ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

Strategic Plan & Budget
October 2021 to September 2022

Enhancing equity in access to COVID-19 tools

28 October 2021

ACT-Accelerator Strategic Plan & Budget, October 2021 to September 2022

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ACT-A co-convening partners:

Gavi The Vaccine Alliance

CEPI

World Health Organization

wellcome

Bill & Melinda Gates foundation

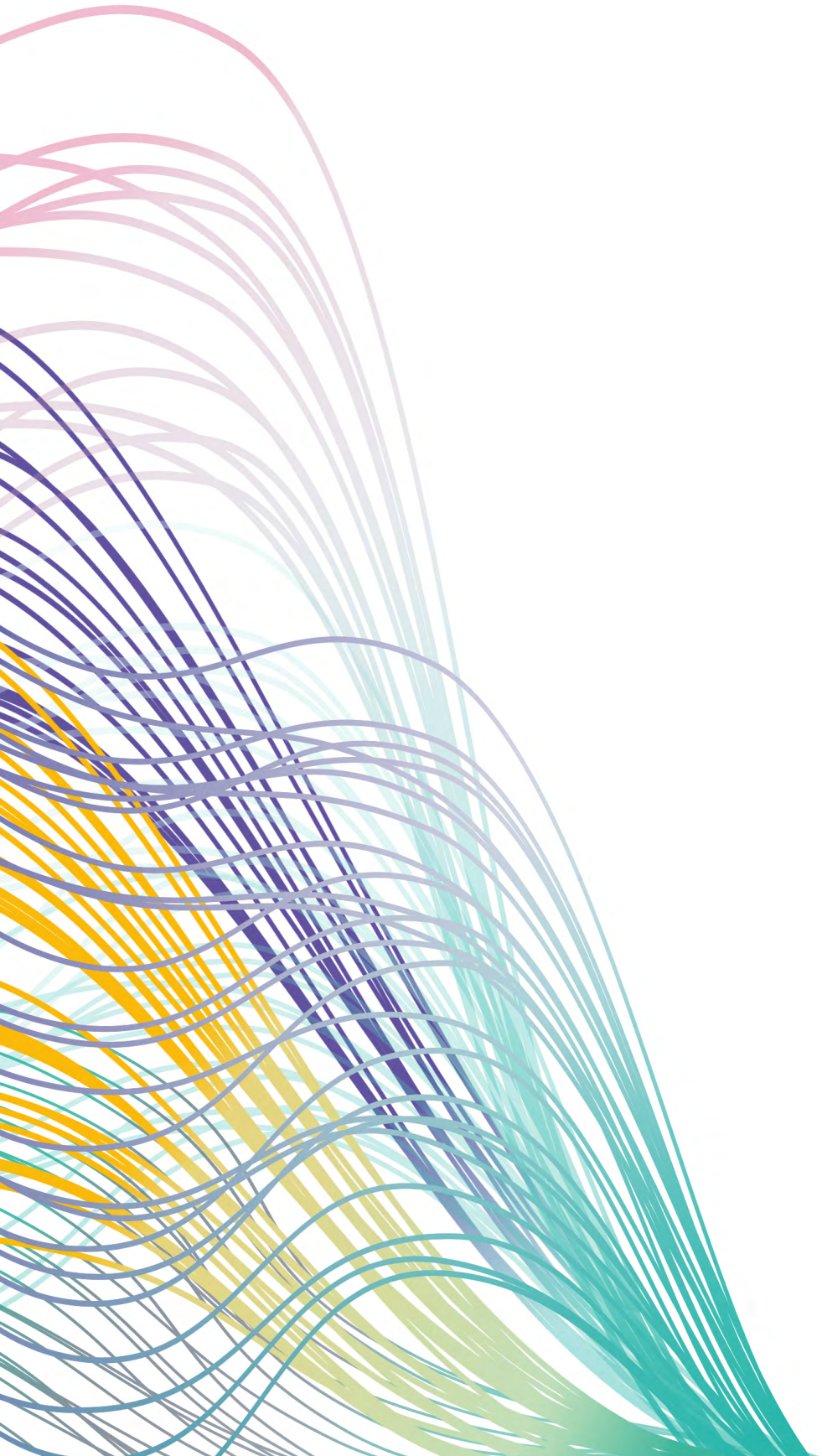
FIND Diagnosis for all

The Global Fund

Unitaid

unicef

World Bank Group



CONTENTS

List of Acronyms vi

About our new ACT-A strategic plan & budget vii

Executive summary viii

PART 1: ACT-A Strategic Plan (October 2021 – September 2022)

1. The ACT-Accelerator in a radically different world 01
2. The ACT-Accelerator's focus & strategic priorities for the next 12 months 05
3. Pillar contributions to closing global gaps in access to COVID-19 tools 08
4. Tracking & accelerating progress in closing gaps in access to COVID-19 tools 26

PART 2: ACT-A Budget (October 2021 – September 2022)

5. Overview of ACT-A funding needs for the next 12 months 31
6. Detailed work packages by strategic priority, Pillar and outcome category 36
7. Financing ACT-A within the broader COVID-19 response 42
8. ACT-A Investment Case 44

Annexes

Annex 1: Taking forward the recommendations of the independent ACT-Accelerator Strategic Review 48

Annex 2: Key assumptions underpinning the budget 51

LIST OF ACRONYMS

Ab	Antibody-detecting
Ag	Antigen-detecting
AMC	COVAX Advance Market Commitment
AU	African Union
AVAT	African Union's African Vaccines Acquisition Trust
C19RM	The COVID-19 Response Mechanism
CDC	Centre for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CHWs	Community Health Workers
CSCOs	Civil Society and Community Organizations
Dx	ACT-A Diagnostics Pillar
EQA	External Quality Assessment
EUL	Emergency Use Listing
FIND	FIND, the Global Alliance for Diagnostics
GAVI	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HCWs	Health Care Workers
HICs	High Income Countries
HSRC	ACT-A's Health Systems & Response Connector
ICs	Inhaled Corticoids
I&L	Indemnification & Liability agreement
IL-6	Interleukin 6
IMF	International Monetary Fund
IMST	Incident Management System Team
LICs	Lower-Income Countries
LMICs	Lower-Middle Income Countries
NAV	Novel Oral Antiviral
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction
PHSM	Public Health and Social Measures
PPE	Personal Protective Equipment
PQ	Prequalification (of products)
RDTs	Rapid Diagnostic Tests
SFP	COVAX Self-Financing Participants
SPRP	COVID-19 Strategic Response and Preparedness Plan
SSRI	Selective Serotonin Reuptake Inhibitor
Tx	ACT-A Therapeutics Pillar
UMICs	Upper Middle-Income Countries
UNGA	United Nations General Assembly
UNICEF	United Nations Children's Fund
Vx	ACT-A's Vaccines Pillar, COVAX
WB	World Bank
WHE	WHO's Health Emergency Programme
WHO	World Health Organization

ABOUT OUR NEW ACT-A STRATEGIC PLAN & BUDGET

The Access to COVID-19 Tools (ACT) Accelerator's strategy and budget are periodically updated to reflect the evolving epidemiological situation, COVID-19 products and pipeline, and financing requirements. The *ACT-Accelerator Strategic Plan & Budget, October 2021 to September 2022* supersedes previous ACT-A strategy and budget, and investment case reports, including the *Rapid ACT-Accelerator Delta Response (RADAR)* urgent appeal launched in August 2021, the *ACT-Accelerator Prioritized Strategy & Budget for 2021* published in April 2021, the *ACT-Accelerator Urgent Priorities & Financing Requirements* published in November 2020, and the *ACT-Accelerator: Status Report & Plan* and *ACT-Accelerator: Economic Investment Case & Financing Requirements* published in September 2020.

The *ACT-Accelerator Strategic Plan & Budget, October 2021 to September 2022* lays out the new focus, strategic priorities, major scopes of work and funding needs for the ACT-Accelerator for the next 12 months. The new strategic plan and budget reflect the decision to extend the work of ACT-A into 2022, acknowledging the substantial changes in ACT-A's external operating environment and the evolving COVID-19 epidemiological situation. Together, these have precipitated a fundamental rethink of ACT-A' s immediate priorities and the most effective ways to deploy the tools necessary to mitigate the COVID-19 pandemic.

This document was developed under the leadership and direction of the ACT-A Pillar Co-Conveners and Agency Leads in consultation with the broader ACT-A partnership, including the Facilitation Council.

The *ACT-Accelerator Strategic Review* has also been a critical input to the development of this strategic plan and budget. Where applicable, references are provided in the document to various aspects of the review that have influenced changes in ACT-A's overall approach. Annex 1 provides further information about how each of the main recommendations from the Strategic Review are being taken forward.

This strategic plan and budget document is organized into 2 parts:

- **Part 1:** The **ACT-A Strategic Plan** is comprised of four sections. Section 1 describes the overall context for the strategic plan and budget. This sets the scene for Sections 2 and 3, which introduce ACT-A's new focus, overarching objective and strategic priorities for the next 12 months, and provide further detail on Pillar-specific targets, strategies and activities. A new approach to tracking and accelerating ACT-A's contribution to globally agreed targets for more equitable access to COVID-19 tools is described in Section 4.

- **Part 2:** The **ACT-A Budget** has four sections. ACT-A's funding needs for the period October 2021 to September 2022 and detailed work packages by strategic priority, Pillar and outcome are addressed in Sections 5 and 6. Section 7 provides an overview of ACT-A's financing needs within the overall context of the investment required to support the global COVID-19 response. A proposed investment case for ACT-A is provided in Section 8. Part 2 (ACT-A's budget) will be updated as needed, taking into account the changing epidemiological situation, financing requirements, and progress made in reaching global targets for access to COVID-19 tools.

This document is complemented by more detailed, Pillar-specific information. Hyperlinks to the latter are provided in the text or in footnotes where applicable. This document is also complemented by the *What is the ACT-Accelerator, how is it structured and how does it work?* document which will be updated to reflect changes introduced in ACT-A's set up and ways of working.

EXECUTIVE SUMMARY

The ACT-Accelerator is operating in a world that has radically changed in the last 18 months. The development and introduction of new COVID-19 vaccines, treatments, and tests has fundamentally changed the fight against SARS-CoV-2. Yet, too few countries have access to these tools, resulting in a two-track pandemic, with different geographies, countries and populations experiencing dramatically different health, economic and societal impacts.

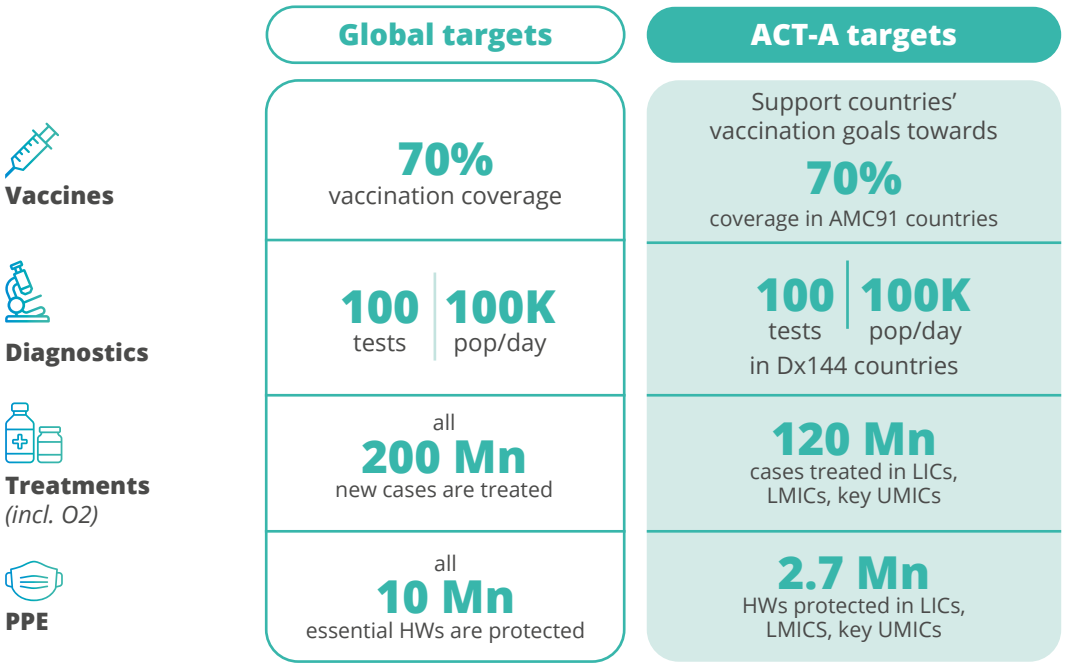
COVID-19 will be with us for the foreseeable future. While vaccines are a powerful weapon, the world needs the full suite of tools (including tests, treatments, and public health and social measures) to save lives, protect the vulnerable, reduce the risk of new variants, and achieve full economic and societal recovery.

Market forces, geopolitical interests and national trade decisions are now actively influencing the local availability and affordability of COVID-19 tools. Solving the escalating inequity in access requires a globally coordinated effort more than ever.

Reflecting its original mandate, but considering the current global context, the ACT-Accelerator is shifting its primary aim from being *the* global solution for equitable allocation of COVID-19 tools to **addressing inequities in access to COVID-19 tools** for populations living in underserved areas and countries, including humanitarian settings.

Leaders have affirmed support for the ambitious global coverage targets for COVID-19 tools that were established by the World Health Organization (WHO), and ACT-A Pillars, to end the acute phase of the pandemic. The ACT-Accelerator's work is crucial to support countries in achieving their vaccination, testing, treatment and personal protective equipment (PPE) targets in light of the global targets (see Fig. 0.1).

***Fig 0.1**. ACT-A contributions to accelerating progress towards global targets for access to COVID-19 tools*



Building on its unique structure – as the only global, integrated end-to-end platform for developing and scaling access and delivery of COVID-19 vaccines, tests, treatments, and PPE - ACT-A has five new strategic priorities for the next 12 months. These include tracking overall gaps and barriers in access to COVID-19 tools; helping to close global gaps in access to vaccines, tests, treatments and PPE; and fully integrating Pillar delivery support with national COVID-19 response mechanisms. Reflecting key recommendations of the *ACT-Accelerator Strategic Review*, ACT-A's work will be more closely driven by country and community needs, follow a results-based approach that is anchored in the global targets for access to COVID-19 tools, and align with the efforts of other actors and initiatives that focus on resolving inequities in access to COVID-19 tools.

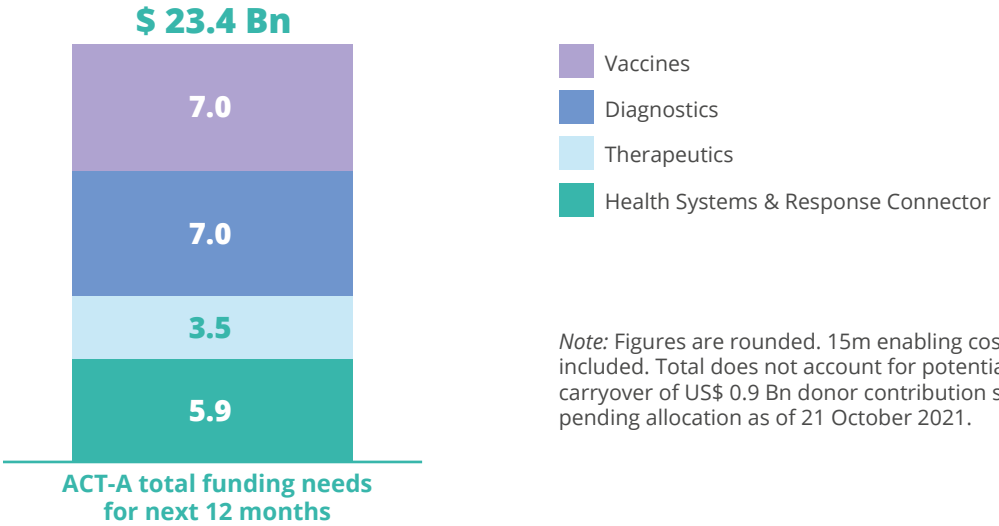
A consolidated view of the coverage achieved for each COVID-19 tool, barriers to their access, and donor pledges is essential for tracking progress and advocating for the resources required to end the pandemic. ACT-A will strengthen national Strategic Preparedness and Response Plans and support a multi-agency, multi-stakeholder effort, including through enhanced engagement with the private sector and civil society, to bring together the different sources of information and data required for monitoring and communicating its contribution towards the global vaccination, testing, treatment, and PPE targets.

Based on the evolving context and refreshed strategic priorities outlined above, the ACT-A Pillars have developed new budgets for the period October 2021 to September 2022 that total **US$ 23.4 billion**[1] (see Fig. 0.2).

Fully funding the ACT-A's 12-month budget will help ensure that all countries can access essential volumes of safe and effective vaccines, tests, and treatments needed to end the COVID-19 crisis. Ending the pandemic is a global public good, in the interests of all countries. The ACT-Accelerator is the only global initiative that offers a comprehensive, integrated strategy to end this crisis everywhere.

We must ACT now, and ACT together, to end the pandemic.

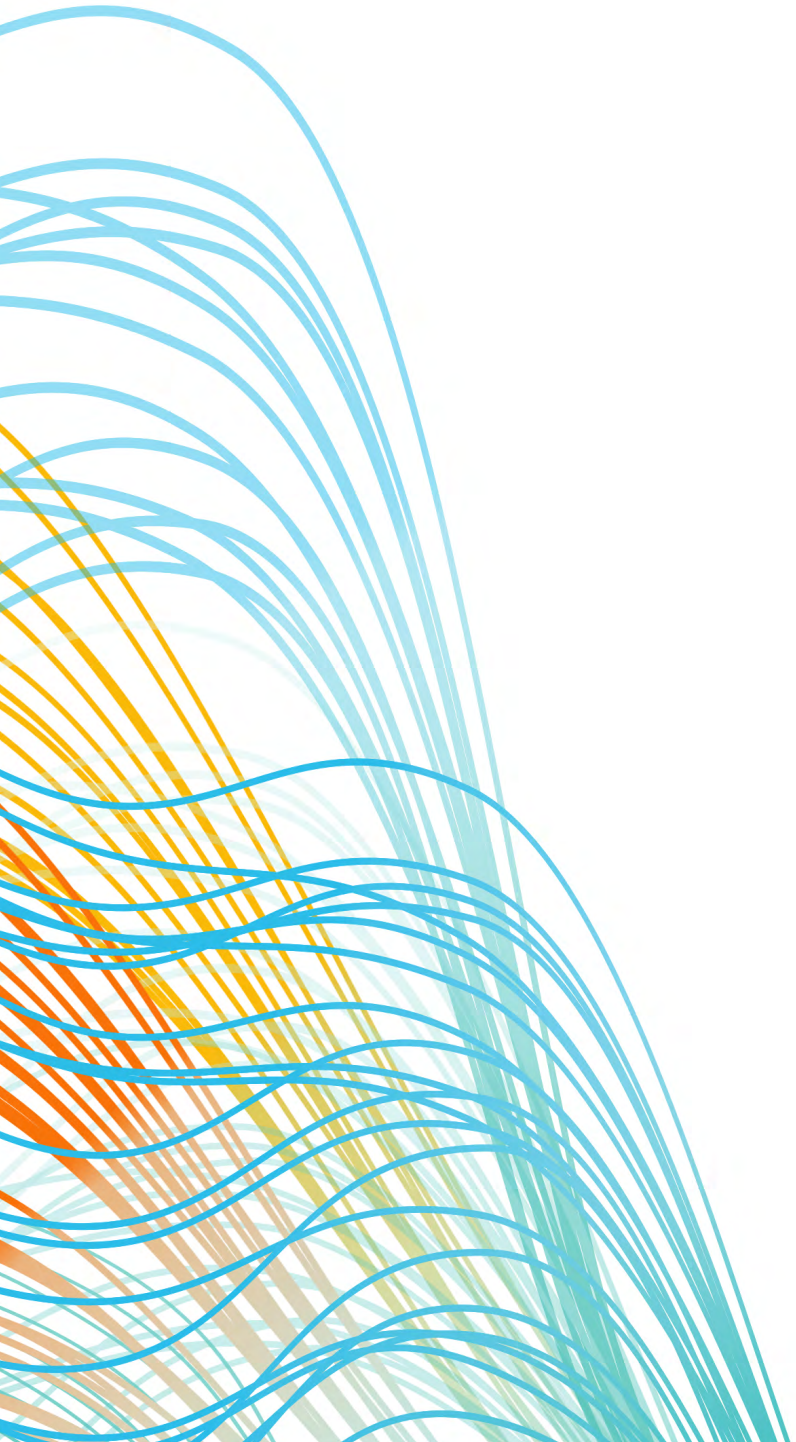
Fig. 0.2. *ACT-A funding needs from Oct 2021 to Sep 2022 by Pillar, figures in US$ billion*



[1] This figure also accounts for and supersedes the prior ACT-Accelerator funding asks.

PART 1:
ACT-A Strategic Plan

(October 2021 – September 2022)



1

THE ACT-ACCELERATOR IN A RADICALLY DIFFERENT WORLD

The introduction of new COVID-19 countermeasures has fundamentally changed the fight against COVID-19, but because of escalating inequities in access to these tools, the world is experiencing a two-track pandemic. It is increasingly clear that COVID-19 will be with us for the foreseeable future, requiring a globally coordinated effort which leverages the full package of COVID-19 tools as the world's best hope for bringing an end to the pandemic.

New medical countermeasures have changed the fight against COVID-19

The ACT-Accelerator was launched in April 2020, less than three months into the COVID-19 pandemic, at a time when there was no clear view to the expected length or severity of the crisis, and when there were a limited number of tools available to prevent or address rapidly escalating disease. Just 18 months later, as the result of an unprecedented international, public-private effort, several safe and effective COVID-19 medical countermeasures exist and are starting to be deployed widely.

Seven vaccines, across four different platforms, have been approved for use[2] – and are proving to reduce transmission, severity and mortality from COVID-19.[3] Three therapeutic interventions[4] (neutralising monoclonal antibodies, IL-6 receptor blockers, and corticosteroids) combined with medical oxygen are now being used as lifesaving options for severe and critical cases of COVID-19. Several new diagnostic tools[5]– sequencing equipment, antigen rapid tests and antibody rapid tests[6]– are more readily available.

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[2] Status of COVID-19 Vaccines within WHO EUL / PQ evaluation process. Geneva: World Health Organisation; 2021 (https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_29Sept2021_0.pdf, accessed 13 October 2021).
[3] In addition, 194 vaccines are in pre-clinical development and 126 vaccines are in clinical development phases. COVID-19 – Landscape of novel coronavirus candidate vaccine development worldwide. Geneva: World Health Organisation; R&D Blueprint; 2021
[4] A living WHO guideline on drugs for COVID-19. BMJ 2020; 370:m3379. 4 September 2020 (doi: https://www.bmj.com/content/370/bmj.m3379, accessed 13 October 2021).
[5] List of SARS-CoV-2 Diagnostic test kits and equipments eligible for procurement according to Board Decision on Additional Support for Country Responses to COVID-19 (GF/B42/EDP11). Geneva: Global Fund, October 2021 (https://www.theglobalfund.org/media/9629/covid19_diagnosticproducts_list_en.pdf, accessed 4 October 2021) .
[6] Note that based on current data, WHO does not recommend the use of antibody-detecting rapid diagnostic tests for patient care but encourages the continuation of work to establish their usefulness in disease surveillance and epidemiologic research. Advice on the use of point-of-care immunodiagnostic tests for COVID-19. Scientific Brief. Geneva: World Health Organisation; 8 April 2020. (https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19, accessed 13 October 2021).

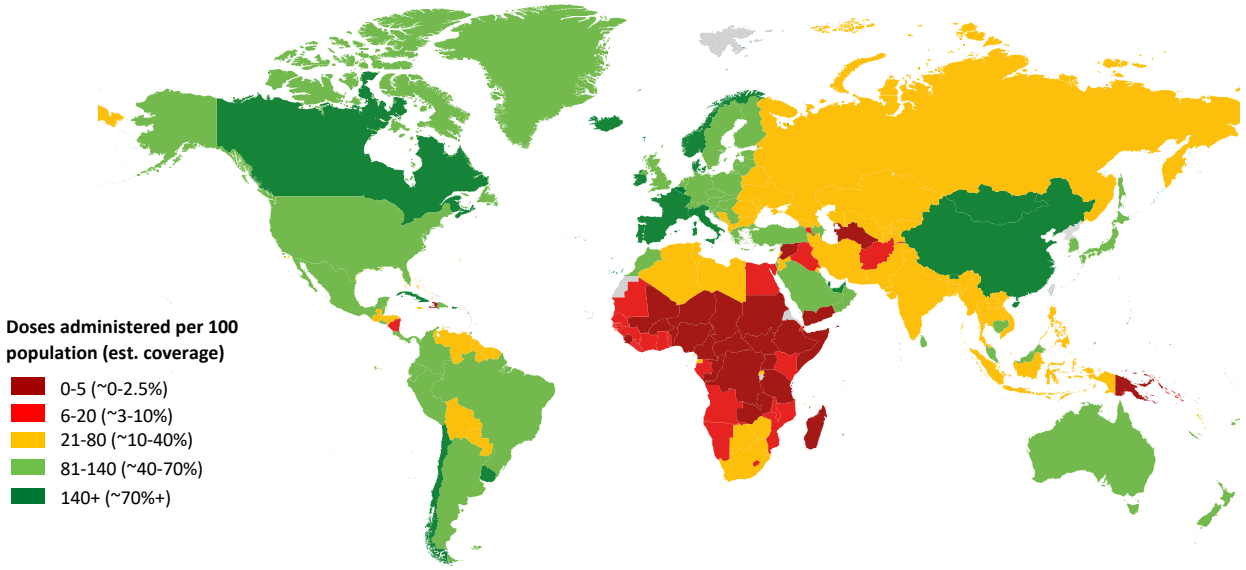
Inequitable access to COVID-19 tools has created a 2-track pandemic.

But too few countries have access to these COVID-19 tools. For example, of the nearly 6.6 billion doses of COVID-19 vaccine administered globally by mid October 2021[7], the vast majority (75%) have been administered in high-and upper-middle income countries (see Fig. 1.1), while only a small fraction (0.5%) have been administered in low-income countries. Vaccination coverage ranges from 1% to over 70%, largely depending on a country's wealth.[8]

Similarly, of the more than 3.5 billion tests reported globally as of October 2021, only 0.4% were performed in low-income countries. The daily testing rate (number of tests per 100,000 population) in high-income countries is more than 55 times the daily testing rate in low-income countries (see Fig. 1.1).[9]

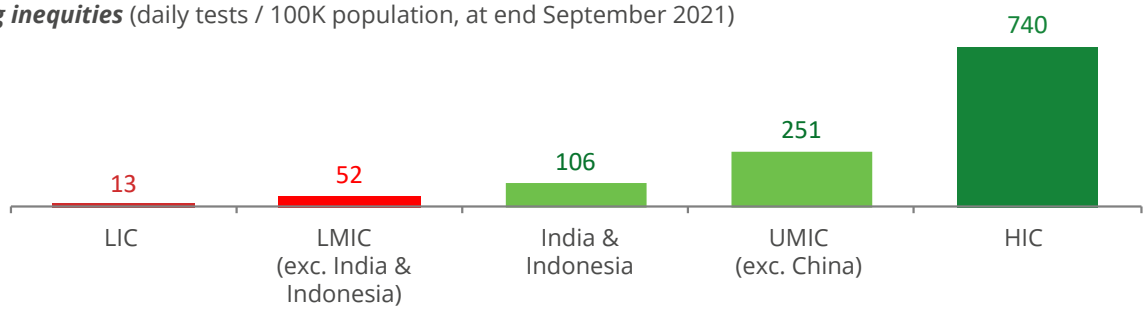
Fig.1.1. *Inequities in access to vaccines and tests*

Vaccine inequities (total vaccine doses administered per 100 population, as of mid-October 2021)



Note: Assumes 2 doses per fully vaccinated person;
Source: *WHO Coronavirus (COVID-19) Dashboard, accessed 11 October 2021*

Testing inequities (daily tests / 100K population, at end September 2021)



Source: FIND SARS-COV-2 TEST TRACKER, accessed 6 October 2021

[7] WHO Coronavirus (COVID-19) Dashboard. Geneva: World Health Organisation (https://covid19.who.int/, accessed 13 October 2021).
[8] Strategy to Achieve Global Covid-19 Vaccination by mid-2022. Geneva: World Health Organisation; October 2021. (https://reliefweb.int/sites/reliefweb.int/files/resources/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf, accessed 13 October 2021).
[9] COVID-19 Test Tracker. FIND, 2021 (https://www.finddx.org/covid-19/test-tracker/, accessed 6 October 2021).

Because of this inequitable access to COVID-19 tools, the world is experiencing a two-track pandemic, with different geographies, countries and populations - especially the unprotected, untested, and unvaccinated - experiencing dramatically different health, economic and societal impacts.

In short, where vaccination coverage is high, morbidity and mortality from COVID-19 is significantly reduced and infection rates are no longer closely correlated with hospitalization or death rates. Where vaccination coverage is low, recurring new or repeated waves of disease continue to overwhelm hospitals, and scarce supplies of life-saving oxygen, treatments and PPE are rapidly depleted.

COVID-19 will be with us for the foreseeable future

Vaccines are a powerful weapon against COVID-19. But in the face of continued SARS-CoV-2 transmission we still need to deploy the full suite of COVID-19 tools (including, tests, treatments, PPE and other public health and social measures) to save lives, protect the vulnerable, reduce the risk of new variants, and enable economic and societal recovery.

SARS-CoV-2 is still spreading at a very high rate around the world (oscillating between 2.5 and 5.5 million new cases per week)[10] and the pandemic is very dynamic. While currently available vaccines have been able to reduce morbidity and mortality from COVID-19, they have not been able to completely stop transmission. Given the high reproduction rate of the Delta variant, many experts believe that countries will not be able to achieve herd immunity, even if 100% vaccination coverage was feasible.[11] Countries may therefore continue to experience repeated waves of SARS-CoV-2 virus into 2022 and beyond among unprotected individuals. The frequency and magnitude of these waves will be a function of the level of population immunity achieved, either from vaccination or natural infection; the use of public health and social measures implemented; and the characteristics and transmissibility of new variants.

Sustained transmission will also lead to further evolution in the SARS-CoV-2 virus. If this gives rise to even more transmissible variants, more 'Delta-like' surges should be expected, even in countries with high vaccination coverage. If this evolution gives rise to variants with properties of immune escape, new versions of the current set of COVID-19 vaccines, tests and treatments will need to be developed to ensure their continued efficacy.

Vaccination alone will not be enough to end the pandemic, which is why it is critical that while vaccination coverage is increased around the world, countries continue to apply the full suite of COVID-19 countermeasures (including tests, treatments, PPE and public health and social measures) to reduce the spread of the virus, save lives, protect the vulnerable, reduce the risk of new variants, and enable full economic and societal recovery.

[10] WHO Coronavirus (COVID-19) Dashboard. Geneva: World Health Organisation (https://covid19.who.int/, accessed 13 October 2021).
[11] Campbell F et al. Increased transmissibility and global spread of SARS-CoV-2 variants of concern as at June 2021. Euro Surveill; 2021;26(24):pii=2100509

A globally coordinated effort is crucial for solving the escalating inequity in access to all COVID-19 tools

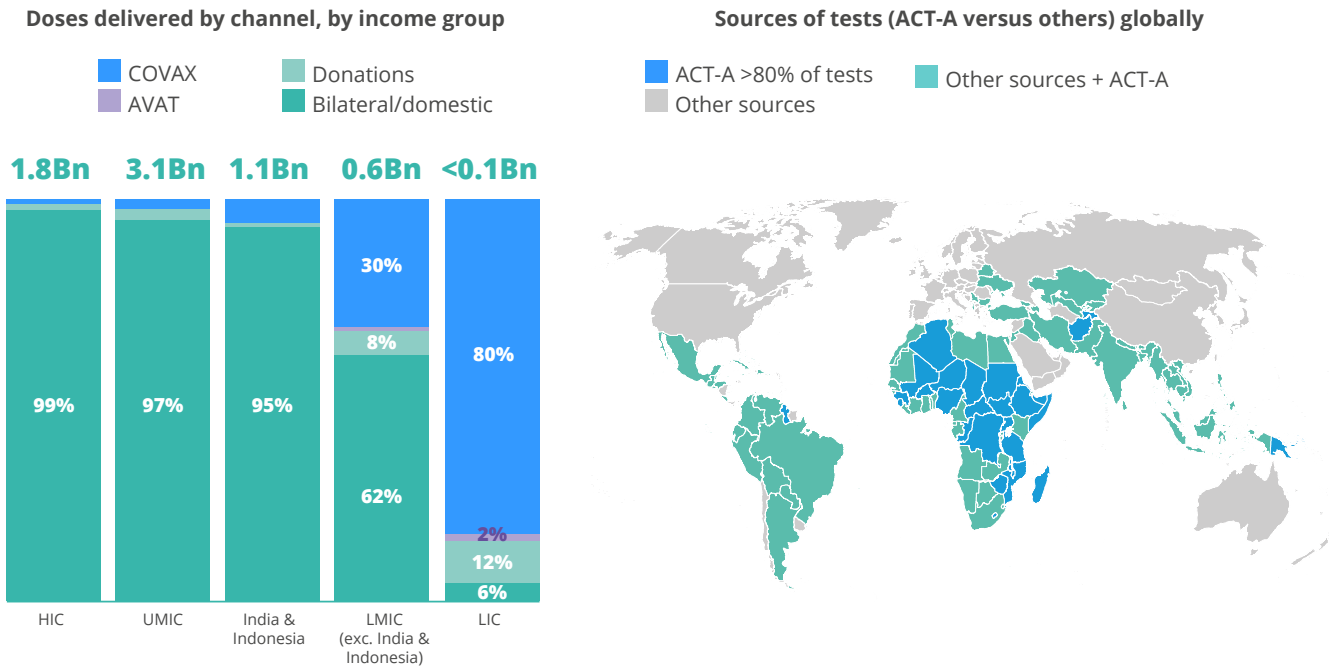
Against this backdrop, ACT'As operating environment has changed dramatically. Market forces, geopolitical interests and national trade decisions are now influencing the local availability of COVID-19 tools. And there has also been a proliferation of important global and regional initiatives, particularly the African Vaccines Acquisition Trust (AVAT) and Quad Vaccine Partnership.12

Civil Society and Community Organizations (CSCOs) have significantly contributed to enhancing access to COVID-19 tools and are now key players in the COVID-19 tools delivery ecosystem. Increased coordination and engagement with the private sector is also needed, building on the essential role it played in driving many of the scientific breakthroughs that led to the discovery and scaling of COVID-19 tools.

This added ecosystem complexity brings major coherence and coordination challenges, but also important opportunities. Going forward, ACT-A must sharpen its role, focusing where gaps in access to COVID-19 tools persist, especially in LICs, LMICs and other underserved areas, where ACTA's support has proven to be essential (see Fig. 1.2).

Political momentum in support of the overall equitable access to COVID-19 tools agenda and work of ACT-A is growing. On 6 September 2021, G20 Health Ministers reinforced the critical role of ACT-A in deploying the full arsenal of COVID-19 tools, and the need for more open, resilient, diversified and reliable global supply chains to sustain access to these tools. The US-hosted COVID-19 Summit held on 22 September 2021 during the 76th UN General Assembly galvanized new political support for equitable access to COVID-19 tools, emphasizing the targets that anchor the global response and ACT-A's work for the next 12 months.

Fig. 1.2. *Crucial role of ACT-A in ensuring equitable roll-out of tools in underserved areas*



Source: WHO Coronavirus (COVID-19) Dashboard, FIND SARS-COV-2 TEST TRACKER, accessed 6 October 2021

[12] Fact Sheet: Quad Summit. United States: The White House [statement], March 2021 (https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/12/fact-sheet-quad-summit/, accessed 16 October 2021)

2

THE ACT-ACCELERATOR'S FOCUS & STRATEGIC PRIORITIES FOR THE NEXT 12 MONTHS

ACT-A's new overarching objective is to resolve growing inequities in access to essential COVID-19 tools, with five new strategic priorities focusing on: tracking gaps and barriers to access; contributing to closing global gaps in access to vaccines, tests, treatments and PPE; and fully integrating Pillar delivery support with national COVID-19 response mechanisms. Major shifts in ACT-A's ways of working include: ensuring its work is more driven by country needs; intensifying a more results-based, target-driven approach; and closely aligning its efforts with other actors and initiatives focused on resolving inequities in access to COVID-19 tools.

The overarching objective for ACT-A for the next 12 months

Anchored in its original aims of accelerating the development and equitable delivery of COVID-19 tools globally, and taking into account the current context and state of the pandemic, ACT-A will shift its focus from being *the* global solution for equitable allocation of COVID-19 tools to **addressing growing inequities in access to COVID-19 tools** for underserved countries and areas. Building on its unique structure – as the only global, integrated, end-to-end platform for developing, scaling access and delivering vaccines, tests, treatments and PPE – ACT-A will sharpen its focus on supporting countries in achieving national coverage objectives and in closing gaps in access to COVID-19 tools, especially in countries that are not on track to meet the global coverage targets to achieve an end to the acute phase of the pandemic.[13]

Sharpening ACT-A's strategic priorities to solve the escalating inequity

To achieve its overarching objective, ACT-A will work towards **5 new strategic priorities** (see Fig 2.1).

The first strategic priority is to **closely track overall gaps and crucial barriers to accessing Vaccines, Tests, Treatments and PPE** especially in LICs, LMICs and lagging Upper Middle-Income Countries (UMICs) to ensure ACT-A's work is focused whereit is needed most. All sources of support for access to COVID-19 tools, whether channeled through ACT-A or through other global, bilateral, and regional initiatives, as well as domestic resources, will be accounted for as part of this effort (see Section 4 for further details). Strategic priority 1 is considered an 'enabling' priority as it will draw from and inform the work of all ACT-A Pillars.

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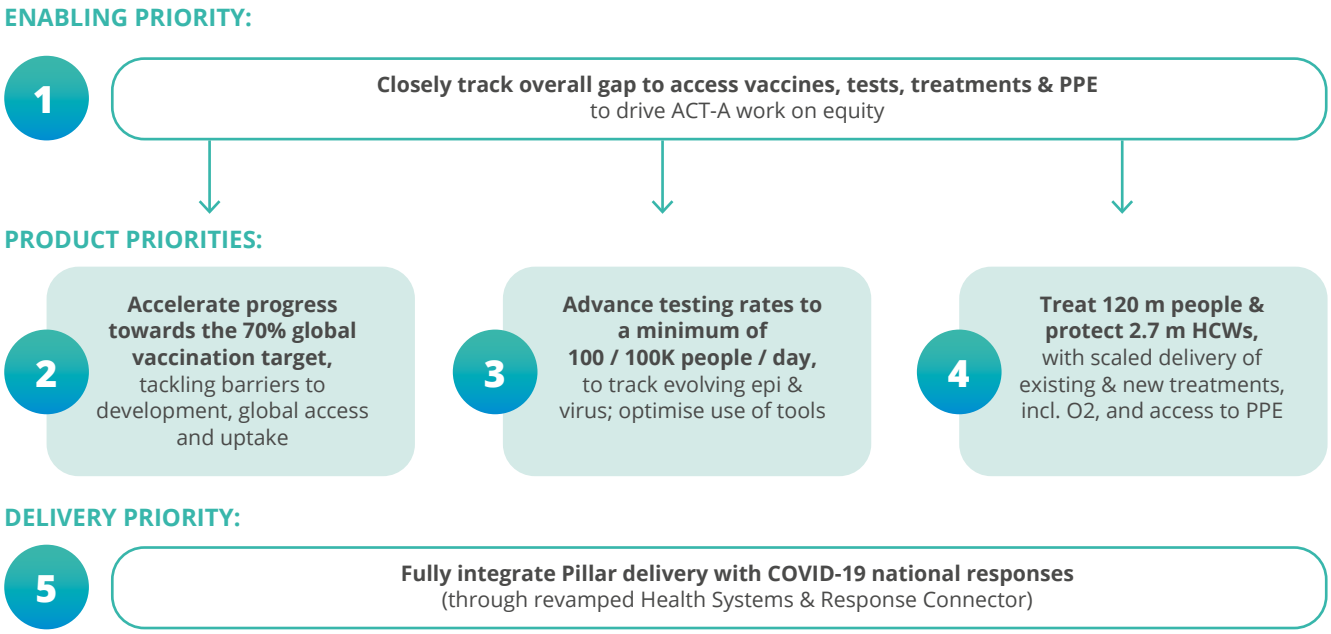
[13] See Section 5 for more details on global targets for access to COVID-19 tools and ACT-A's contribution to them.

Fig. 2.1. ACT-A's strategic priorities for October 2021 to September 2022



In order to achieve its new objective of addressing the escalating inequity in access to tools, ACT-A will...

- **focus on its areas of unique value-add**, which would otherwise not happen without ACT-A's collective action
- **adopt a target-driven approach**, aiming to accelerate progress toward the global targets by contributing where there are the greatest needs
- **generate transparency, accounting for existing mechanisms**, to fill in the gaps in knowledge and focus where access is most limited
- **ensure fair and balanced representation of countrie**s in its strategic and operational work, and
- **act as an enabler of the COVID-19 response** at global, regional and country levels.

Strategic priorities 2, 3 and 4 are 'product' priorities, focused on closing the substantial gaps towards the global targets for vaccines, tests, treatments and PPE, taking into account countries' needs, capacities and preferences.

For vaccines, ACT-A will support countries in achieving their coverage ambitions, **accelerating progress towards the 70% global vaccination target** (see Section 3.1). For tests, ACT-A will help lagging countries **advance testing rates to a minimum of 100 tests per 100,000 inhabitants per day** (see Section 3.2).

Strategic priority 4 is focused on **saving 120 million lives and protecting 2.7 million health workers** in the face of sustained SARS-CoV-2 transmission, in LICs, LMICs and key UMICs. Under this strategic priority, ACT-A will focus on helping underserved countries close gaps in equitable access to new and existing COVID-19 treatments, including medical oxygen (see Section 3.3) and personal protective equipment (PPE) (see Section 3.4).

Strategic priority 5, is a 'delivery' priority and seeks to ensure that **ACT-A's Pillar delivery support is fully integrated with national COVID-19 response mechanisms**. Through the revamped Health Systems & Response Connector, ACT-A will ensure that delivery support feeds into and enables wider response efforts, and that it interfaces more seamlessly with countries and their health systems (see Section 3.4).

Honing ACT-A's ways of working to deliver these new strategic priorities

In order to deliver on its overarching objective and new strategic priorities, and taking into account recommendations provided through the *ACT-Accelerator Strategic Review*, ACT-A will adjust its ways of working in three ways:

1. **ACT-A's work will be more explicitly driven by country and community needs and by a deeper understanding of access gaps.** Increased focus will be given, in ACT-A's upstream work, to product optimization and to ensuring product specifications take into account country needs, capacities and preferences. Increased focus will also be given in ACT-A's downstream work to support in-country uptake of all COVID-19 tools and to the resolution of critical access gaps, especially in underserved countries and areas.

2. **ACT-A will intensify a more outcome-based, target-driven approach.** This will be reflected in ACT-A's workplans and budgets, in its collective advocacy and resource mobilization narratives, and in its regular (i.e., quarterly) reporting. ACT-A's contribution to global targets on access to COVID-19 tools will also be measured and accounted for as part of wider monitoring of progress in meeting those global targets (see Section 4).

3. **ACT-A will more closely align its efforts with other actors/initiatives focused on resolving inequities in access to COVID-19 tools**. Ensuring timely access to COVID-19 tools globally, particularly in LICs and LMICs, requires the coordinated action of multiple stakeholders across sectors: governments, multilateral organisations, CSCOs, and the private sector. ACT-A will further strengthen coordination with global and regional entities (such as AVAT, the Quad). ACT-A will also deepen its engagement with key multi-stakeholder initiatives, for example via the Facilitation Council and the *Multilateral Leaders Taskforce* on scaling COVID-19 tools, which provide access to constituencies with the power to resolve trade, financial, and political issues affecting access to COVID-19 tools.

   ACT-A will, in addition, further strengthen its support and coordinate its outreach to the private sector, across vaccines, tests, treatments and PPE. It will leverage industry knowledge and capacity in its strategic discussions and operations, to accelerate regulatory pathways, demand forecasting, procurement and supply planning, trade facilitation, and monitoring. ACT-A will also deepen its relationships with CSCOs, and leverage their work to ensure greater impact from the roll-out of tools in countries and communities.

More details on how the main recommendations of the ACT-Accelerator Strategic Review are being taken forward are provided in Annex 1 of this document. As these recommendations are implemented, ACT-A will continue to update and refine its processes and ways of working, drawing on the findings of the review, lessons learned, and ongoing feedback from the ACT-A Council, recipient countries, and other stakeholders.

3

PILLAR CONTRIBUTIONS TO CLOSING GLOBAL GAPS IN ACCESS TO COVID-19 TOOLS

This section provides an overview of each Pillar's specific contributions to ACT-A's overall objective and strategic priorities. Each sub-section includes a description of the current context relative to that Pillar's work as well as Pillar-specific priorities, targets and activities. Major deliverables/milestones over the next 12 months and a summary of achievements from 2021 are also provided. Finally, as a cross cutting area of work, activities focused on ensuring equitable access and allocation are highlighted.

ACT-A Vaccines Target: Support countries' individual goals and solutions in light of the global vaccination target of 70% coverage in AMC91

3.1 Vaccines

Co-convened by CEPI, GAVI, UNICEF and WHO

COVAX, ACT-A's vaccines pillar, has an overall goal to accelerate the end of the acute phase of the COVID-19 pandemic by the end of 2021 and to support countries' needs and own goals to control the disease and reopen society in 2022 and beyond, contributing towards the 70% global vaccination target in 2022.

Context. Although more than 6.8 billion doses of COVID-19 vaccine had already been administered by mid-October 2021, and global production is now reaching 1.5 billion doses per month, the world is not well-positioned to end the pandemic in the near term. In areas of high vaccination coverage, there have been large reductions in serious disease, hospitalization and death. However, vaccine access is highly inequitable with coverage ranging from 1% to over 70%, depending largely on a country's wealth. Ongoing inequitable access raises the real risk that further SARS-CoV-2 variants emerge, causing surges of disease and slowing or even reversing the reopening of societies and economies, whatever their current vaccination status.

Shifts since April 2020. Multiple major shifts in the context of vaccines have occurred since the establishment of COVAX in April 2020. First, although a number of COVID-19 vaccines have been authorized for use since the beginning of 2021, the emergence of variants and move to provide boosters has continued to shift the operating landscape COVAX is delivering within. Second, while COVAX remains the only global procurement and delivery mechanism, it is now complemented by other regional and bilateral approaches. Third, although the largest scale-up of vaccine manufacturing in history is gaining pace, it remains fragile and susceptible to export restrictions and regulatory, manufacturing and shipment delays. Finally, in-country delivery is being tested, with some countries facing challenges ranging from service delivery to cold chain equipment, knowledge management, monitoring and surveillance, and vaccine hesitancy.

Vaccine access is highly inequitable with coverage ranging from 1% to over 70%, depending largely on a country's wealth

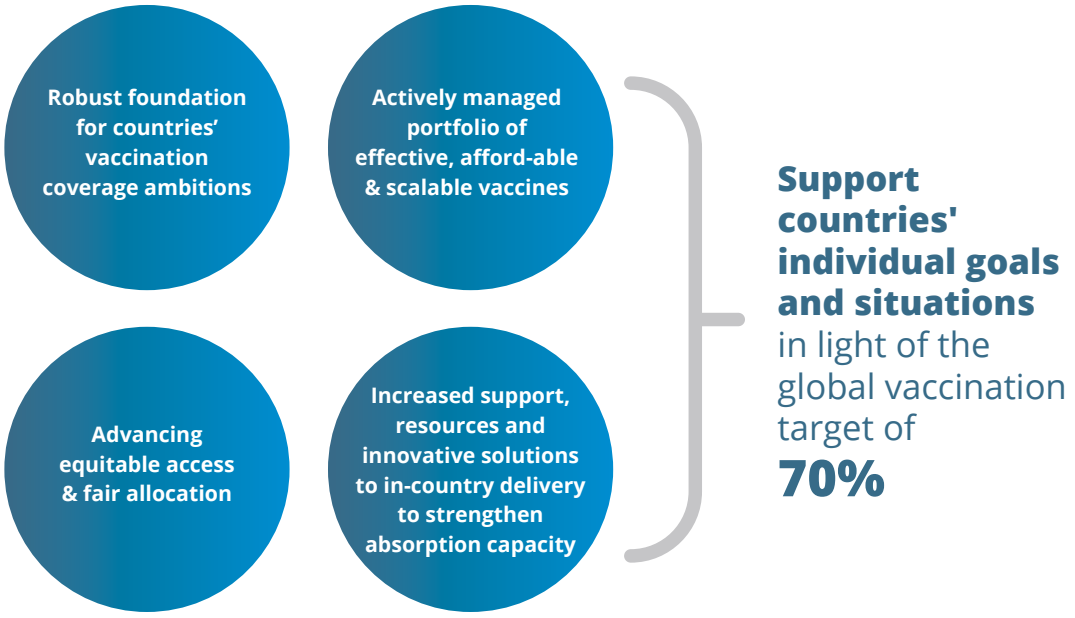
Setting a target. In 2022, in line with the global target set by the WHO, the world aims to achieve an average vaccination coverage of 70% in all countries. Around 5 billion doses still need to be administered to achieve this goal. Each country is setting its own vaccination coverage target depending on its specific context, notably demographic and economic structure. COVAX is committed to supporting countries in reaching their vaccination ambitions, without disrupting routine immunisation activities.

COVAX has a central role in addressing supply uncertainty and skewed distribution, especially for AMC countries. Current pledges of US$ 10 billion to the COVAX AMC, alongside signed cost sharing agreements, and confirmed dose donations, will allow AMC91 countries to achieve c. 43% coverage. Additional donations and dose contributions to COVAX of up to 800 million doses have also been pledged (although these are still being confirmed). According to published data, there is additional coverage of 7-8% from non-COVAX sources to date, including bilateral dose donations.[14] Finally, COVAX will aim to provide a further vital contribution to support AMC91 countries in meeting their targets by securing an additional 600 million doses for supply, which will complement other sources and manage the downside risk that additional doses are needed to provide effective immunity.

Delivery of COVAX funded doses will be supported by stronger global and regional coordination and through catalytic investments into critical areas such as cold chain, human resources, programme management and vaccine hesitancy.

COVAX priorities. In support of the coverage objective, COVAX will deliver against four strategic priorities:

Fig. 3.1. *COVAX – Oct'21-Sept'22 strategy at a glance*



[14] WHO Coronavirus (COVID-19) Dashboard. Geneva: World Health Organisation (https://covid19.who.int/, accessed 3 October 2021).

Pillar priorities & activities. The activities that will deliver the priorities of the Vaccines Pillar for the period October 2021 to September 2022 are displayed in the table below. This work feeds into **ACT-A's strategic priority #2**.

Vaccines priorities and associated activities

1. Continue to build a robust foundation for countries' vaccination coverage ambitions, by pooling demand, supply & resources, complemented by other procurement mechanisms

- Implement an updated country participation model, with a focus on AMC countries while offering SFPs the opportunity to procure future doses and participate beyond procurement
- Continue to support countries in achieving their vaccination coverage targets, through Advance Purchase Agreement doses and dose donations (alongside other sources of supply)
- Aspire to provide AMC countries at least 600 million doses, in addition to already secured supply
- Sustain a robust and diverse portfolio, able to absorb shocks and respond to preferences

2. Support a portfolio and pipeline of effective, affordable and scalable vaccines in the context of variants, boosters, sustained transmission and emerging platform preferences, ensuring sustained and early access to new vaccines, shaping the market for the long term

- Support investments in the development of improved product characteristics preferred by AMC92 and support tech transfer and manufacturing scale-up via maintenance of a supply marketplace and, if capacity and resources are available, the establishment of sustainable manufacturing capacity in regions lacking significant capacity, with support to overcome IP barriers where needed
- Continue engagement with countries and manufacturers on market-shaping to support the development of a healthy market and affordably priced vaccines
- Tackle evidence generation more systematically when there are meaningful differences between HICs and L(M)ICs and when interventions could prevent and control disease, and to manage future risk of additional variants

3. Advance equitable access and fair allocation, evolving the mechanism to take into account prior vaccination levels and dynamic alignment of supply with country absorptive capacity, to support countries in their overall coverage ambitions

- Evolve the allocation mechanisms to take into account additional elements for allocation of supply, reflecting boundary conditions (e.g., total population coverage accounting from all sources of supply and absorptive capacity)
- Be the global mechanism to address coverage inequity, supporting countries to achieve their own coverage ambitions, and actively promoting access to those most at risk of being left behind, including, within countries, to marginalised and underserved populations
- Create the evidence-base to steer donations towards participants with highest gaps in vaccination coverage, while also advocating for COVAX to be prioritised in production queues

4. Offer increased support, resources, and innovative solutions to in-country delivery to strengthen absorption capacity, while minimizing risks to routine immunization and other essential health services

- Real-time identification of bottlenecks based on absorption rates and more targeted and streamlined support to scale-up delivery, especially in high priority countries
- Improve coordination of technical partners and funders to help prioritise technical support (including health and community systems strengthening), funding and advocacy
- Proactively engage and collaborate with other bodies that support the delivery of vaccines (e.g., AU/WB/PAHO)
- Advocate for political leadership and commitment, as well as for operational funding and technical support
- Support efforts in closing the immediate and long-term funding delivery gap, both through direct funding support to countries and facilitation of access to other funding routes, recognizing that COVAX will be one of several partners
- Support the integration of COVID-19 vaccination into existing immunizations programs and capitalization of the range of investments that have been done that can be leveraged in the broader immunization agenda

Major Vx milestones over the next 12 months

- By April 2022: Generate clinical evidence for expanded and optimized use of available vaccines, including for 3rd dose strategies, with a focus on LMIC use, and consistent with the Charter for Equitable Access to COVID-19 Tools
- Invest in next generation vaccines with optimized profiles, including those with potential to mitigate impact of future variants of concern. First interim efficacy results from second generation portfolio expected by Q1 2022
- Dec 2021: Allocate all available doses including the 1.4 billion doses currently forecasted to be available to the AMC92 by the end of 2021 per the September COVAX Facility supply forecast[15]
- Focus on supporting low-income countries, which are currently receiving fewer than one in seven of non-COVAX supplied doses – and 27 of the AMC91 have no non-COVAX supply
- Provide additional COVAX delivery funding as part of a coordinated COVAX effort to continue to support countries to scale-up delivery and mitigate key risks to routine immunisation and other essential health services, with a focus on countries without sufficient other sources of external financing

[15] COVAX supply forecast; 8 September 2021. Geneva: COVAX; 2021 (https://www.gavi.org/sites/default/files/covid/covax/COVAXSupply-Forecast.pdf, accessed 3 October 2021).

Box 3.1. *Major achievements to September 2021 for COVAX, the Vaccines Pillar*

425 Mn doses

So far, COVAX has shipped 425 million vaccines to **144** participants; 338 million of these vaccines went to 86 AMC countries

12.3 Bn

So far, COVAX has been able to raise **>$12.3B** for across the value chain to date

13 vaccines

R&D support enabled access to a portfolio of **13** vaccines/candidates across **4+** technology platforms

Innovative mechanisms

Tackled need to harmonize and revamp procurement terms (model I&L) and established the COVAX No Fault Compensation scheme for AMC. Introduced first EULs for vaccines and the COVAX Humanitarian Buffer

38 days

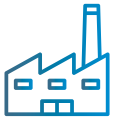
COVAX made it possible for the first international vaccine deliveries in lower income countries to take place within **38** days from introduction in the first few high-income countries (HICs)

405 Mn doses

The fair and equitable allocation mechanism was established across partners over 2-3 months and ready in time and has to-date allocated **>405** million vaccines to 139 participants

>100 countries

COVAX assessed and supported the roll-out planning process in **>100** countries with the development of National Deployment and Vaccination Plans



Manufacturing Taskforce

Ensured the sufficient ramp-up of manufacturing capacity, establishing the COVAX Marketplace for critical input supplies, and planning for regional manufacturing hubs

ACT-A Diagnostics Target:
100 tests / 100K individuals / day in LICs, LMICs & lagging UMICs

3.2 Diagnostics

Co-convened by FIND and The Global Fund, with WHO

The Diagnostics Pillar has an overall objective to significantly increase access to COVID-19 tests and sequencing, which will ensure effective test, trace, isolate, and treat strategies, as well as early identification and containment of new variants.

Context. The rapid development and roll-out of SARS-CoV-2 tests has proven critical to global surveillance, public health measures, and clinical care. Unparalleled innovation in the development of diagnostic tools led to 28 WHO emergency use listed tests[16], the commercialisation of hundreds more PCR kits and rapid tests, and expanded use of genomic sequencing to detect SARS-CoV-2 variants on a global basis. Many countries have been able to identify surges and limit transmission through widespread use of tests coupled with public health interventions. Test-trace-and-isolate strategies and test-and-treat strategies have supported public health containment and swiftly identified patients to link to early oxygen therapy and effective treatments as they became available, saving thousands of lives. However, testing inequity has been massive: of the more than 3 billion tests reported across the world, only 0.4% of these have been performed in LICs. Across LICs, LMICs and lagging UMICs, testing rates are not much better, ranging from <1% to 10% of testing rates in wealthy countries, due to lack of funding, diagnostic access, and infrastructure. Poor access to tests and sequencing data perpetuates transmission, leaves us blind to the extent of the pandemic in many countries, and hampers our ability to identify and respond to variants as they arise. And yet, with limited vaccine supply through 2022, persistent vaccine hesitancy, and the continued threat of emerging variants, testing linked to treatment and public health measures is the primary line of defence against COVID-19 in many LICs and LMICs.

Of the >3 Bn tests reported across the world, only 0.4% of these have been performed in LICs

Setting a target. High-income countries test for COVID-19 at rates approaching 750 tests per 100,000 individuals per day, while rates across most LICs and LMICs are routinely <50 tests per 100,000 per day[17]. Over the next 12 months, the ACT Diagnostics Pillar will support the procurement of 988 million tests to advance testing rates to a minimum of **100 tests per 100,000 individuals per day**[18] **in LICs, LMICs, and UMICs — well below the test rates of HICs, but a critical threshold to ensure effective public health interventions**.

Diagnostics Pillar priorities. In order to achieve equitable access to testing linked to public health interventions by September 2022, the Diagnostics Pillar aims to deliver on critical priorities in LICs, LMICs and UMICs: to **increase availability of effective and affordable tools**, to **update testing strategies and ensure optimal use of tools in countries**, to **strengthen capacity for countries to test including supporting novel methodologies**

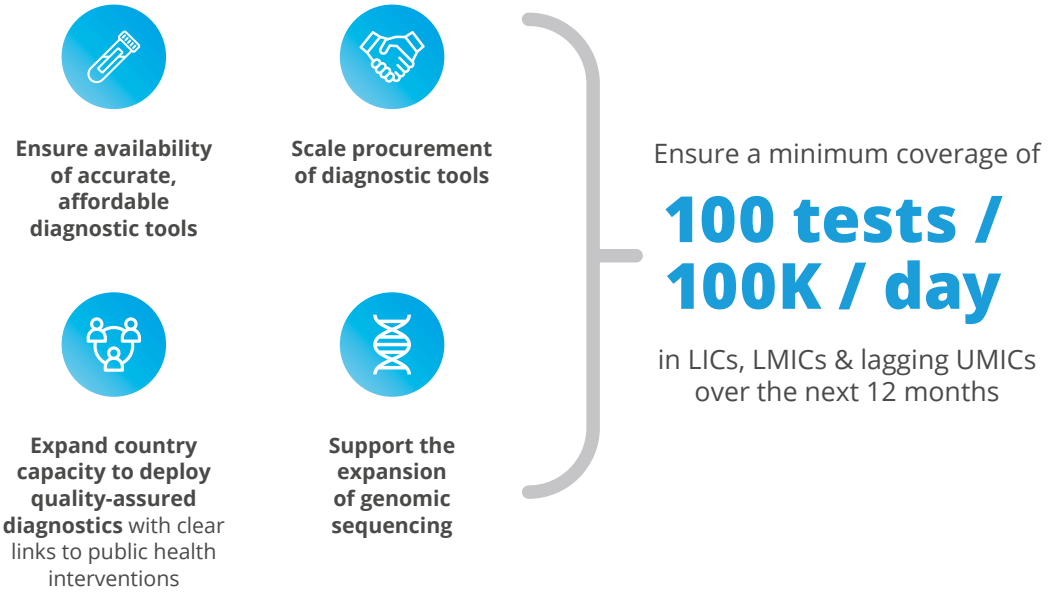
[16] WHO EUL for IVDs detecting SARS-CoV-2. IVDs for SARS-CoV-2 under assessment for Emergency Use Listing. Geneva: World Health Organisation, 2021 (https://extranet.who.int/pqweb/sites/default/files/documents/211012_IVDs_SARS-CoV-2_Assessment_EUL.pdf; 13 October 2021).
[17] WHO COVID-19 dashboard average daily testing rates per 100 K population; LIC:13, LMIC excl. India: 52, India:125, UMIC:206 & HIC:740
[18] The target of 100 tests per 100,000 individuals per day is the 40th percentile of current global testing rates

such as decentralized community-based testing and self-testing, and to **expand genomic surveillance programmes**, including strengthening the integration of epidemiological and genomic data.

Major shifts in Dx Pillar focus. An urgent step change in the use of diagnostics is needed to narrow the global equity gap. This will require strengthening existing testing models, while **implementing new, decentralized, community-based testing models**. In parallel, genomic sequencing efforts need to be expanded significantly to support wider surveillance efforts for new SARS-CoV-2 variants. Upstream emphasis must be put on tests for new variants and to differentiate SARS-CoV-2 from other respiratory pathogens, and to support manufacturers in submitting high-quality dossiers for EUL approval, so the number of approved products increases and competitive prices are further reduced. ACT-A estimates the need to deliver more than 980 million molecular and rapid antigen tests in the next 12 months in LICs, LMICs, and UMICs to support an adequate public health response to the pandemic as it continues to evolve. Expanded diagnostic testing will also require strengthening existing molecular testing infrastructure, including both laboratory and health systems, which have been significantly underfunded and are facing unsustainable pressures.

Dx Pillar priorities & activities. Against this context and shift in focus, the activities that will deliver the priorities of the Diagnostics Pillar for the period October 2021 to September 2022 are displayed in the table below. This work feeds into **ACT-A's strategic priority #3**.

Fig.3.2. *Diagnostics Pillar – Oct'21-Sept'22 strategy at a glance*



Diagnostics priorities and associated activities

1. Ensure availability of accurate, affordable diagnostic tools through expanded local manufacturing and support for market entry

- Invest in expanded local manufacturing capacity to bring 3 additional accurate, affordable, multi-pathogen molecular tests to market
- Ensure diagnostic tests remain accurate against known and emerging variants
- Diversify supply by supporting emergency use listing of additional tests and deploying priority market shaping interventions to support expanded access

2. Scale procurement of diagnostic tools based on policy and the evolving evidence of their optimal use

- Support the procurement and optimal use of 988 M diagnostic tools, including molecular and Ag RDT tests
- Support procurement to enhance genomic sequencing capacity and surveillance efforts

3. Expand capacity for countries to deploy quality-assured diagnostic tools throughout the health system and increase community-based testing with clear link to public health interventions

- Support generation of evidence for expanding use cases for testing and setting testing policies and strategies, including the use of digital tools
- Invest in workforce development (i.e., lab staff, HCWs, CHWs, etc.) required to expand community-based testing programs
- Facilitate in country technical and operational assistance to expand decentralized community-based testing, including self-testing, and strengthen the link between testing and treatment
- Enhance testing through advocacy, communication, and community engagement efforts underpinned by local context and behavioral research insights

4. Support the expansion of genomic sequencing, including strengthening the integration of epidemiological and genomic data for public health action

- Support national, regional, and global efforts to expand genomic sequencing capacity and sustainability by building on in-country policies, laboratory and digital infrastructure

Major Dx milestones over the next 12 months

- Support the development and market entrance of 3 accurate, affordable, multi-pathogen, point-of-care molecular tests for COVID-19 and other respiratory pathogens by October 2022
- Ensure a minimum of 4 additional COVID-19 tests meet the requirements to receive Emergency Use Listing by October 2022
- Support the pre-requisite technical assistance, laboratory strengthening, training, and advocacy efforts required to enable all countries reach minimum testing target of 100 tests /100k / day over the next year, notably through expanded community use of Ag RDTs
- Enable expansion of genomic sequencing capacity and regular reporting of SARS-CoV-2 genetic sequence data to reach at least 75% of countries on a monthly basis

Box 3.2. *Major achievements and key challenges to Sept 2021 for the Diagnostics Pillar*

R&D and product assessment

Market shaping & manufacturing

Procurement

Demand generation & in-country delivery

Major achievements to date:

- 90+ diagnostic tests assessed against quality benchmarks to inform regulation and country procurement
- EUL approval of 28 diagnostic tools

- Invested in expanded manufacturing capacity of 4 diagnostics tests to enable regional diversification
- Further price reductions for select molecular products including Cepheid Xpert Xpress SARS-CoV-2 assay with price of $14.90 from $19.80
- Reduced Ag RDT prices to $3 or less

- Procured 128+ million diagnostic tools to date[19] through collaborative Dx Consortium
- $634Mn in funding for diagnostic tools deployed through Global Fund's C19RM

- $50Mn in funding awarded to expand work in LMICs and enhance uptake of COVID-19 tools and link to effective treatment via joint FIND/ Unitaid RFP
- $90M in funding to support roll-out of diagnostics tools via Global Fund's COVID-19 Response Mechanism
- Collaborated on mapping global sequencing capacity in order to direct future partner activities and investment
- Trained 42,200+ health care workers in nearly 200 countries
- Launched regional round-table series to increase bi-directional communication with countries & partners
- Published report quantifying impact of Ag RDT testing strategies in various settings & use cases
- Supported development of 5 Ag RDT data collection applications

Key challenges:

- Regulatory approval delays

- Challenges in manufacturing & supply with limited local manufacturing

- Challenges in supply chain and customs clearance
- Limited international and national funding
- High pricing of tools and shipping costs

- Variable perceptions of importance / utility leading to lack of prioritization by national governments
- In-country governance and financing structures
- Insufficient laboratory capacity, human resources, and data management
- Lack of or insufficient national testing strategies and case definitions

For more information, refer to the forthcoming ACT-A Q3 update (to be published in October 2021).

[19] 40 M molecular tests, 68 M Ag RDTs, and 20 M sample collection kits

ACT-A Therapeutics Target:
~120 Mn
cases treated in LICs, LMICs & UMICs

3.3 Therapeutics

Co-convened by Unitaid and Wellcome, with WHO

The Therapeutics Pillar supports access to safe and effective therapeutics of assured quality to save millions of lives from COVID-19 and to minimise its global health and economic threat.

Context. With the challenges of an evolving pandemic and difficulty in large scale uptake of vaccines, therapeutics will remain critical in the COVID-19 response, saving lives and reducing the burden on health systems (see Section 1). Among existing options, medical oxygen and corticosteroids are mainstays of treatment for **severe and critical** COVID-19, along with recent additions to clinical guidelines. ACT-A is working to drive uptake of existing products and support equitable access to novel therapies for LICs and LMICs – despite challenges in supply, price, and implementation. To date, there have been few recommended therapeutics to treat **mild and moderate** cases in outpatient settings. But if proven effective, emerging oral outpatient drugs - deployed with tests -could fundamentally change the response. One example – subject to clinical review – could be the antiviral compound molnupiravir, for which promising interim results were recently announced. Effective oral outpatient drugs would offer a widespread, scalable way to stop disease progression, ease strain on health systems and reduce deaths.

Challenges in LIC/LMIC access to Tx due to limited treatment options, limited supply of effective products made available for LICs / LMICs, funding and prohibitively high prices in L/MICs

Setting a target. Approximately 200 million COVID-19 cases are expected globally in the next 12 months[20], with potential for increased case numbers due to new variants or continued transmission amongst the vaccinated[21]. The Therapeutics Pillar aims to treat **up to ~120 million[22] of these cases** (6-8 million severe and 113 million mild / moderate), **focusing on LICs, LMICs and UMICs**.

Therapeutics Pillar priorities: To achieve that target by September 2022, the Therapeutics Pillar will prioritize **deployment of existing effective products**, including medical oxygen for severe and critical cases, **introduction of new COVID-19 therapies** once proven, especially those with a profile conducive to access in LICs and LMICs, and **strengthening of research efforts** to enrich the therapeutic clinical pipeline. Alongside this, there will be a need to ensure country readiness for effective implementation of tools, including supporting a test-and-treat strategy for outpatient care in eligible patients.

Major shifts in Pillar focus: The Pillar focus will reflect emerging products, including – if proven effective – oral outpatient medicines, coupled with decentralized testing to inform their use. For emerging products, advanced preparation is needed to ensure adequate, timely supply across LICs, LMICs and UMICs. Building on the lessons from the last year, adequate infrastructure and mechanisms to support allocation will be critical to ensure that products are deployed where most needed. Work to identify those at highest risk will be needed. For outpatient treatments, test and treat approaches will be key to ensure timely detection and linkage to care, in order to treat patients who may benefit most, such as those in high-risk groups and healthcare workers.

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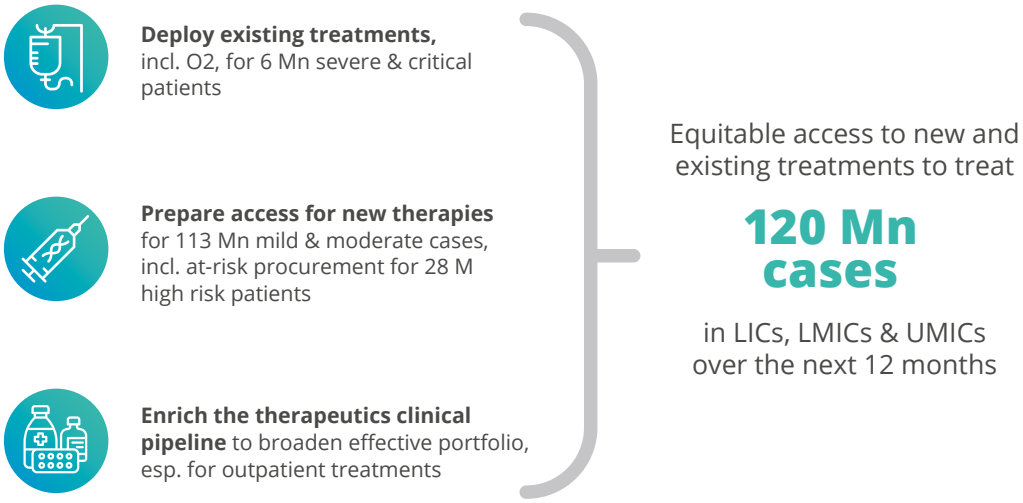
[20] Figures reflect current best estimate based on extrapolation of WHO ESFT 12-week estimates of COVID-19 cases per country to annual figures, and reducing by vaccination coverage assumptions as per COVAX target vaccination rates (70% by Q3'22); however, these will change as the disease epidemiology evolves, including potential emergence of variants or deviation in vaccine rollout.
[21] Surge budget mitigates risks associated with Delta variant, at 35% extra hospitalized cases when extrapolated to a year.
[22] All mild/moderate, and a subset of severe/critical in line with estimated cases treated via medical oxygen work packages described below.

Fig. 3.3. Therapeutics Pillar – Oct'21-Sep'22 strategy at a glance



Pillar priorities & activities. Against this context and shifts in focus, the activities that will deliver the priorities of the Therapeutics Pillar for the period October 2021 to September 2022 are tabulated below. This work feeds into **ACT-A's strategic priority #4**.

Therapeutics priorities and associated activities

1. Ensure the successful uptake of existing products for up to 6-8 million severe and critical patients, including medical oxygen, corticosteroids (such as dexamethasone) and other drugs in WHO guidelines, as available

- support and inform procurement of WHO recommended treatments including medical oxygen, related services & equipment
- support the repair, maintenance and scale up of local medical oxygen production, ensuring future sustainable supply
- provide visibility on country demand and mobilize resources to support adequate and timely supply of therapeutics
- support implementation of regulatory and policy guidance including uptake of clinical guidelines.

2. Enable access to new COVID-19 therapies for up to 113 million treatment courses for mild and moderate cases, including at-risk procurement for up to 28 million highest risk patients, subject to evidence, WHO recommendations and product availability

- support work such as voluntary licensing, technology transfers, diversification of supply base including local production as relevant, regulatory and policy processes, demand forecasting and dissemination of policy and regulatory guidance to accelerate the availability of safe and efficacious products
- utilize market interventions such as conditional awards or advanced purchase agreements to ensure timely availability of supply

- support country introduction, including demand generation and training, and coordinate procurement with regional partners such as Africa CDC and PAHO
- support procurement and country allocation for at-scale deployment of proven products as available, maintaining flexibility on procurement budgets across individual products to adapt to a changing clinical pipeline

3. Accelerate and intensify research efforts to enrich the clinical pipeline and broaden the portfolio of effective tools, especially for outpatient treatment, including combinations of therapeutics

- continue support for ongoing global platform trials, including the evidence generation infrastructure to accelerate data collection globally via 4-8 global platform trial arms in support of access to effective therapeutics in LICs, LMICs and UMICs
- provide funding for pre-clinical screening for global platform trials and support 1-4 promising novel antivirals further upstream (with focus on oral, outpatient products)

Access & Allocation work led by WHO will inform this priority by:

1. **Designing an allocation process and mechanism for Tx** in development to bridge the gaps in access
2. **Tailoring allocation for different therapeutics to target LICs and LMICs for expedited access**
3. **Implementing allocation process in coordination with agencies**
4. **Ensuring pricing is transparent and sustainable for countries with limited purchasing power**
5. **Developing a governance structure to manage allocations**
6. **Establishing reporting and accountability mechanisms for procurers**, particularly bilateral procurement activities, as needed

Major Tx milestones over the next 12 months

- Rapid inclusion of new COVID-19 treatments into WHO living guidelines when high-quality clinical data demonstrate efficacy
- Supply of oral outpatient drug secured by end of Nov 2021 through conditional award(s), subject to recommendations, quality assurance, and manufacturer submissions
- Support procurement of up to 28 million treatment courses for highest risk mild/moderate patients over the next 12 months, depending on product availability, clinical guidance, and volumes changing with evolution of needs
- Results from CTA-funded ReACT MMV, a South Africa-based Phase 2 exploratory study in mild patients by early 2022
- Address essential medical oxygen needs of 6-8 million severe and critical patients by September 2022
- Support delivery of 110-140 million cubic meters[23] to LICs, LMICs & UMICs by the end of 2021

[23] Informed by the work of the Oxygen taskforce, including estimates from the PATH oxygen needs tracker, which suggested that 10.8 cubic meters of oxygen were required per day across low- and middle-income countries.

Box 3.3. *Major achievements and key challenges to Sept 2021 for the Therapeutics Pillar*

R&D and product assessment

Market shaping & manufacturing

Procurement

Demand generation & in-country delivery

Major achievements to date:

- 3 new recommendations in WHO living guidelines inclusion for 2 therapeutics in past quarter
- Began support for development of one novel antiviral programme
- Solidarity PLUS trial expanded to researchers in over 600 hospitals in 52 countries to test 3 new drugs in hospitalized COVID-19 patients
- Signed MoUs with 2 multinational O2 suppliers to set up long-term programmes
- Issued invitations to manufacturers to submit expression of interest for prequalification for 2 products
- Procured US$ 467 Mn worth of medical oxygen supplies (as of Sept 17 '21)
- Oxygen assistance in India, Bangladesh & Zambia
- Advocacy for O2 through the Every Breath Counts coalition
- Work initiated in over 20 countries to support rapid, integrated adoption of diagnostics / therapeutics
- Training provided on clinical management of COVID-19 patients

Key challenges:

- Timely read-outs from robust and high-quality clinical trials
- Access challenges, esp. biologics & novel products: limited supply, affordability, access terms, licensing to enable supply for all LICs, LMICs and UMICs
- Links between Dx, Tx, and Vx strategies

For more information, refer to the forthcoming ACT-A Q3 update (to be published in October 2021).

Ensure all countries have the technical, operational and financial resources to translate new COVID-19 tools into effective health interventions

3.4 Health Systems & Response Connector

Co-Convened by The Global Fund, World Bank and WHO, with UNICEF

The Health Systems & Response Connector (HSRC) ensures all countries have the necessary technical, operational and financial resources to translate new COVID-19 tools into national response interventions to stop transmission save lives.

Context. To maximize the impact of the vaccines, diagnostics and therapeutics provided to help countries fight COVID-19, it is essential that country health systems, communities and health and care workers are supported in prioritizing their needs, securing financing and effectively translating tools into public health and clinical interventions to reduce transmission and saves lives.

This requires technical and operational assistance and the integration of specific initiatives into coherent national response plans. It also requires protecting the health system and the health work force.

Setting a target. The HSRC aims to help countries to: turn vaccines into well-prioritized vaccination campaigns; turn tests into effective test-and-treat approaches, community-based testing strategies to support public health measures, and the platform for disease surveillance; and deploy therapeutics into life-saving clinical pathways. This means strengthening national response mechanisms, overcoming health systems bottlenecks and barriers - including gender barriers - and putting communities and users at the centre and maintaining other essential health services, supporting integrated service delivery platforms.

In addition to provide support to achieve the product-specific targets of the other Pillars, the HSRC has one specific target of its own: to cover the PPE needs to protect all essential health and care workers. This means providing high quality PPE to over 2.7m health and care workers, including the community health workers who play such a vital role in many countries' health systems.

HSRC priorities. HSRC will provide coordinated support to countries **in planning, financing and tracking delivery against targets, provide coordinated technical, operational and financial support to countries to ensure the translation of tools into effective health interventions**, complementing the work of the product Pillars and to enable the delivery of national Strategic Preparedness and Response Plans, and **protect the health system and health workforce**.

Major shifts in HSRC focus. HSRC will fully integrate WHO's Health Emergencies programme to ensure alignment with national Strategic Preparedness and Response Plans. The refreshed HSRC will include UNICEF to enhance its capacity for on-ground implementation, the IMF for tracking and monitoring efforts and World Bank's operational team for coordination on financing. Strengthened collaboration with the other product pillars on supporting the service delivery of tools, as well as driving activities around response outcomes, will be critical to ensure the translation of tools into effective interventions.

The COVID-19 pandemic has led to a change in health-care-seeking behaviour in many countries. Risk Communication and Community Engagement allied with measures to ensure the continuation of essential health services not only have a crucial role in the reduction of morbidity and mortality, but are also crucial for the roll out and take up of COVID-19 tools. The HSRC will therefore drive ACT-A's increased efforts to fund and promote a response that that is led by and responsive to the needs of communities. Gender equity and human rights are the principles that will underpin all of these efforts.

Health Systems and Response Connector priorities and associated activities

HSRC deliverables & work packages. Against this context and shifts in focus, HSRC priorities and activities for the period October 2021 to September 2022 are tabulated below. This work feeds into **ACT-A's strategic priorities 1, 4 & 5**.

1. Support coordinated country planning, financing and tracking against delivery targets

- Gain clear understanding of needs and current capacity to meet that demand
- Support countries in developing national deployment strategies for COVID-19 tools
- Support countries in closing financing gaps, notably by raising awareness on available financing mechanisms and alignment opportunities with other multilateral and bilateral investments in COVID-19 response
- Measure "real-time" availability and absorption of tools in countries

2. Support coordinated technical, operational and financial support to countries to ensure translation of tools into effective health interventions

- Work with COVAX to address surge staffing and other infrastructure needs (e.g., need to set up ultra cold chain infrastructure) to support effective vaccine deployment, through training and operational support
- Work with the Dx pillar to ensure that the expansion of community-based testing programs and other testing approaches are tightly linked to the development and execution of coherent public health interventions, through training, operational support and technical assistance
- Work with the Tx and Dx pillars to support countries in delivering more effective "test & treat" strategies, and to optimize clinical care pathways, through technical assistance and operational support

3. Ensure health systems and workforce protection and capacity strengthening

- Address cross-cutting bottlenecks to the deployment of tools. This includes health system organization, surge response and vaccination workforce requirements, systems monitoring, basic health infrastructure, political engagement and intra-government coordination as well as working with communities and civil society to tackle demand-side and utilization barriers such as fear and stigma
- Minimize knock-on effect of COVID-19 on other essential health services, including reduced access to health facilities; reduced ability to pay for services; reduced staffing available to provide care; disrupted supply chain systems and lack essential medical supplies; and lowered service capacity at health care facilities, displacement of funding
- Ensure that health and community care workers are supported to apply appropriate IPC practices, including through access to the necessary personal protective equipment and training, to ensure the safe functioning of health systems and the safe use of COVID-19 tools

Major HSRC milestones over the next 12 months.

- Countries conduct regular needs and gaps analysis based on epidemiological & essential supplies forecast to inform national planning and response activities, while also identifying potential situations of concern
- Countries have integrated and “up-to-date” plans, resource requirements & financing allocations for vaccination, testing and clinical management on COVID-19 partners platform
- Countries have at least 80% of their financing gaps for delivery met, primarily through domestic funding and, where required, are supported through concessional and/or grant financing
- Countries have “real-time” monitoring of availability and absorption of new COVID-19 tools & tracking against delivery targets
- Product pillars are supported to meet their targets by aligning with and leveraging national response capabilities, engaging communities and addressing immediate health systems bottlenecks
- Countries reach pre-pandemic essential health service delivery levels by supporting them to minimize COVID-19 knock-on effects and strengthen community resilience
- Essential health and community care workers are kept safe by providing PPE and strengthening infection and control measures

Box 3.3. *Major achievements and key challenges to Sept 2021 for the Health Systems & Response Connector*

R&D and product assessment

Market shaping & manufacturing

Procurement

Demand generation & in-country delivery

Major achievements to date:

- Developed knowledge sharing platform early on
- Released flagship report "Transforming the Medical PPE Ecosystem"

- Procured US$ 734 Mn worth of PPE

- Led consultations with countries to understand actions taken, key needs and bottlenecks
- Essential health services monitoring and data analysis to inform national response efforts
- Facility and household phone surveys on service delivery and demand side barriers for COVID-19 and essential health services
- RMET tools in support of ACT-A financial planning and prioritization
- Grant and TA for strengthening country response, monitored monthly health service delivery levels and addressed demand-side barriers for COVID-19

Key challenges:

- Limited innovation in the PPE space

- No quantitative targets set
- Inadequate response to oxygen crisis (oxygen subsequently moved to Tx pillar)

- Insufficient focus on country and health workers needs
- Insufficient integration across pillars and coordination with country response
- Limited budget and displacement of funding affecting response efforts and protection of essential health services

For more information, refer to the forthcoming ACT-A Q3 update (to be published in October 2021).

4

TRACKING & ACCELERATING PROGRESS IN CLOSING GAPS IN ACCESS TO COVID-19 TOOLS

A consolidated view of the coverage achieved with each COVID-19 tool, barriers to their access, and donor pledges is essential for tracking progress and advocating for the resources required to end the pandemic. ACT-A will support a multi-agency, multi-stakeholder effort to bring together the different sources of information and data required for monitoring and communicating its contribution towards the global vaccination, testing, treatment, and PPE targets.

Global minimum targets on vaccination, tests, treatments and PPE

WHO, as the global normative agency on health, has set ambitious vaccination and testing targets to control COVID-19 and end the pandemic, and with ACT-A's co-convening Agencies set minimum coverage targets to improve access to therapeutics and PPE. These targets anchor the new ACT-A strategic plan and budget and will drive ACT-A's work for the next 12 months (see Fig. 4.1).

Fig. 4.1. *ACT-A contributions to achieving global targets in access to COVID-19 tools by end September 2022*

	Global targets	ACT-A targets
Vaccines	**70%** vaccination coverage	Support countries' vaccination goals towards **70%** coverage in AMC91 countries
Diagnostics	**100** tests | **100K** pop/day	**100** tests | **100K** pop/day in Dx144 countries
Treatments *(incl. O2)*	all **200 Mn** new cases are treated	**120 Mn** cases treated in LICs, LMICs, key UMICs
PPE	all **10 Mn** essential HWs are protected	**2.7 Mn** HWs protected in LICs, LMICS, key UMICs

These global targets have been reaffirmed by global leaders, most recently at the Global Summit on COVID-19 hosted in the margins of the 76th UN General Assembly. The ACT-A Facilitation Council provides a high-level forum for the ongoing tracking and review of progress towards these targets, including through support to the work of ACT-A Pillars.

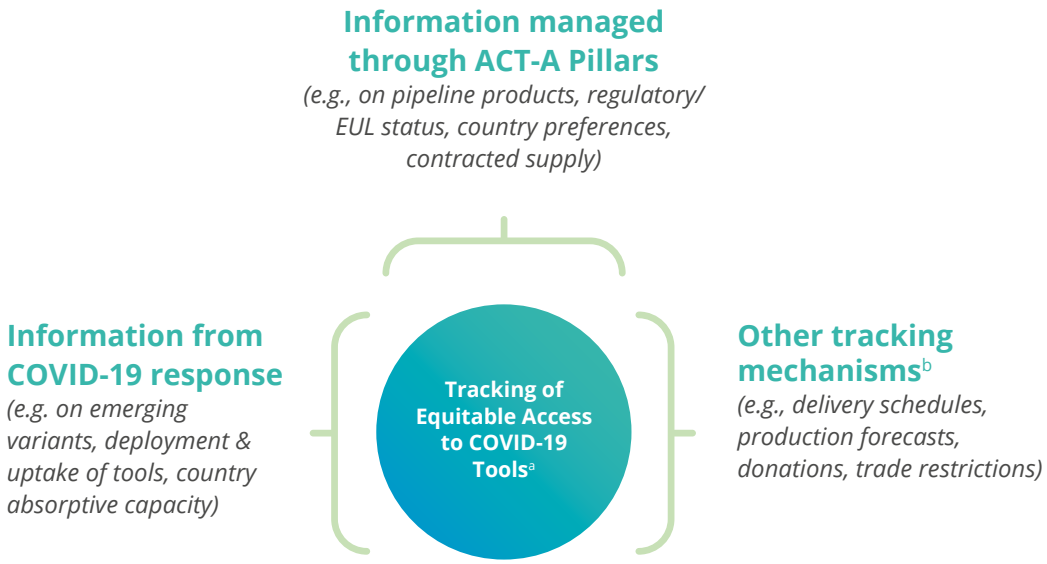
Consolidating data on the roll out of COVID-19 countermeasures globally

A consolidated view of coverage, access barriers and pledges across all COVID-19 tools is essential for tracking progress, increasing transparency, enhancing accountability and advocating for the resources required to end the pandemic.

ACT-A will lead a multi-agency, multi-stakeholder effort, which includes industry and civil society, to bring together the different sources of information and data required for monitoring progress towards the global vaccination, testing, treatment, and PPE targets (see Fig. 4.2). The refreshed Health Systems & Response Connector, with its original and recent partners such as the IMF, will take this work forward, drawing and expanding on relevant initiatives.

The consolidation of all available information on the coverage and uptake of COVID-19 tools will help identify where ACT-A agencies can bring greatest value in this rapidly evolving landscape and demonstrate their contribution.

Fig. 4.2. *Consolidating information on the rollout of COVID-19 countermeasures*



[a] *with the new HSRC Pillar leading this multi-agency, multi-partner effort*
[b] *e.g., manufacturers, global civil society, regional initiatives*

Enhancing the work of stakeholders to advocate in support of ACT-A's role in closing access gaps for COVID-19 tools

Empowered with a consolidated view of access to COVID-19 tools globally, key stakeholders can work more effectively with the ACT-A Pillars to advocate for the actions necessary to achieve equitable access. With real time, actionable information on resource requirements, ACT-A stakeholders can also better advocate for action to address major political barriers and key challenges to reaching the global targets.

Fig. 4.3 illustrates some of the key opportunities provided by high-level fora over the coming 12 months to regularly take stock of progress toward the global targets, and reinforce the political momentum and support needed to achieve the ambitious goals for the roll out of COVID-19 countermeasures to end the pandemic.

Fig. 4.3. *Timeline of key events & stocktake opportunities to UNGA 2022*

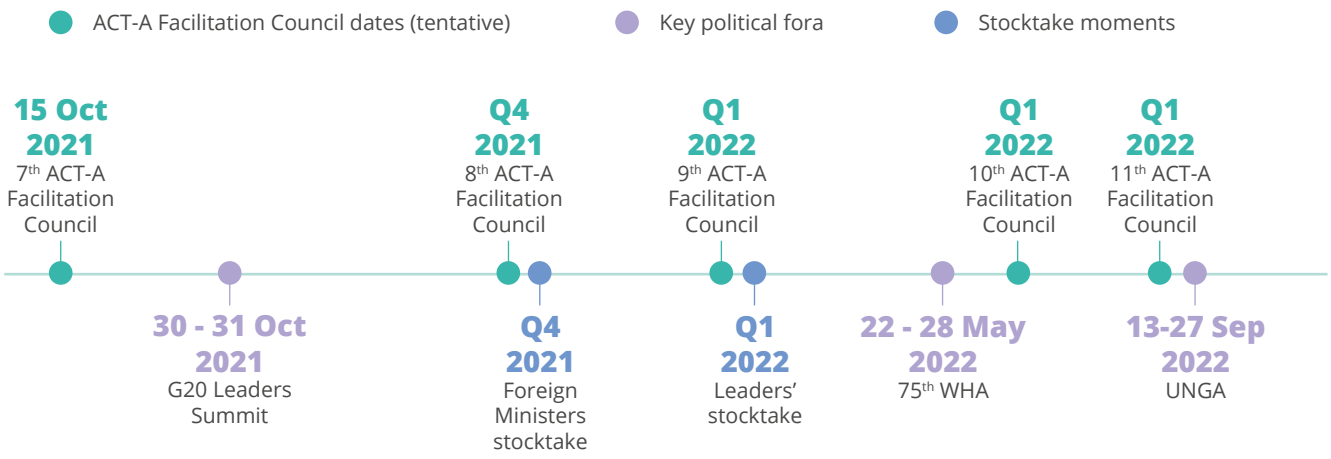


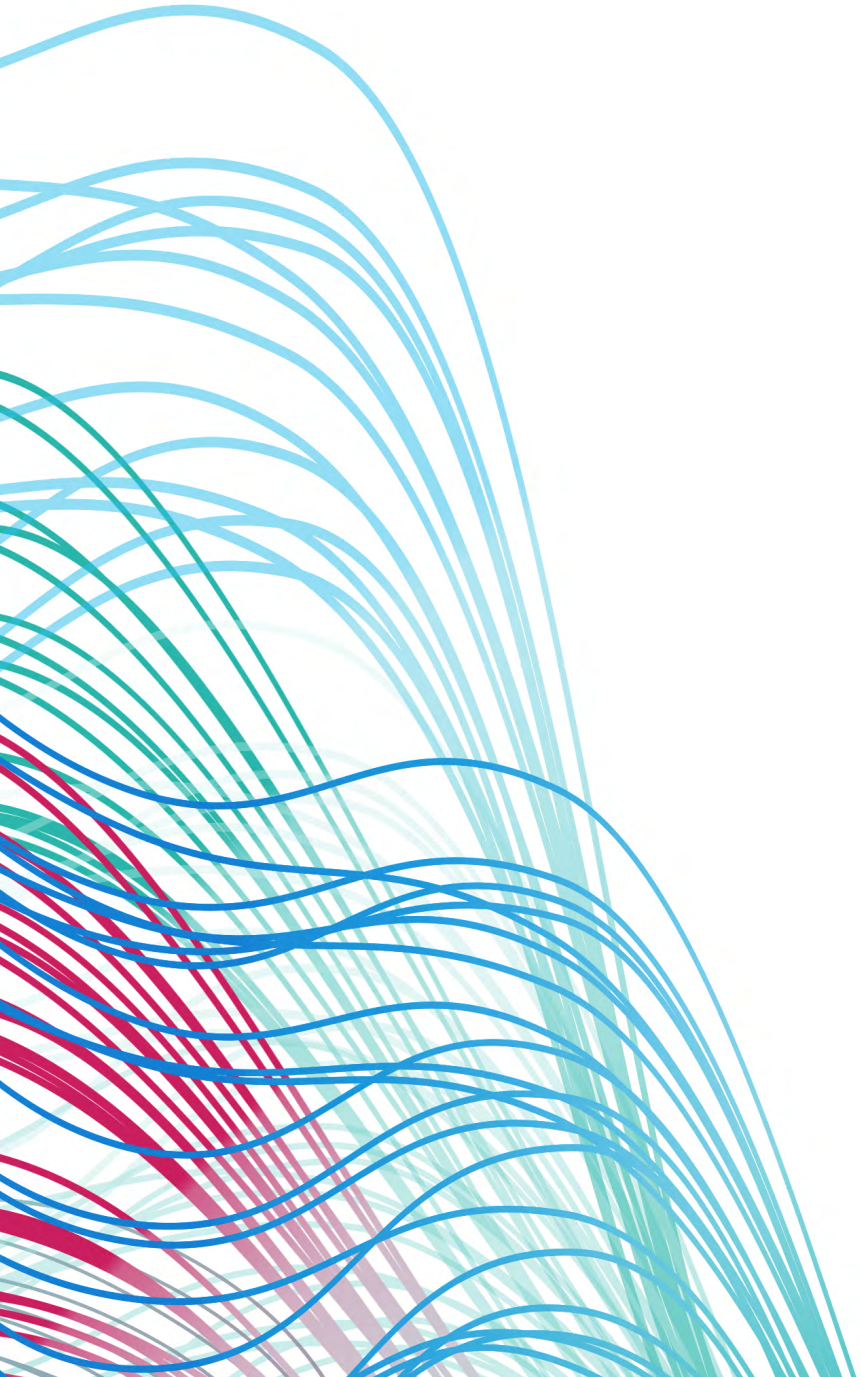
Table 4.1. *ACT-A's contribution to closing global gaps in access to COVID-19 tools 'at-a-glance'*

Global targets	**>70% of the population fully vaccinated in every country and income category by UNGA 2022**[24,25]	**100 tests per 100'000 inhabitants per day in all countries**	**Ensure sufficient genomic sequencing capabilities and data sharing efforts globally**	**Oxygen readily accessible for inpatient health facilities in all countries in the near-term and no later than 2022; Therapeutics available in 2021, and new non-IV treatments available in 2022**	**Enhanced access to PPE healthcare workers in 2021, with surge capacity available for every region in 2022**
Description of global gap	Achieving the global vaccination coverage target will require the deployment of a further 5 billion doses.	Approximately 4 billion COVID-19 tests (RDT and molecular) are needed globally to ensure all countries implement COVID-19 testing at a rate of 100 per 100k population per day.	Genomic surveillance capabilities needs to be enhanced, especially in LICs and LMICs. While 2/3 of HICs have already reported more than 1'000 sequences, no LICs have done so to date.[26]	200 million new COVID-19 cases expected in the next 12 months globally to need treatments Out of these, 142 million new cases are forecasted LICs, LMICs and UMICs.	Access to PPE is a serious issue in parts of the world, especially in LICs and LMICs. In some countries, fewer than 15% of healthcare facilities have access to the PPE they need.
Pillar contribution to global target & gap (over the next 12 months)	**Support countries' own vaccination goals towards the global target of 70%.** Donor-funded supply through COVAX (pledges to COVAX AMC and confirmed donations) correspond to c.2.4B doses. COVAX is looking to secure an additional 600M doses as explained in Section 3.1.	LIC/LMIC and UMIC countries that are testing below the global target of **100/100k/ inhabitants per day** achieve and sustain this level of testing over the next 12 months.	Increasing genomic surveillance capacities in LICs and LMICs. **75% of countries sharing virus sequence data** on a publicly accessible database each month[27].	Outpatient treatments provided for **113 million cases in LICs, LMICs and key UMICs**. Inpatient treatments provided for **6 million cases in LICs, LMICs and key UMICs**.	PPE provided for **2.7 million health workers and community health workers in LICs, LMICs and key UMICs**.

[24] Global COVID-19 Vaccination – Strategic Vision for 2022. Geneva: World Health Organisation, 15 September 2021 (Global COVID-19 Vaccination – Strategic Vision for 2022, accessed: 19 October 2021).
[25] WHO's Interim target is 40% coverage in all countries by end of 2021.
[26] GISAID submission tracker (https://www.gisaid.org/submission-tracker-global/, accessed: 19 October 2021).
[27] COVID 19 Strategic preparedness and response plan - Monitoring and evaluation framework. Geneva: World Health Organisation; 11 May 2021 (https://www.who.int/publications/i/item/WHO-WHE-2021.07-eng; accessed: 19 October 2021).

PART 2:
ACT-A Budget

(October 2021 – September 2022)



5

OVERVIEW OF ACT-A FUNDING NEEDS FOR THE NEXT 12 MONTHS

ACT-A will need US$ 23.4 billion over the next 12 months to support equitable access to COVID-19 tools, especially in underserved (or lagging) countries and areas. Fulfilling this need will enable ACT-A partners to undertake critical investments in R&D, product assessment, policy and guidance, procurement of tools and in-country technical assistance and delivery.

Overview

By mid-October 2021, donors had pledged a generous US$ 18.7 billion to ACT-Accelerator partners, including: US$ 12.8 billion for Vaccines, US$ 1.8 billion for Diagnostics, US$ 1.6 billion for Therapeutics, and US$ 1.7 billion for the Health Systems & Response Connector.

Delivering on ACT-Accelerator's new strategic plan requires US$ 23.4 billion over the next 12 months.

A total of US$ 23.4 billion is now required for ACT-A to deliver its overarching objective and strategic priorities for the period October 2021 to September 2022. This figure is approximately 60% of ACT-A's Sep 2021 ask, reflecting prioritized needs in the current global context.[28] This figure also accounts for and supersedes the prior ACT-A funding asks, although it does not account for potential carryover of US$ 0.9 billion donor pledges still pending allocation as of October 2021.[29]

In recognition of the changing nature of this pandemic, the ACT-Accelerator may update the total ask before the end of the period, to reflect the evolving global need.

Funding needs by Pillar and major outcome category

Following a request from major donors to understand how to link ACT-A's budget to outcome categories, total funding needs have been segmented into four categories: upstream support, procurement needed to help close gaps to the global targets for all tools, procurement to expand coverage and mitigate risks, and technical assistance & delivery support. This segmentation is shown in Fig. 5.1.

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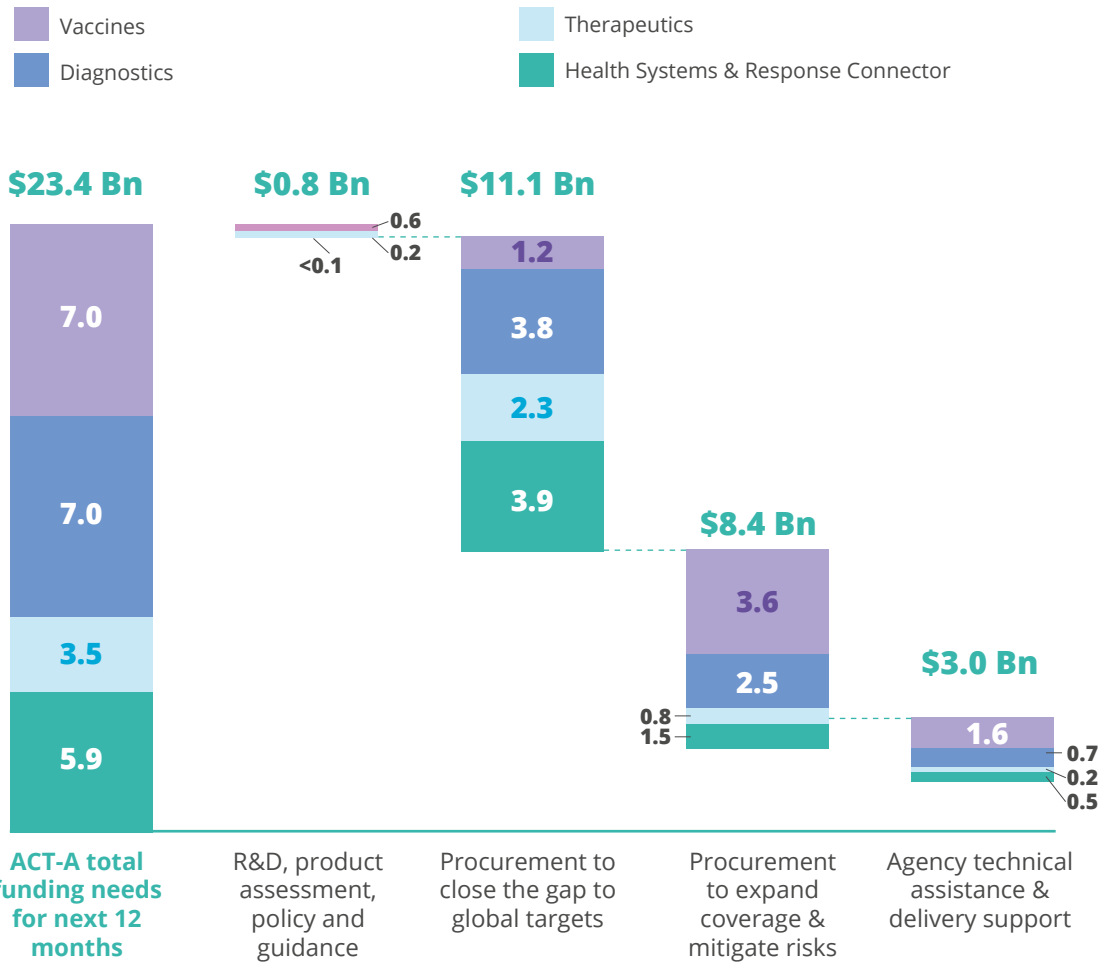
[28] Key factors influencing the lower cost include: the smaller spend on R&D (as many tools now exist and are being scaled up and scaled out); increasing vaccination coverage and a lower number of cases requiring therapeutics and oxygen; and lower unit costs across all tools.

[29] The ACT-A Strategic Plan & Budget: October 2021 to September 2022 supersedes the Rapid ACT-Accelerator Delta Response (RADAR) urgent appeal launched in August 2021, the ACT-Accelerator Prioritized Strategy & Budget for 2021 published in April 2021, the ACT-Accelerator Urgent Priorities & Financing Requirements published in November 2020.

Of the total US$ 23.4 billion needed for ACT-A, US$ 0.8 billion is needed for upstream support, including R&D, product assessment, policy and guidance. US$ 11.1 billion is needed to help procure tools to help lagging countries close gaps in reaching the global vaccination, test, treatment and PPE targets. US$ 8.4 billion is needed to support further procurement of tools, to expand coverage and mitigate risks associated with tools roll out, surges and with variants[30]. Finally, US$ 3.0 billion is needed for critical activities to enable in-country deployment, critical infrastructure investments and local technical assistance.[31]

Fig. 5.1. *ACT-A Funding needs from Oct 2021 to Sep 2022 by Pillar and major outcome category, figures in US$ billion*



Note: Figures are rounded. 15m enabling costs included as part of R&D, product assessment, policy and guidance. Total does not account for potential carryover of US$ 0.9 Bn donor contribution still pending allocation as of 21 October 2021.

[30] This figure may be updated as and if necessary, to reflect evolving global need.
[31] Note that Agencies may communicate different numbers for resource mobilization purposes when they consider total funding needs until the end of 2022.

Funding needs by strategic priority, Pillar and major outcome category

Table 5.1 provides an overview of funding needs by strategic priority and major outcome category. Most Pillar work packages can be mapped directly to a specific strategic priority except for the Health Systems & Response Connecter which contributes to three strategic priorities as shown below. Table 5.2 provides a consolidated view by Pillar and major outcome category.

Table 5.1. *Funding needs by strategic priority and major outcome category, figures in US$ million*

Strategic Priority	Pillar	R&D, product assessment, policy and guidance	Procure-ment to close the gap to glob-al targets[a]	Procure-ment to expand coverage & mitigate risks	Agency technical assistance & delivery support	**Total funding need**
Closely track overall gap to access vaccines, tests, treatments and PPE	HSRC[b]	15	n/a	n/a	204	**219**
Accelerate progress towards the 70% global vaccination target, tackling barriers to development, global access and uptake	Vaccines[c]	584	1,218	3,582	1,598	**6,981**
Advance testing rates to a minimum of 100/100K people/day, to track evolving epi & virus; optimise use of tools	Diagnostics	26	3,791	2,476	691	**6,984**
Treat 120 m people & protect 2.7 m HCWs, with scaled delivery of existing & new treatments, incl. O2, and access to PPE	Therapeutics	215	2,282	834	175	**3,506**
	HSRC	n/a	3,379	1,352	n/a	**4,730**
Fully integrate Pillar delivery with COVID-19 national responses (through revamped Health Systems & Response Connector)	HSRC	n/a	475	190	282	**947**
TOTAL		**840**	**11,145**	**8,434**	**2,950**	**23,369**

[a] Or country target, if lower than global target.
[b] Includes 15 million for enabling costs, including management costs and ACT-A Hub running costs.
[c] Pending confirmation by GAVI Board on December 15, 2021.

Table 5.2. *Funding needs by Pillar and major outcome category, figures in US$ million*

Pillar	R&D, product assessment, policy and guidance	Procurement to close the gap to global targets	Procurement to expand coverage & mitigate risks	Technical assistance & delivery support	**Total funding need**
Vaccines	584	1,218	3,582	1,598	**6,981**
Therapeutics	215	2,282	834	175	**3,506**
Diagnostics	26	3,791	2,476	691	**6,984**
HSRC[a]	n/a	3,854	1,542	486	**5,881**
Other enabling costs	15[b]	n/a	n/a	n/a	**15**
TOTAL	**840**	**11,145**	**8,434**	**2,950**	**23,369**

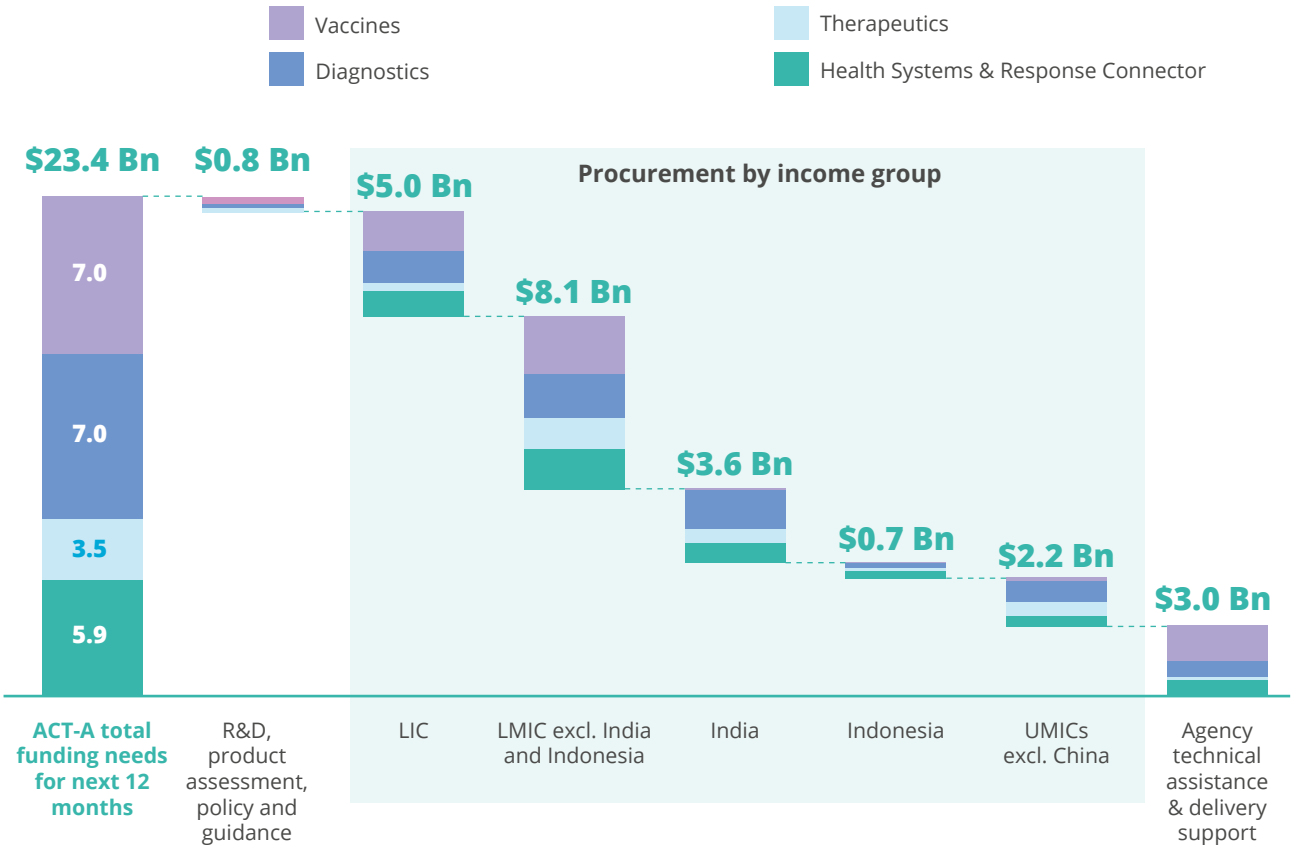
[a] Bottlenecks management and TA for interdependency with essential health services included within procurement figures.
[b] For enabling costs, including management costs and ACT-A Hub running costs.

Funding needs by country income group, Pillar and major outcome category

Fig. 5.2 provides an overview of ACT-A's 12 month funding needs, with a breakdown of procurement costs by country income group. This split is illustrative, showing for example that more than 50% of the total ACT-A funding need (approx. US$13 B) is required to support procurement of COVID-19 tools for LICs and LMICs (not including India and Indonesia)

Of note, almost 60% of the procurement ask for diagnostics, treatments and PPE addresses needs in LICs and LMICs (excluding India and Indonesia), highlighting the commitment of ACT-Accelerator towards the most vulnerable economies.

Fig. 5.2. *Funding needs with procurement costs by income group, figures in US$ billion*



Note: Figures are rounded. Breakdown by income group is illustrative and largely proportional to population, accounting for different financing assumptions by country income group (these vary by Pillar and product). Vaccine breakdown assumes 100 Mn doses allocated to LICs; 500 Mn additional doses assigned proportionally to the population in LICs & LMICs, excluding India and Indonesia; US$ 0.5 Bn ancillary costs for donated doses split proportionally to the population in all supported countries. Actual split will depend on the allocation mechanisms applied by COVAX in future Allocation rounds. 15 m enabling costs included as part of R&D, product assessment, policy and guidance. Total does not account for potential carryover of US$0.9 Bn donor contributions still pending allocation as of 21 October 2021.

6

DETAILED WORK PACKAGES BY STRATEGIC PRIORITY, PILLAR AND OUTCOME CATEGORY

ACT-A's funding needs for the period October 2021 to September 2022 can be broken down into individual work packages to provide stakeholders with a more detailed understanding of Pillar and Agency activities and funding needs by area of work.

Table 6.1 provides a detailed breakdown of the ACT-A's total funding needs, listing all individual work packages to outline the key activities and deliverables for ACT-Accelerator Pillars and Partners over the next 12 months. Within each strategic priority, work packages are grouped by Pillar and then by outcome category.

Table 6.1. *Detailed work packages by strategic priority, Pillar and major outcome category, figures in US$ million*

Work packages	Agency leads	Funding need
Grand total		**23,369**
Strategic Priority 1 - Closely track overall gap to access vaccines, tests, treatments & PPE		**219**
Health systems & Response Connector		**204**
Agency technical assistance & delivery support		
Country readiness planning, demand generation and financing	WHO, UNICEF, GFF	102
Implementation monitoring and tracking against delivery targets	WHO, UNICEF, GFF	61
Real-time country needs and gaps analysis	WHO, UNICEF, GFF	41
Other		15
Enabling costs	WHO	15[a]

Work packages	Agency leads	Funding need
Strategic Priority 2 - Accelerate progress towards the 70% global vaccination target, tackling barriers to development, global access and uptake		**6,981**
Vaccines		**6,981**
R&D, product assessment, policy and guidance		
Research and clinical trials to accelerate vaccine development	CEPI	350
Vaccine manufacturing hub	WHO	100
Research on new vaccines	WHO	91
Prequalification and support to regulatory authorities to facilitate market entry and ensure quality and safety	WHO	13
Policy and guidance for vaccines	WHO	13
Monitor and assess the impact of new SARS-CoV-2 variants on vaccines research	WHO	11
Coordination and collaboration on vaccines research	WHO	5
Equitable Access for vaccines	WHO	2
Procurement to close the gap to global targets		
COVAX contribution to reach country-specific coverage targets in LICs (100m doses)	COVAX	673
Vaccine doses ancillary costs (for donated doses)	COVAX	545
Procurement to expand coverage & mitigate risks		
COVAX contribution to expand coverage targets and mitigate risks (500m doses)	COVAX	3,582
Agency technical assistance & delivery support		
Vaccination delivery costs	UNICEF, WHO, GAVI	1,329
Operational support for in-country delivery of vaccines	WHO	114
Technical assistance to countries to expand capacity to deploy quality assured vaccines	WHO	99
Field operations and working with partners rolling out vaccines throughout the health system and communities	WHO	57

Work packages	Agency leads	Funding need
Strategic Priority 3 - Advance testing rates to a minimum of 100 / 100K people / day to track evolving epi & virus; optimise use of tools		**6,984**
Diagnostics		**6,984**
R&D, product assessment, policy and guidance		
R&D for three accurate, affordable point of care molecular tests	FIND, Unitaid	15
External evaluation of tests against known and emerging variants	FIND	6
Support of Emergency Use Listing (EUL) process and other regulatory work of 4 additional tests	FIND, WHO	5
Procurement to close the gap to global targets		
Procurement of approx. 600m tests for countries testing below target	ACT-A Dx partneship	3,346
Procurement sequencing tools	ACT-A Dx partneship	445
Procurement to expand coverage & mitigate risks		
Procurement of tests for countries testing above target	ACT-A Dx partneship	2,032
Additional procurement sequencing tools	ACT-A Dx partneship	444
Agency technical assistance & delivery support		
Expand genomic sequencing capacity and sustainability by building on in-country policies, laboratory and digital infrastructure	WHO, ACT-A Dx partnership	279
Invest in workforce development to expand community-based testing programs	WHO, FIND, ACT-A Dx partnership	200
In-country technical and operational assistance to expand decentralized community-based testing, including self testing, and strengthen the link between testing and treatment	WHO, FIND, Unitaid, ACT-A Dx partnership	145
Generation of evidence for expanding use cases for testing and setting testing policies and strategies, including the use of digital tools	WHO, FIND, ACT-A Dx partnership	62
Advocacy and community engagement on testing	ACT-A Dx partnership	5

Work packages	Agency leads	Funding need
Priority 4 - Treat 120 m people & protect 2.7 m HCWs, with scaled delivery of existing & new treatments, incl. O2, and access to PPE		**8,237**
Therapeutics		**3,506**
R&D, product assessment, policy and guidance		
Upstream efforts to broaden and accelerate therapeutics pipeline	Wellcome, WHO	154
Ongoing global platform trials	Unitaid, Wellcome	50
Prequalification and support to regulatory authorities to facilitate market entry and ensure quality and safety of therapeutics	WHO	4
Policy and guidance for safe, effective, affordable and equitable access to therapeutics	WHO	4
Monitor and assess the impact of new SARS-CoV-2 variants on therapeutics research	WHO	2
Coordination and collaboration on therapeutics re-search	WHO	1
Procurement to close the gap to global targets		
Oxygen procurement & delivery[b]	Global Fund, UNICEF, Unitaid, WHO	888
Approx. 85m Repurposed / Novel therapeutics courses for mild/mod patients	Global Fund, UNICEF	850
Market interventions incl. ~28M Repurposed/Novel therapeutics courses for mild/mod patients	Global Fund, UNICEF	283
Approx. 4.3m Repurposed therapeutics courses for severe/critical patients	Global Fund, UNICEF	121
O2 sources and medical devices CAPEX	Global Fund, UNICEF	82
Therapeutics and oxygen procurement	WHO	58
Procurement to expand coverage & mitigate risks		
Oxygen procurement for surges	Global Fund, UNICEF	400
Approx. 39m Repurposed / Novel therapeutics courses for mild/mod patients for surges	Global Fund, UNICEF	392
Approx. 1.5m Repurposed therapeutics courses for severe/critical patients for surges	Global Fund, UNICEF	42

Work packages	Agency leads	Funding need
Agency technical assistance & delivery support		
Field operations and working with partners rolling out therapeutics and oxygen throughout the health system and communities	WHO, UNICEF	79
Operational support for in-country delivery of therapeutics	WHO, UNICEF	42
Country introduction of therapeutics (incl demand generation, training, roll-out support)	Unitaid, UNICEF	40
Technical assistance to countries to expand capacity to deploy quality assured therapeutics	WHO	14
Access & allocation of therapeutics	WHO	<1
Health Systems & Response Connector		**4,730**
Procurement to close the gap to global targets		
PPE to protect essential frontline health workers	Global Fund, UNICEF	3,379
Procurement to expand coverage & mitigate risks		
PPE to protect additional frontline health workers	Global Fund, UNICEF	1,352
Strategic Priority 5 - Fully integrate Pillar delivery with COVID-19 national responses (through revamped Health Systems & Response Connector), managing vulnerabilities, financing, risks & health systems interface		**947**
Health Systems & Response Connector		**947**
Procurement to close the gap to global targets		
Protecting the health work force	Global Fund, UNICEF, WHO	200
Bottlenecks management and TA for interdependency with essential health services	Global Fund, WHO, UNICEF, GFF	118
Working with the Therapeutics and Diagnostics Pillars to support countries in delivering more effective “test & treat” strategies, and to optimise clinical care to save more lives	WHO, Global Fund, GFF	86
Working with the Diagnostics Pillar to help countries use tests to implement effective public health measures	WHO, Global Fund, GFF	71

Work packages	Agency leads	Funding need
Procurement to expand coverage & mitigate risks		
Protecting the health work force	Global Fund, UNICEF, WHO	80
Bottlenecks management and TA for interdependency with essential health services	Global Fund, WHO, UNICEF, GFF	47
Working with the Therapeutics and Diagnostics Pillars to support countries in delivering more effective "test & treat" strategies, and to optimise clinical care to save more lives	WHO, Global Fund, GFF	34
Working with the Diagnostics Pillar to help countries use tests to implement effective public health measures	WHO, Global Fund, GFF	29
Agency technical assistance & delivery support		
Management cost associated with procurement of Therapeutics, Diagnostics and PPE	WHO, Global Fund, GFF, UNICEF	282

[a] Enabling costs include ACT-A Hub running costs.
[b] Budget reflects funds needed for oxygen procurement, market-shaping, and associated technical support.

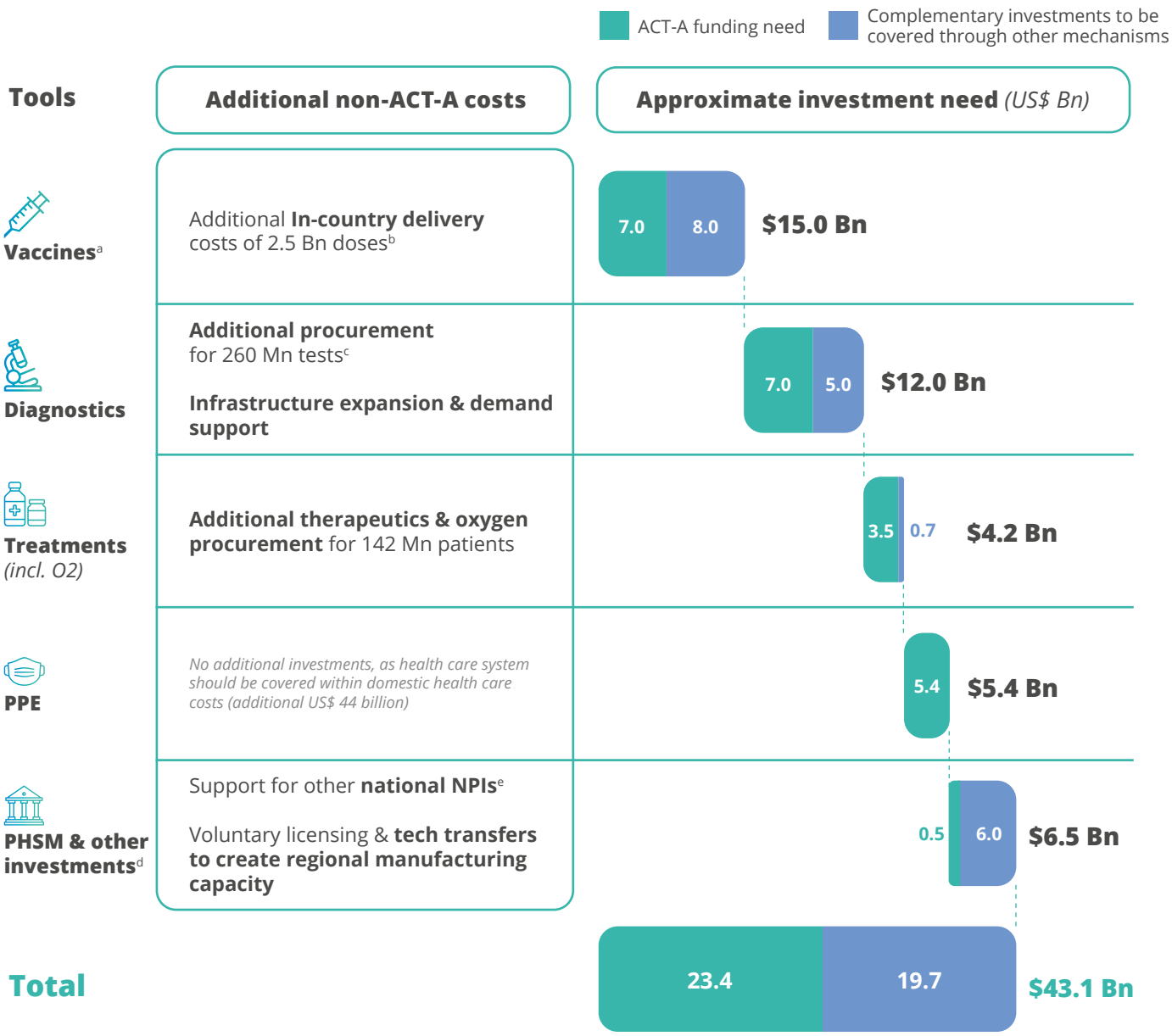
7

FINANCING ACT-A WITHIN THE BROADER COVID-19 RESPONSE

ACT-A's funding needs reflect only part of the total investment needed to support the global COVID-19 response over the next 12 months, which is estimated to be at least US$ 43 billion

The ACT-Accelerator is at the core of the global COVID-19 response, covering US$ 23.4 billion of the total investment need which is focused on achieving equity in LICs, LMICs and underserved UMICs. The remaining investment needed, approximately US$ 19.7 billion, includes additional procurement of tools, additional in-country support (e.g., delivery, infrastructure expansion and demand support) and additional support to implement public health and social measures. These investments are complementary to and beyond the remit of ACT-A but they are essential to end the acute phase of the pandemic in all countries, and will therefore require support through other mechanisms (See Fig.7.1).

Fig. 7.1. *Financing global equitable access to COVID-19 tools, distinguishing between need covered through ACT-A and other mechanisms, figures in US$ billion*



Notes: (a) No additional vaccine procurement costs included, as substantial risk mitigation budget already costed for this purpose as part of the COVAX facility. (b) WHO Strategy to Achieve Global COVID-19 Vaccination by mid-2022 .(c) Procurement need beyond ACT-A to achieve 100 tests per 100,000 inhabitants per day in all 144 Diagnostics consortium countries. (d) Public health and social measures, based on IMF estimates of costs of non-pharmaceutical interventions (US$ 4 Bn) and voluntary licensing and technology transfers to create regional manufacturing capacity (US$ 1 Bn for vaccines, raised to US$ 2 Bn to include manufacturing scale-up for other tools). IMF (2021), A Proposal to End the COVID-19 Pandemic. (e) Non-pharmaceutical interventions.

8

ACT-A INVESTMENT CASE

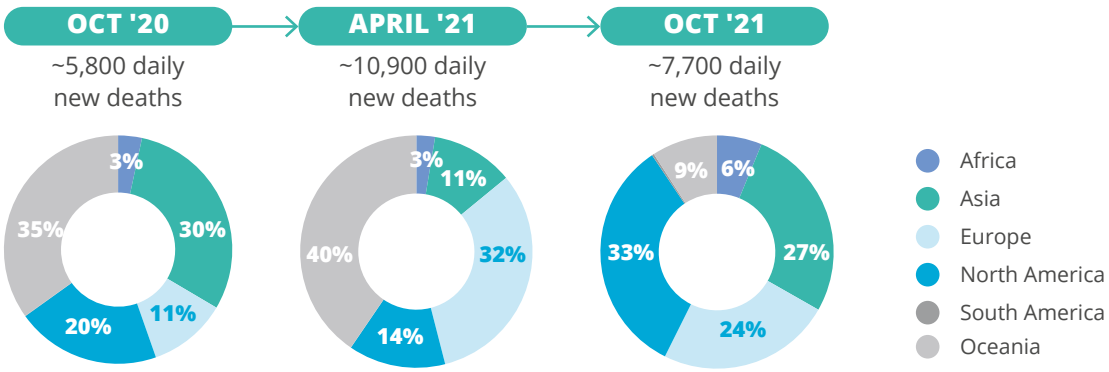
Inequities in access to COVID-19 tools could lead to >5 million preventable deaths, and a global loss of US$ 5.3 trillion by 2026.

Achieving the COVID-19 tools global coverage targets could prevent 5 million deaths by September 2022, greatly reduce the risk of new variants of concern, and save US$ 5.3 trillion over the next five years by enabling economic recovery everywhere. ACT-A is the only global, end-to-end solution to tackle the acute phase of the pandemic; fully financing it is an urgent global necessity.

The COVID-19 pandemic is not over

Despite a high degree of vaccine coverage in many high-income countries, new waves of COVID-19 continue to spread around the globe keeping transmission and mortality levels high. These rates are increasing relative to last year (See Fig.8.1). As of early October 2021, the number of daily new cases worldwide exceeds 400,000, and approximately 7,700 people are dying of COVID-19 every day. Exactly one year ago the number of recorded COVID-19 deaths was at only 5,800, roughly a quarter less than today's rates.

Fig. 8.1. *Number of recorded COVID-19 deaths over time and by region*



Source: COVID-19 Data Repository by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (retrieved on 6 October 2021).

Inequities in access to COVID-19 tools could lead to >5 million preventable deaths

Although there has been sufficient supply to have vaccinated the most vulnerable 40% of the world's population, many health workers and populations at risk in LICs and LMICs are still unprotected. As of early October 2021, the number of vaccine doses administered in high-income countries exceeded that in low-income countries by a factor of 31x (133 vs. 4 per 100 population). Meanwhile, the average daily testing rate in high-income countries outperformed that in low-income by a factor >55x (740 vs. 13 per 100,000 inhabitants). These escalating inequities are not only morally unacceptable, they also directly translate into increased deaths and stifled economic recovery. If today's staggering inequities in access to lifesaving COVID-19 tools persist, conservative calculations estimate an avertable death toll of >5 million lives over the next 12 months.

Unless the pandemic is under control everywhere, the virus will mutate into new, dangerous variants

While we continue to see high COVID-19 transmission, the virus will continue to mutate and new variants will evolve. All countries - including high-income countries – face the risk of new waves of illness even among fully vaccinated people. New variants may compromise the effectiveness of the COVID-19 tools we have today. The only way to counter this is to rapidly reduce transmission through access for all to the full suite of COVID-19 tools including tests, treatments and PPE. We need more than vaccines for pandemic response. If we fail to make these tools accessible to all, the world will continue to face a considerable risk of having to re-introduce stringent public health and social measures to contain a mutated virus that evades vaccines, tests and resists treatments.

The impact of economies adapting to 'living with COVID-19' will reduce global output by US$ 5.3 trillion, a staggeringly high multiple of the cost to fund ACT-A

According to the IMF[32], the emergence of new and highly infectious virus variants that require rigorous public health and social measures could result in global GDP losses of up to US$ 5.3 trillion by 2026. Two thirds of this economic toll will be borne by high-income countries. In this case, GDP losses will exceed the comparatively small ACT-A budget presented in this document by a multiple of >240x.

The ACT-Accelerator is the only global, end-to-end solution to tackle the pandemic

A globally coordinated approach is the only way to defeat the virus. The latest data on access to vaccines and diagnostics clearly show that market forces and bilateral deals alone will not close the equity gap in low-income countries. As of October 2021, 80% of the total supply of vaccines to low-income countries came from COVAX. In more than 20 low-income countries more than 80% of the tests performed are being delivered through ACT-A agencies. ACT-A is the only mechanism in place to deliver equitable access to COVID-19 tools worldwide, and as shown in many low- and lower-middle income countries rely heavily on ACT-A to access these tools.

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[32] Kristalina Georgieva. Overcoming Divides and Removing Obstacles to Recovery [speech]. United States: IMF; 5 October 2021 (https://www.imf.org/en/News/Articles/2021/10/05/sp100521-md-curtain-raiserovercoming-divides-and-removing-obstacles-to-recovery, accessed on 7 October 2021).

Fully funding the ACT-A US$ 23.4 billion investment need is urgent

Fully funding ACT-A's US$ 23.4 billion budget is urgent. Up front financing is required to address the need for speed in closing equity gaps in access to tools.

For each month of delay in fully funding ACT-A, the global economy could lose almost four times the 12 month ACT-A budget.

Financing ACT-A

Access to COVID-19 tools (vaccines, diagnostics, therapeutics, PPE) has emerged as the principal fault line along which the global recovery splits countries into two blocs: those countries where activities are normalizing (almost all advanced economies) and those that are still facing high COVID-19 hospitalizations and deaths.

Enduring economic recovery is not assured anywhere, even in countries where infection rates are currently very low, as long as the virus circulates elsewhere. According to the October 2021 World Economic Outlook of the IMF, there could be an additional cumulative US$ 5.3 trillion Global GDP loss between 2022-2026 if the impact of COVID-19 extends into the medium term.

To save lives and support a broad-based economic recovery, urgent action is needed by key stakeholders (private sector, domestic authorities, International Financing Institutions, and sovereign donors) to end to the acute phase of the pandemic by ensuring adequate financing is available to fully finance the ACT-A budget and in-country costs.

Many countries face the crushing combination of higher spending to fight the pandemic and lower revenues due to COVID-19 containment measures. This combination hits low-income countries especially hard, given their limited fiscal resources. Even prior to the pandemic, around half of low-income developing countries were already in or at high risk of debt distress.

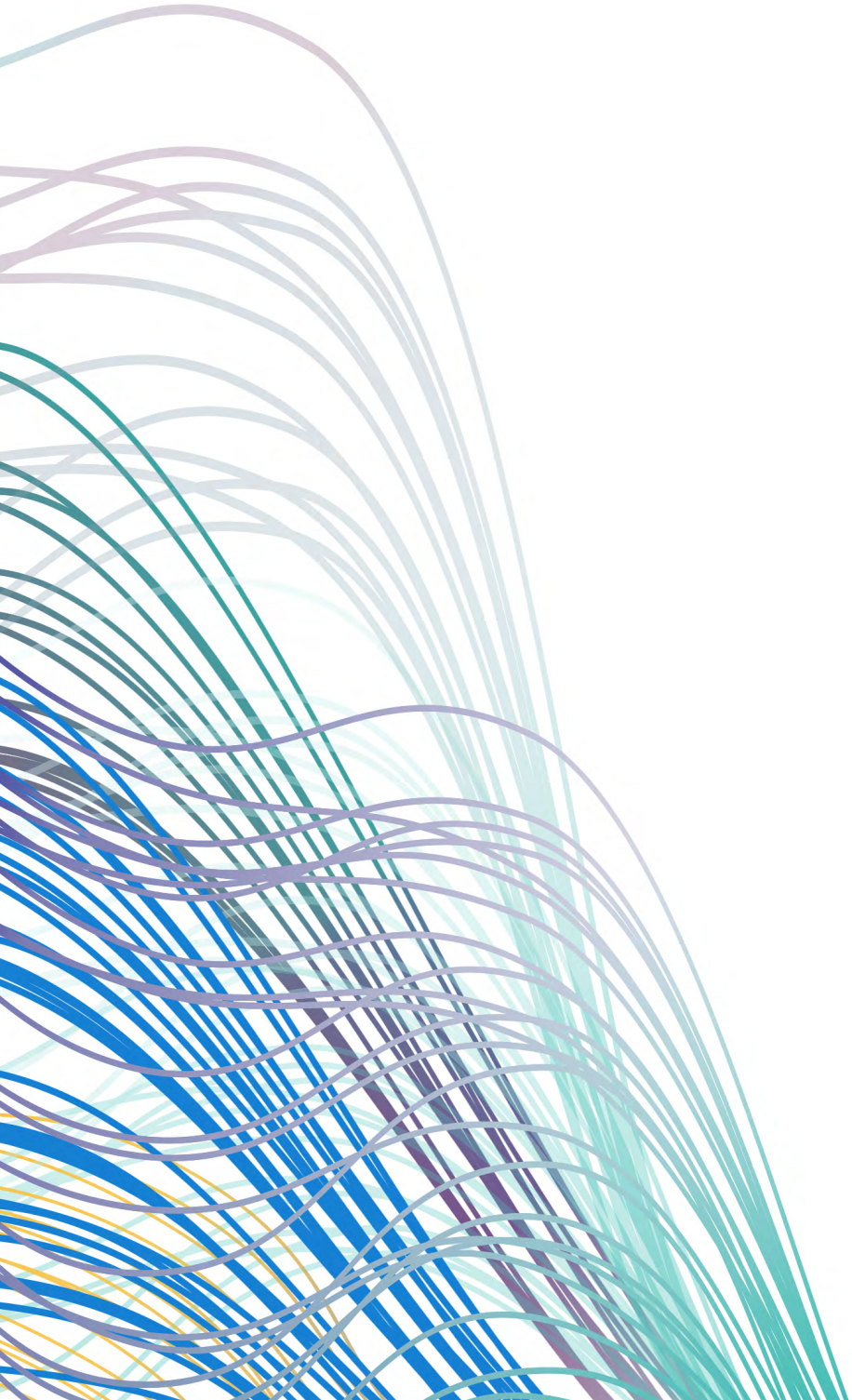
Given the limited fiscal space of LICs/LMICs, and the massive global externalities of ongoing COVID-19 transmission, **there is a strong case for grant financing of ACT-A**. Concessional financing from multilateral development banks is an important complementary resource stream (as also outlined in the IMF Pandemic Proposal, May 2021).

The ACT-A Facilitation Council emphasises the particular importance of grant financing for:

- Immediately responding to acute COVID-19 emergencies in vulnerable settings (*e.g., tests and oxygen for surges*)
- Investing in global common goods (*e.g., clinical trials, global surveillance*)
- Supporting the procurement and roll out of COVID-19 tools in highly debt-constrained countries (*e.g., vulnerable economies with high debt-to-GDP ratios*)

While the local roll-out of COVID-19 tools will be enabled through ACT-A, its success will also require additional funding beyond the resources provided to ACT-A for in-country delivery.

Annexes



ANNEX 1: TAKING FORWARD THE RECOMMENDATIONS OF THE INDEPENDENT ACT-ACCELERATOR STRATEGIC REVIEW

The independent *ACT-Accelerator Strategic Review* was commissioned by the World Health Organization on behalf of the ACT Accelerator partners and as host of the ACT-Accelerator Hub. It was carried out by Dalberg Global Development Advisors between 1 August and 1 October 2021. The final report included the specific recommendations in the table below. The table below outlines how the review recommendations will be taken forward.

Recommendation	How ACT-A will carry it forward	Timeframe
Mandate		
1. Continue ACT-A whilst there is still value in global coordination on COVID-19 tools along the entire value chain, likely throughout 2022.	Partner Agencies agreed to continue the ACT-A collaboration until at least end Sep 2022 per the strategic plan. The need for another extension will be reassessed in Jun 2022.	Immediate
Health systems and country support		
2. In addition to maintaining the urgency and focus on R&D efforts, increase strategic emphasis on downstream work. This means supporting in-country product uptake and working to close the equity gap for currently available tools.	This strategic emphasis on supporting in-country product uptake and addressing gaps in equitable access to COVID-19 tools is well reflected in ACT-A Pillar's delivery work and in the new ACT-A strategic priorities and targets which are anchored in globally agreed targets for equitable access to COVID-19 tools (see Sections 2 & 3).	Immediate
3. Focus the HSC mandate to be more clearly on response and supporting gaps in country readiness and tool uptake not currently covered by the Pillars.	The new and sharpened focus of the Health Systems & Response Connector will better connect Pillar delivery work with the COVID-19 response and in so doing help address critical bottlenecks affecting tool uptake at country level in support of national COVID-19 response priorities (see Section 3.4).	Immediate
4. Further link ACT-A to national COVID-19 responses by working with WHE IMSTs at all levels to better connect dynamic country needs with pillar-level strategic planning across the value chain, enabling ACT-A to take a more proactive, country-centred, and demand-driven approach.	As part of the refocused Health Systems & Response Connector workplan (see Section 3.4), IMSTs will play a key role in connecting the Pillars to the COVID-19 response and country level operations, opening an important additional channel for Pillars to identify and respond to changing country needs.	Immediate

Recommendation	How ACT-A will carry it forward	Timeframe
Health systems and country support		
5. Support use of concessional finance as a complement to grant funding.	This approach is fully supported. The Financial Working Group of the ACT-A Facilitation Council has already been developing a financing framework that clarifies which sources of funding (concessional finance or grant based) could be best leveraged to cover ACT-A funding needs.	Q1 2022
Participation and engagement		
6. Increase and enhance L/MIC, CSO, and Community representation and involvement in ACT-A.	This importance of this engagement is fully recognized. ACT-A partners will explore opportunities to increase engagement of LICs, LMICs, and CSOs in existing global and Pillar/Agency mechanisms, including but not limited to the ACT-A Facilitation Council and its working groups, the Gavi AMC mechanism, Global Fund's C19RM, and through other available agency mechanisms (e.g. WHO's Member State briefings).	Q4 2021
7. Re-affirm the mandate of the Facilitation Council and set up a regular communication channel with the Principals Group.	The need to extend the mandate of the Council and strengthen its role in line with its TORs was discussed at the 7th Council meeting on 15 October 2021. A proposal to extend the mandate of the council will be shared with ACT-A Co-Hosts. Work is underway with the Co-Chairs and the Principals group to establish a way forward that meets the needs of both groups. A one-off session will be held between the Facilitation Council and the smaller Principals Group to enhance ways of working.	Immediate
Communication and information sharing		
8. Align around ACT-A's collective brand to support stronger and more consistent messaging to external audiences, including i) building common advocacy messages in support of resource mobilisation efforts and ii) enabling external stakeholders to more easily understand and engage with the partnership	The benefits of ensuring consistent messaging across ACT-A communications are well recognized. The ACT-A Agency Communications Focal Points will be asked to propose options on strengthening joint ACT-A communications going forward. With the maturing of the ACT-A and its downstream focus, ACT-A will update its information product "How ACT-A Works" to include clear and up to date descriptions of the different ACT-A entities, how they work and available channels for engagement. Following discussion on the ACT-A Strategic Review findings at the 7th Council meeting, the Council is exploring how it can play a more active role in promoting and advocating ACT-A's work over the next 12 months.	Q4 2021

Recommendation	How ACT-A will carry it forward	Timeframe
Communication and information sharing		
9. Build countries' awareness of the full range of products, support, and financing options available from ACT-A partners to boost overall country engagement and ensure ongoing connectedness with national response plans.	The ACT-A Agency Communications Focal Points will be asked to develop proposals on how to increase country awareness of the full range of products, support, and financing options available from ACT-A partners.	Q4 2021
10. Launch a 'data sharing framework' to enhance the quality and increase availability of aggregated programmatic and financial reporting.	Building on the new ACT-A Strategic Plan and Budget (and the strategic priorities and targets set within), ACT-A will enhance its quarterly reporting so that ACT-A's specific contribution to globally agreed targets for access to COVID-19 tools are accounted for and reflected in wider, global monitoring efforts (e.g. in the lead up to UNGA 2022). In keeping with its TORs, the Council discussed ways to support this work during the 7th Council meeting. Council Co-Chairs have proposed to establish a Working Group to focus on tracking progress.	Q4 2021
11. Continue to lead the global movement for equitable response and maintain strong channels of coordination with complementary initiatives for procurement and financing.	This commitment to continue to lead the global movement for equitable access to COVID-19 tools, taking into account the contributions and engagement of others, is well reflected in the ACT-ACT-A's strategic plan for the next 12 months (see Section 2).	Immediate

ANNEX 2: KEY ASSUMPTIONS UNDERPINNING THE BUDGET

These assumptions have been used for costing the procurement funding needs of each of the ACT-A PIllars. All dollar figures shown below are in US$.

VACCINES KEY ASSUMPTIONS

Scope & financing assumptions	Vaccine needs estimated based on total **3.8 billion** population of AMC92 countries. Only adult population covered, with India need capped at 20% of population.
Target & prioritization	Support countries' own vaccination goals, towards the global target of 70%
Available doses and procurement needs	• Donor-funded doses (pledges to COVAX AMC and confirmed donations) account for approximately 2.4 billion doses • COVAX is looking to secure an additional 600 million doses as highlighted in Section 3.1
Key costs	• Vaccine procurement price: $5.2-7/dose

Note: All pending further confirmation at GAVI Board on December 15, 2021.

THERAPEUTICS KEY ASSUMPTIONS

Scope & financing assumptions	**Number of cases** for the next 12 months was estimated via WHO ESFT Tool, by selecting the 50% decrease scenario and extrapolating the ESFT 12-week forecast over the whole budget period. This sums to 142 million new cases in LICs, LMICs and UMICs, excluding China. The extrapolation **accounts for rising vaccination coverage**, assumed to reach 20% by Q4'21, 45% by Q1'22, 70% for Q2'22 and Q3'22. Vaccination coverage is assumed to grant full immunity to the vaccinated population. The estimates also accounts for % beds funded via domestic sources, assumed to be 0% in LICs, 20% in LMICs, 40% in UMICs. Additionally, ACT-A coverage of the medical oxygen need varies by country income group (100% LICs, 60% LMICs, 20% UMICs).

THERAPEUTICS KEY ASSUMPTIONS

Availability of treatment	• Novel oral antivirals (NAVs) for mild/moderate, available from Q1'22 • Selective serotonin reuptake inhibitor (SSRIs) and inhaled corticoids (ICs) for mild/moderate, available from Q4'21 • Oral options for severe/critical, available from Q1'22
Case mix and use cases	**Case mix:** of total 142 million patients, 80% assumed to present mild/moderate symptoms, 15% severe, 5% critical. For hospitalized patients, length of care assumed to range from 7 days for severe to 14 days for critical. **Use cases** • Mild/moderate patients: » In Q4'21, 100% treated with SSRIs/ICSs » From Q1'22, 50% treated with SSRIs/ICSs, 50% treated with NAVs » Prioritized APAs to procure outpatient treatment for 25% patients at highest risk • Severe/critical patients » 25% treated with oral options (not 100% due to foreseen supply chain bottlenecks) » 100% hospitalized patients offered medical oxygenx
Key costs	• NAVs US$10 / course • SSRIs/ICSs US$10 / course • novel oral options for severe/critical US$28 / course • Cost by oxygen source (incl. distribution, planning and TA) » Liquid Oxygen $5,744/bed/year » Gaseous Oxygen $6,452/bed/year » Concentrator $6,700/bed/year » Pressure swing adsorption (PSA) $7,779/bed/year
Other assumptions	An additional sum of cases was included to account for potential variants surges, factoring in 6-weeks of peaks triggering x4 hospitalizations (based on Delta variant impact) – this translates to the equivalent of 35% extra treatments over the course of a year

DIAGNOSTICS KEY ASSUMPTIONS

Scope & financing assumptions	Test needs estimated based on total **5 billion** population of 144 countries in Diagnostics Consortium. **The % tests funded via ACT-A varies by country income group** (100% LICs, 60% LMICs, 20% UMICs excluding China).
Target & prioritization	Total number of tests estimated based on sufficient need to bring **all countries from 0 to 100 tests / 100K people / day**. **75 countries are prioritized** to calculate the "contribution to closing the gap", based on testing rate below target rate in September 2021, plus continued support to countries above target (~6.5 M tests / $60M based on ACT-A support over past 12 months).
Test mix	Assumed split of tests is 85% Antigen RDTs and 15% molecular tests. 0.25% of all molecular samples are sequenced (5% of all positive cases, assuming a 5% positivity rate).
Key costs	• Antigen RDTs » Price $3/ test » Delivery $0.24/test • Molecular tests » Price $15/ test » Delivery $1.95/test • Sequencing tests price: $192.5/ test (delivery inclusive) The 192.5 price point for sequencing include the cost of additional PCRs to confirm positive AgRDTs, so that overall the number of sequencing can be related to the number of tests through a proportion of 0.25% • Waste management cost: $0.044/test • Planning costs » Large country (over 1 million inhab.): $800 000K » Small country (below 1 million inhab.): $590 000

HEALTH SYSTEMS & RESPONSE CONNECTOR: KEY ASSUMPTIONS FOR PPE PROCUREMENT

Scope & financing assumptions	Test needs estimated based on total 5 Billion population of LICs, LMICs and UMICs excl. China. The % PPE funded via ACT-A varies by country income group (100% LICs, 60% LMICs, 20% UMICs excluding China). Procurement for India is capped at 20% of total.
Target & prioritization	Protect the same number of essential health and community health workers per million inhabitants for all in-scope countries, applying the stated financing assumptions: • 750 health workers / million inhabitants • 200 community health workers / million inhabitants These numbers per million inhabitants are sufficient to cover 70% of all workers in LICs. Since other country income groups have more workers per million inhabitants on average, the percentage of workers covered by ACT-A funding will be lower for other country income groups. Prioritize protecting 700 health and community workers per million inhabitants in all countries, to contribute to closing the gap. Prioritized ask includes approximately US$ 500 million to ensure protection of workers for the rollout of ACT-A tools over 12 months. Additionally protect 250 workers per million inhabitants for risk mitigation (e.g., surges, low domestic financing).
Key costs	• $1.7/ day to protect community health workers (CHW) • $8.0/ day to protect other health workers (HW) • Freight & logistics: 20% of PPE price

ACT-A co-convening partners:

Working with goverments, civil society and industry