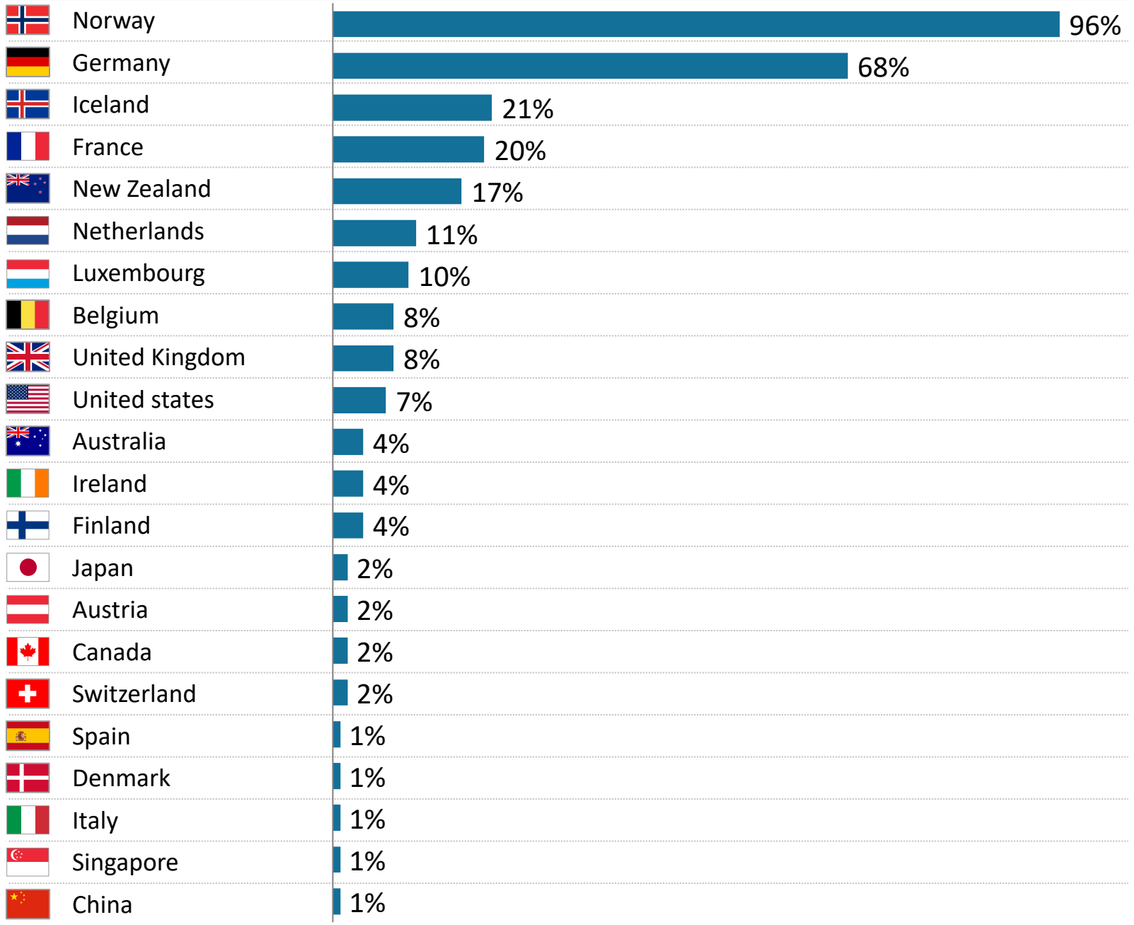
In US$ billion



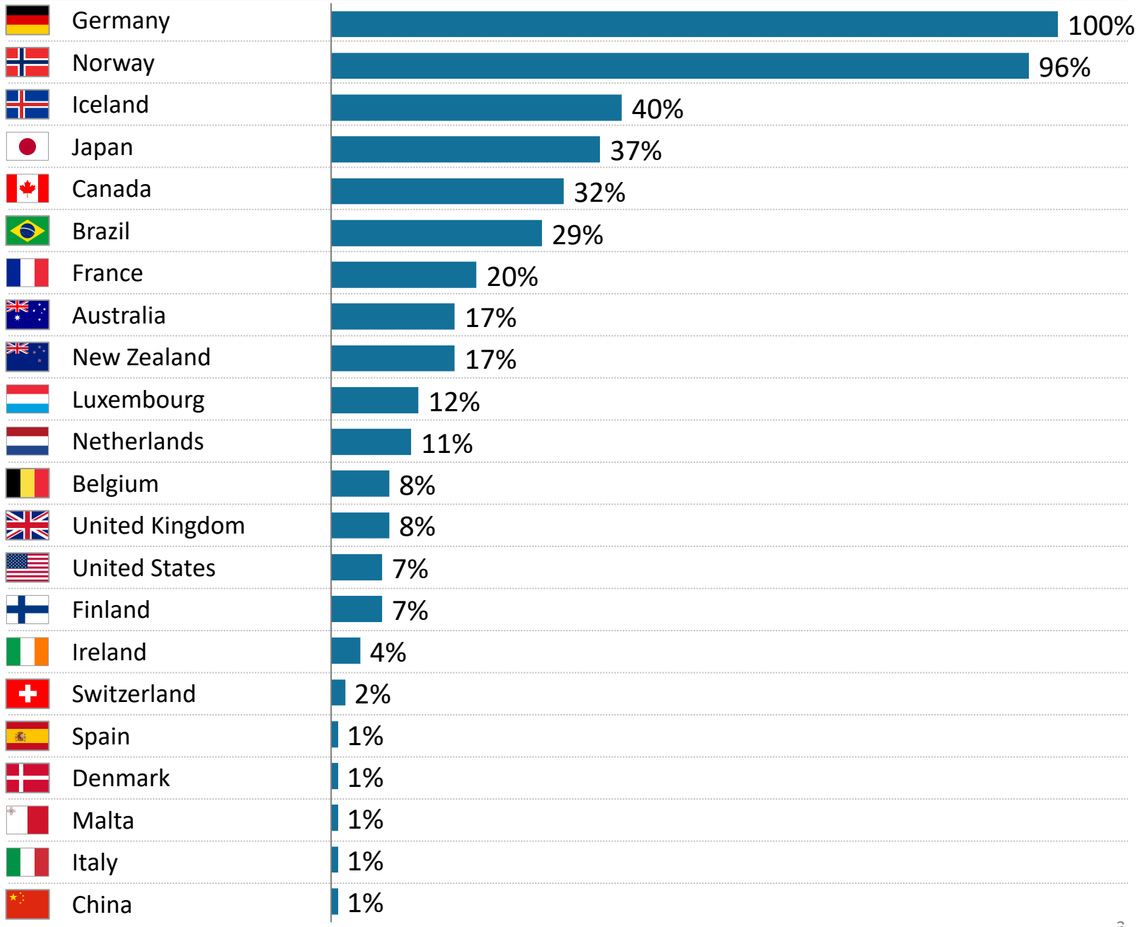
1. Including USD 120 million from the Bill and Melinda Gates Foundation, pending attribution to Pillars 2. As per the Financial Council Financing Framework proposition.
Note: all financial commitments can be accessed at https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker. All figures are rounded.
All commitments since 29 October 2021 in support of the ACT-Accelerator will count towards the ACT-Accelerator Strategy & Budget for 2021-22. Contributions to Pillars are subject to FX variation.

As of 26th April, even if all yet unvalidated pledges are considered only six countries have contributed >25% of their fair share

As it stands today, according to the Commitment Tracker 21 April



And if recent pledges that have not yet been validated are taken into account[1]



1. From AMC Summit, Germany, Canada and Japan

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Driving donors' contribution to the most impactful investments | Pillars have identified urgent priorities within the US$ 15bn remaining gap, totaling **US$ 10.7bn**

Key priorities identified to date

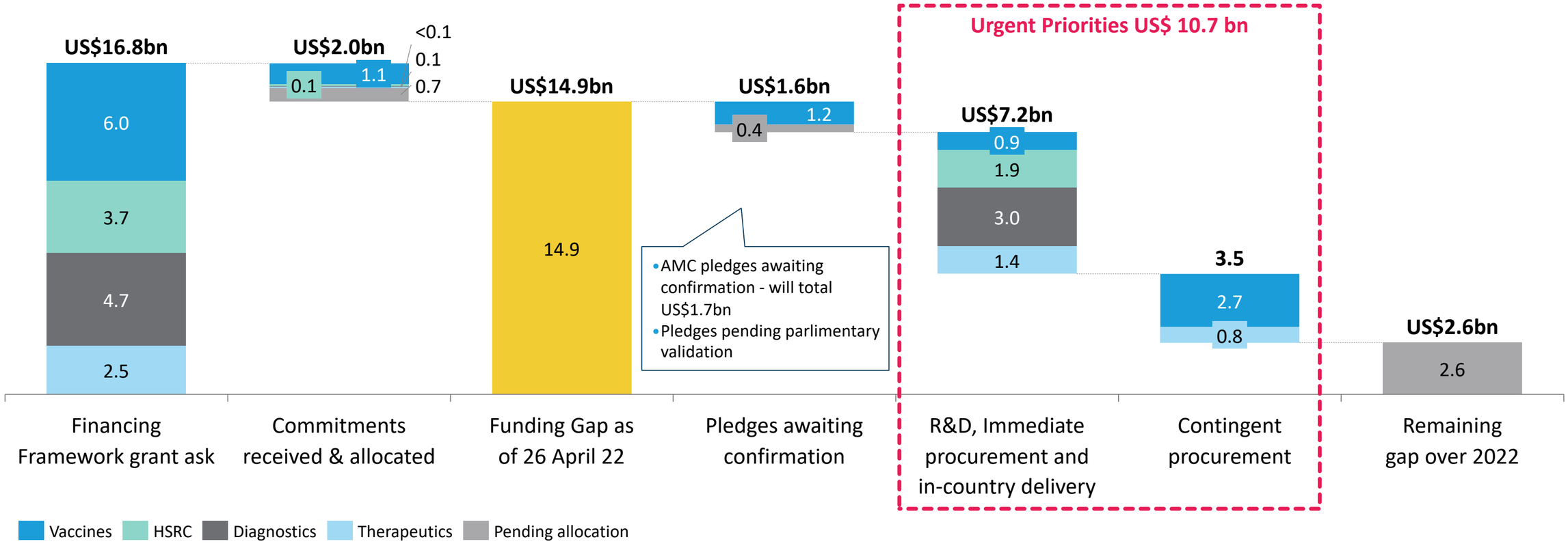
Implied urgent funding priorities – *US$ bn*

	R&D	Immediate Procurement	Contingent Procurement	Delivery
Vaccines • Shifting focus to in-country delivery • GAVI's funding needs for in-country delivery and ancillary costs fully funded • Maintain procurement target but through a contingency pooled fund	0.4	-	2.7	0.5
HRSC • Coordinated country planning, financing, and tracking against delivery targets • Coordinated technical, operational, and financial support to support scale-up of COVID-19 tools • Debottlenecking health systems and maintaining essential health services, while protecting health workers (incl. PPE procurement)	-	0.7	-	1.2
Diagnostics • Scale procurement of diagnostics tools • Expand capacity for countries to deploy diagnostics tools through health systems • Support expansion of genomic sequencing • Support local manufacturing and market entry	<0.1	2.3	-	0.7
Therapeutics • Oxygen procurement, delivery and market shaping • Initial procurement of repurposed/Novel oral antivirals for high-risk mild/ moderate patients[1] • Procurement at scale of repurposed / Novel oral antivirals for mild/moderate patients[1]	-	1.2	0.8	0.2

1. Specific treatment targets are being reassessed based on the clinically recommended use case, country demand, and other factors.

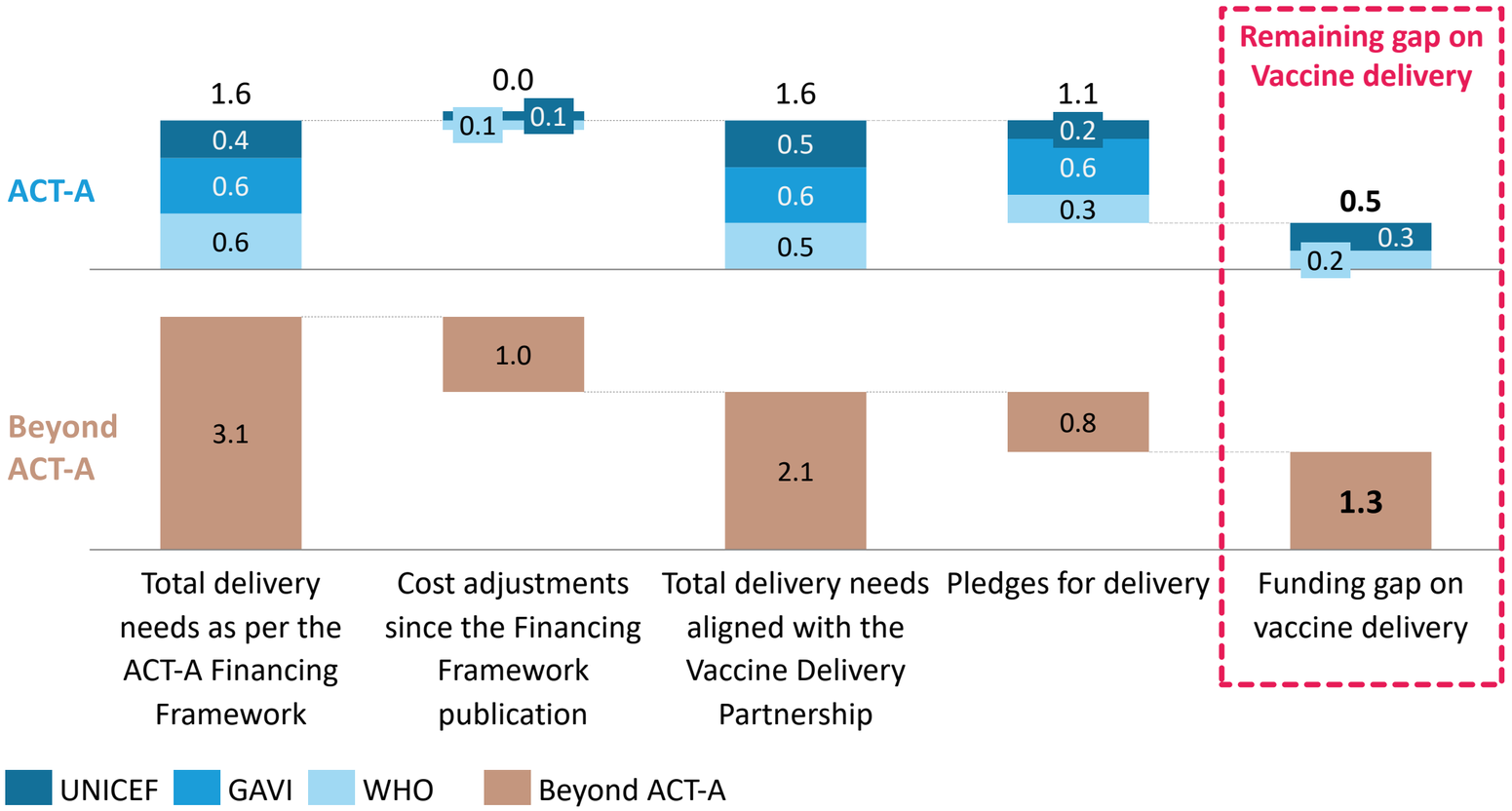
Immediate priorities I Within the ACT-A US$ 15bn remaining gap, **US$ 10.7 bn** are urgently needed to achieve ACT-A 2022 targets

Preliminary view of immediate priorities based on pledges received and initial inputs, as of 26th of April 2022[1]



Deep dive on vaccine delivery I Despite the success of the COVAX AMC event, vaccine delivery still requires **US$ 0.5bn** within ACT-A and **US$ 1.3 bn** beyond ACT-A

Estimated in-country delivery funding gap to achieve 70% Vx coverage in 133 LICs and LMICs – *US$ Bn*

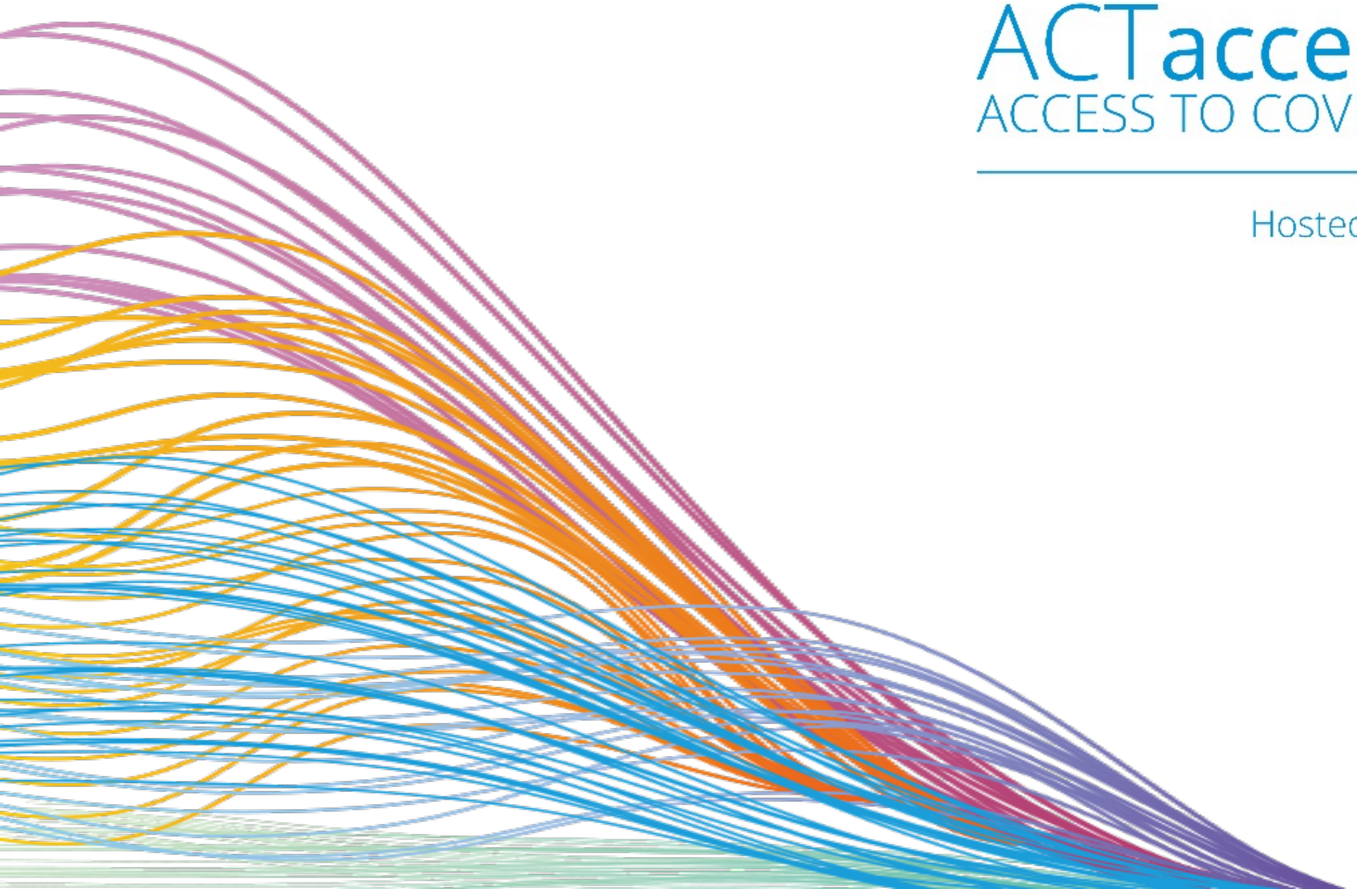


0.5bn
+ 1.3bn
Unfunded investment needs

Potential additional areas of needs

- Countries relying on expensive campaign vaccination programmes
- Support bundling of delivery
- Support implementation of booster strategies
- Strengthening of targeted health systems interventions to protect routine immunization services

1. UNICEF estimation, Jan 2022, UNICEF ask breaks down into US$ 400m for AMC92 and an additional US$ 175m to cover other countries in AMC 133, reflected here in the "Beyond ACT-A" category. 2. Beyond ACT-A, three contributions are considered: US$ 315m from USG, US$ 400 from Mastercard to African CDC (exact amount to be confirmed) and US$ 129m from Germany. Contribution for ACT-A are reported in the ACT-A Commitment Tracker https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker



ACTaccelerator

ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization