

Hosted by World Health Organization

ACT-Accelerator Transition Plan

(01 October 2022 to 31 March 2023)

Sustaining access to tools in the transition to long-term COVID-19 control

28 October 2022

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LIST OF ACRONYMS

ACT-A	Access to COVID-19 Tools Accelerator
AMC	Advance Market Commitment [COVAX]
CEPI	Coalition for Epidemic Preparedness Innovations
CoVDP	COVID-19 Vaccine Delivery Partnership
CSO	Civil Society Organization
СТАР	COVID-19 Technology Access Pool
EPI	Expanded Programme on Immunization
EUL	Emergency Use Listing
FinRM	Finance & Resource Mobilization Working Group [ACT-A Council]
G20	Group of Twenty
GAVI	Global Alliance for Vaccines and Immunization
GFATM	The Global Fund for AIDS, TB and Malaria
HICs	High-Income Countries
HSRC	Health Systems & Response Connector
LMICs	Low- and Middle-Income Countries
IPC	Infection Prevention and Control
MPP	Medicines Patents Pool
NAPHS	National Action Plans for Health Security
NAVs	Novel Antivirals
PHSM	Public Health and Social Measures
POC	Point-of-care
PPE	Personal Protective Equipment
PPR	Pandemic Preparedness and Response
PQ	Prequalification [WHO]
RDTs	Rapid Diagnostic Tests
R&D	Research and Development
RM	Resource Mobilization
SPRP	COVID-19 Strategic Preparedness and Response Plan

TAP	Tracking & Accelerating Progress Working Group [ACT-A Council]
TMTF	Tracking and Monitoring Task Force [ACT-A Council]
WHE	WHO Emergencies Programme

WHO World Health Organization

ABOUT THIS DOCUMENT

The ACT-Accelerator Transition Plan (October 2022 to March 2023) was developed in recognition of the need to set out how and in what form ACT-A's work will continue in the six-month period after the <u>ACT-A</u> <u>Strategic Plan & Budget: Oct 2021 to Sep 2022</u> ends.

This plan provides an overview of changes to be introduced in ACT-A's set-up and ways of working to optimize efficiencies and adapt to the ever-evolving pandemic context. It summarizes cross-cutting and Pillar priority areas of focus and highlights which scopes of work will be maintained, transitioned, sunset, or kept on standby in the event there is a major global surge in cases or mortality due to a significant new SARS-CoV-2 variant. It describes how ACT-A coordination and Facilitation Council functions will be consolidated and streamlined while ensuring readiness in the event a reactivation of support is needed. The plan also includes information on additional Pillar funding needs for the 6-month transition plan period.

This plan is complemented by Pillar transition plans which give further granularity on how specific activities will be taken forward during this period and beyond. Hyperlinks to the latter are provided in the text or in footnotes where applicable. The recently published <u>report of the ACT-A</u>. <u>Facilitation Council Working Group on Diagnostics</u>. <u>and Therapeutics</u> was an additional and important input to this plan, especially to the Diagnostics and Therapeutics Pillar transition plans (See Sections 4.2 and 4.3 respectively).

Finally, while this plan is anchored in the current COVID-19 pandemic, perspectives on key ACT-A learnings that could inform thinking about how to better prepare for and respond to future pandemics have also been collated from across the partnership (e.g., Pillar teams, CSO platform, industry representatives). This information will be published as an addendum and companion to the transition plan in the hope that it may provide helpful insights on how to take forward recommendations from the <u>ACT-A External Evaluation</u>, and inform other ongoing processes and discussions on changes to the global health security architecture needed to make a safer and fairer world (e.g. within the World Health Assembly, G20 and other fora).

EXECUTIVE SUMMARY

The ACT-Accelerator Transition Plan (October 2022 to March 2023) was developed in recognition of the need to set out how and in what form ACT-A's work will continue in the six-month period after the <u>ACT-</u> <u>Accelerator Strategic Plan & Budget: October 2021 to</u> <u>September 2022</u> ends. This plan provides an overview of changes to be introduced in ACT-A's set-up and ways of working to optimize efficiencies and adapt to the ever-evolving pandemic context.

The ACT-Accelerator partnership is operating in a new phase of the pandemic. The pandemic may soon be over, but COVID-19 is here to stay. As the world adapts and learns to live with this virus, countries (and the partners that support them), have started the transition to long-term COVID-19 control. A key part of this transition will see the mainstreaming of current COVID-19 emergency work into routine public health and disease control programmes, some of which may need to be adapted to take on these additional functions. Given that the SARS-CoV-2 virus continues to circulate and evolve, countries will need to maintain capacity to surge in response to future COVID-19 waves while this transition is underway.

OVERARCHING OBJECTIVE & MAJOR AREAS OF FOCUS FOR THE NEXT PHASE

The overarching objective of ACT-A's work in the period October 2022 to March 2023 is to support countries through the transition to long-term COVID-19 control, specifically by ensuring they have sustained access to the vaccines, tests, and treatments they need to manage the SARS-CoV-2 virus. This will require:

- i. Focusing ACT-A's research and development (R&D) and market shaping activities to ensure a pipeline for new and enhanced COVID-19 tools. These activities will include spurring further R&D and innovation on vaccines, tests and treatments, continued exchange of information from COVID-19 research (e.g., via the R&D Blueprint), and strengthening capacities to accelerate regulatory approval and prequalification of new or enhanced products.
- **ii.** Securing longer-term institutional arrangements for sustained access to COVID-19 tools (e.g., vaccines, tests, and treatments, including oxygen). This includes support for distributed manufacturing and generics production, procurement (and allocation

as needed) based on country priorities and demand, and sustaining investments made in key infrastructure (e.g., oxygen production capacity). Longer-term institutional arrangements to maintain procurement support in the future will also be established during this period.

iii. Concentrating ACT-A's delivery work on new product introduction and protection of priority populations, in support of national and international targets. This includes intensifying support for vaccine delivery among high-risk and high-priority use populations in countries with low vaccination coverage levels, enhancing country readiness to roll-out new COVID-19 outpatient treatments, and supporting the integration of COVID-19 testing into routine surveillance, including via increased access to sequencing tools.

ACT-A partners will also, in parallel, maintain critical capacities and functions needed to support countries during a surge(s) in COVID-19. This includes maintaining relevant Pillar functions, for example in the areas of research and development, largescale procurement and delivery (see Section 4), as well as broader coordination and support functions, such as for resource mobilization, advocacy and communications (see Sections 5 and 6).

This transition plan has been developed based on the assumption that the current epidemiological and response situation will continue for the next six months - this is the base case. However, to enable planning to ensure readiness, two surge scenarios have been developed and used to identify activities and functions that would need to be maintained or kept on standby in case needed. The reactivation of these functions will be guided by the work of the <u>WHO Technical Advisory</u> Group on Virus Evolution, which monitors and assesses the impact of SARS-CoV-2 variants on transmissibility, disease severity, diagnostics, and therapeutics, and determines whether a given variant constitutes a variant of interest (VOI) or a variant of concern (VOC) according to WHO definitions. (See Section 3 for details).

PILLAR PRIORITIES FOR THE TRANSITION PERIOD

Vaccines (COVAX): Considering the current COVID-19 vaccines context, in particular changing demand for products, including variant containing vaccines,

and the need to sustain delivery support, COVAX has identified several priorities for the transition period. It will focus its R&D work to incentivize further innovation on COVID-19 vaccines, especially with potential need to include them in routine programes going forward. It will continue its policy and regulatory work to guide COVID-19 vaccination, including its integration into broader EPI programmes, and expedite prequalification of COVID-19 vaccines currently under Emergency Use Listing. In the area of procurement, COVAX will seek to secure early access to variant containing vaccines and will rephase existing supply for the remainder of 2022 to minimize wastage and enable servicing of demand in 2023. It will continue to focus its delivery support on helping CoVDP-34 countries reach optimal protection among high-risk groups and national targets.

Diagnostics: The ACT-A Diagnostics Pillar is shifting from an acute response to long-term COVID-19 management with a focus on scale and sustainability. It will focus its upstream R&D, manufacturing and regulatory activities on ensuring the availability and supply of safe, effective, affordable, accessible technologies and on expanding local manufacturing, technology transfer, support for market entry and regulatory approval. It will also scale its support to sustain self-testing and will expand fit-for-purpose genomic sequencing systems to guide public health action for COVID-19 management, as well as overall emergency preparedness, readiness and response. Together with the Therapeutics Pillar, it will increase its support to countries to address diagnostic barriers related to the roll out of new COVID-19 therapeutics.

Therapeutics: New COVID-19 therapeutics have now become available. Supporting countries with the roll out of test-to-treat initiatives, together with the Diagnostics Pillar for those at highest risk of severe disease is a priority focus for the Therapeutics Pillar. The Pillar, has also reorganized and refocused its downstream work on securing, procuring and deploying WHO-recommended therapeutics, including oxygen, to close the access gap in LMICs. The Oxygen Emergency Taskforce will continue to address COVID-19 oxygen, needs, while transitioning to support the development of national roadmaps to address broader oxygen needs, including for health emergencies.

Health Systems & Response Connector (HSRC): Given the evolving context, HSRC activities will be transitioned to individual agencies while keeping warm some selected activities that would need to be reactivated in case of a surge scenario. Tools to support tracking of the rollout of and coverage with COVID-19 countermeasures (e.g. <u>Global Access to COVID-19</u> <u>Tracker</u>) will also be maintained during this period.

MAINTAINING ACT-A SUPPORT FUNCTIONS

The **ACT-A Hub** will continue to support partnershiplevel coordination meetings and support to the ACT-A Tracking and Monitoring Task Force that will continue the work of key Facilitation Council Working Groups during this period. It will also continue to support the development of joint products for tracking and reporting progress (e.g., via the commitment tracker, ACT-Accelerator website, reports, communications products).

The **ACT-Accelerator Facilitation Council** will go into a standby mode after its 12th meeting and will meet as a full group only if needed (e.g. in the event of a major surge in COVID-19 mortality requiring high-level political support). Key Council and Working Group functions will be taken forward by the new Tracking and Monitoring Task Force (TMTF).

The **ACT-A CSO Platform** will continue its role of convening and mobilizing civil society and community representatives who are engaged in those workstreams, Pillars and work of the Facilitation Council Task Force that remain active in the next phase of ACT-A's work.

MAINSTREAMING ACT-A FINANCING DURING IN THE TRANSITION PHASE

A new ACT-A budget has not been developed for this transition plan as many scopes of work under the 2021-2022 ACT-A strategic plan are being carried forward and implemented during this period, and ACT-A Agencies are integrating a lot of COVID-19 costs into their ongoing work and programmes.

However, in recognition that the pandemic has evolved considerably since the last strategic plan and budget was released in October 2021, and hence the operating environment for ACT-A and its Pillars, an exercise was undertaken with the ACT-A Pillars to identify any funding gaps for the next six months. The exercise adjusted the financing gaps to reflect realities of the current pandemic situation, the current demand for COVID-19 countermeasures, and available or expected resources. As discussed with the ACT-A Facilitation Council Finance and RM Working Group (FinRM), the exercise focused on needs of ACT-A agencies. Using a common set of assumptions about the epidemiological situation and existing tools, the Pillars identified a funding gap of US\$ 386 million for ACT-A Pillars and agencies (See Annex 1 for details).

Going forward, the ACT-A Hub will continue to coordinate the monitoring and tracking of ACT-A financing during the transition period (i.e. via the ACT-A commitment tracker). ACT-A partner agencies will, however, primarily utilize their regular RM processes and networks to address financing gaps. The new ACT-A Tracking and Monitoring Task Force will provide an important forum for maintaining a coordinated approach to tracking financing requirements and pledges and facilitating resource mobilization for ACT-A if needed in this next phase.

Given that SARS-CoV-2 continues to circulate and evolve, there continues to be a risk that a new, more serious and/or more transmissible variant may emerge. ACT-A Agencies and the FinRM Working Group concurred that providing estimates of the resources required under the two surge scenarios described in section 3 could be counterproductive. The major uncertainties around essential assumptions for costing a response to such scenarios - related to factors such as the effectiveness of tools, severity of disease, at-risk populations, etc. - result in a very wide range of potential costs. That said, building on the ACT-A experience, it was recognized that if a new, significant and more deadly variant emerges, which evades current countermeasures, tens of billions of dollars could be rapidly required to mount an effective emergency response on a global scale.

NEXT STEPS AND LOOKING TO THE FUTURE

This transition plan covers the period 01 October 2022 to 31 March 2023. The need to extend, adapt or supplement this plan will be considered in Q1 of 2023 (or sooner if there is a major surge in COVID-19 associated deaths), in discussion with the ACT-A Agencies, Council Co-Hosts and Co-Chairs and implementing partners, taking into account the evolving epidemiological and response situation.

It is widely recognized that the ACT-Accelerator was a ground-breaking initiative that was instrumental in advancing access to COVID-19 tools during the pandemic. ACT-A experiences - including findings from the recently completed external evaluation of ACT-A - are already being considered in WHO Member State processes, board-level discussions of ACT-A partner agencies, and other fora. These learnings have informed and will continue to inform thinking about a new pandemic instrument, pandemic financing, and core capacities needed for a future pandemic countermeasures platform.

This transition plan is anchored in the current COVID-19 pandemic, and does not provide specific recommendations about how to address other pandemic pathogens. However, in recognition that discussions on how to better prepare for future pandemics are ongoing, ACT-A partners have compiled some key learnings and reflections based on their experiences over the last three years. These have been included in an addendum to this plan in the hope that they may be useful for those PPR deliberations.

L ACT-A IN A NEW PHASE OF THE PANDEMIC

THE PANDEMIC IS NOT OVER, BUT COUNTRIES ARE ALREADY TRANSITIONING TO LONG-TERM COVID-19 CONTROL

At a global level, the number of COVID-19 cases and deaths reported each week, while still high overall¹, has declined between June and September 2022 (see Fig. 1.1). Many countries, however, continue to experience recurring waves or outbreaks, and there is concern that countries in the northern hemisphere, which are entering the winter flu season, could experience more waves in the coming months.

While the SARS-CoV-2 virus is still circulating and evolving, the pattern of recurring waves or outbreaks observed in many countries since March 2021 is expected to continue, with significant waves being driven by new, more transmissible variants – as was seen with Omicron at the end of 2021.

Given this outlook, it is clear that COVID-19 will be with us for the longterm. Many countries are already adapting to this 'new normal' and have started to consolidate and mainstream their COVID-19 activities into their routine disease control programmes. Ensuring all countries have equitable and sustained access to COVID-19 vaccines, tests and treatments will be crucial in this transition period.

COVID-19 NEEDS TO BE ADDRESSED ALONGSIDE OTHER URGENT HEALTH PRIORITIES

The health impacts of the pandemic have been severe and wide-ranging. WHO estimates that the actual number of deaths from COVID-19 during the period January 2020 to end December 2021 was nearly threefold higher than the number of COVID-19 deaths reported.² Many of these excess deaths were attributed to pandemic-related disruptions of essential health services. According to WHO, 90% of the countries surveyed at the end of 2021 in the '3rd Global Pulse survey on continuity of essential health services during the COVID-19 pandemic' faced ongoing disruptions. Disruptions were reported in all healthcare settings and affected all major health areas, including sexual, reproductive, maternal, newborn, child and adolescent health, nutrition, cancer care, mental, neurological and substance use disorders, HIV, hepatitis, TB, malaria, neglected tropical diseases, care for older people, and routine immunization services.³

In addition to contributing to excess mortality, pandemic-related service disruptions have also contributed to the reversal of important health gains. For example, in July 2022, new WHO and UNICEF data on global immunization rates showed the largest



Fig. 1.1: COVID-19 cases reported weekly by WHO region, as of 12 October 2022.

Source: WHO Coronavirus (COVID-19) Dashboard, <u>https://covid19.who.int</u>, accessed 12 October 2022

¹ Just under 4.2 million new, confirmed COVID-19 cases were reported in the week ending 7 September.

² https://www.who.int/data/stories/global-excess-deaths-associated-with-covid-19-january-2020-december-2021/ ³ WHO 7 February 2022 https://www.who.int/news/item/07-02-2022-essential-health-services-face-continued-disruption-during-COVID-19-

pandemic.

sustained decline in childhood vaccinations seen in nearly 30 years.⁴ An estimated 25 million children under the age of 1 year did not receive basic vaccines, which is the highest number since 2009.

As countries adapt and learn to live with COVID-19, increased attention and focus now urgently needs to also be given to addressing other pressing health priorities. In the near term, this may require harnessing opportunities to utilize COVID-19 activities to simultaneously address other health needs, for example through delivery approaches that mutually benefit essential health services.

THE CURRENT GEOPOLITICAL AND FINANCING LANDSCAPE ADDS FURTHER COMPLEXITY

For nearly two years, COVID-19 dominated the global political agenda. Today, the world is facing multiple competing crises. Several regions are dealing with a second public health emergency of international concern – Monkeypox. Others are grappling with food insecurity, energy insecurity, conflict, and more extreme and more frequent climate-related events.

In this context, available financing for global health, for the current pandemic, and by extension for the ACT-A agencies, is becoming increasingly constrained.

Increased attention is also being directed to the future, to strengthening the global health architecture for pandemic prevention, preparedness, and response (PPR).

Given the need to direct (or redirect) resources and political attention across many equally important issues, sustaining high-levels of momentum and engagement for ACT-A's work in this period will be challenging. However, while preparing the future PPR agenda is important, it should not divert critical political attention away from the current COVID-19 response at a time when accelerating coverage levels across all COVID-19 tools remains urgent.

2 ACT-A'S FOCUS FOR THE NEXT 6 MONTHS: SUPPORTING THE SHIFT TO LONG-TERM COVID-19 CONTROL

This section provides an overview of the three crosscutting areas of focus for ACT-A's implementation work for the next six months. A description of related scopes of work to be implemented for each is also provided.

Considering the previously-outlined changes in the overall pandemic context, the overarching objective of ACT-A's next phase of work will be to support countries as they transition to long-term COVID-19 disease control, in particular by ensuring they have sustained access to the vaccines, tests and treatments needed to manage it. ACT-A partners will also, in parallel, maintain critical capacities and functions to support a surge in COVID-19 (See Fig 2.1). ACT-A partners will support the transition to long-term COVID-19 disease control by:

- i. Focusing Research and Development (R&D) and market shaping activities to ensure a pipeline for new and enhanced COVID-19 tools
- ii. Securing longer-term institutional arrangements for sustained access to COVID-19 vaccines, tests and treatments (including oxygen) for routine programmes as well as national response mechanisms
- **iii. Concentrating delivery work** on new product introduction and the protection of priority populations, in support of national and international coverage targets



Fig. 2.1: Key areas of focus of ACT-A's work for the next six months (October 2022 to March 2023).

In parallel, and as reflected in Fig 2.1, ACT-A partners will also maintain readiness during this period to provide surge support in the event this is needed (see Section 3 for details).

MANTAINING R&D AND MARKET SHAPING ACTIVITIES TO ENSURE A PIPELINE FOR NEW AND ENHANCED COVID-19 TOOLS

Under this area of focus, ACT-A partners will continue to:

- Spur further R&D and innovation on COVID-19 vaccines (including new variant containing vaccines under development), tests and treatments
- Coordinate exchange of information from COVID-19 research (e.g., via WHO's R&D blueprint) to ensure evidence-informed policy recommendations on the use of tools
- Support the strengthening of regulatory capacities needed to accelerate approval and prequalification of new and enhanced products (e.g., through the establishment of pathways from emergency use to full regulatory approval)

SECURING LONGER-TERM INSTITUTIONAL ARRANGEMENTS FOR SUSTAINED ACCESS TO COVID-19 VACCINES, TESTS AND TREATMENTS

This will involve:

- Increasing access to COVID-19 countermeasures through continued support for distributed manufacturing (e.g., via the mRNA vaccine technology transfer hubs and biomanufacturing training hubs) and generics production (e.g., for oral antiviral treatments)
- Continuing to support the procurement (and allocation as needed) of COVID-19 vaccines, tests and treatments, based on country priorities and demand for those tools, while clarifying longerterm institutional arrangements needed to maintain that support in the future

- Securing early access to new and enhanced COVID-19 tools
- Sustaining investments made during the COVID-19 response in key infrastructure (e.g., in oxygen production capacity) to ensure continued access during recurring waves/outbreaks, while transitioning to also address broader health and health systems needs

FOCUSING DELIVERY WORK ON NEW PRODUCT INTRODUCTION AND PROTECTION OF PRIORITY POPULATIONS

This will include:

- Targeting intensified support for vaccine delivery, especially among high-risk and vulnerable populations⁵, with a particular focus on select countries with low coverage levels via the COVID-19 Vaccine Delivery Partnership
- Enhancing country readiness to introduce and roll-out new COVID-19 outpatient treatments for priority (high-risk) populations, including through support for procurement and for implementing and scaling of test-and-treat strategies, bolstered by community engagement, test-and-treat literacy and advocacy, as well as through continued support for the installation and operationalization of oxygen-related equipment
- Supporting the integration of COVID-19 testing into routine surveillance with targeted communitybased approaches to raise testing levels, and via increased access to sequencing tools that can expand capacity to monitor emerging variants of interest

In addition to these three focus areas, and as outlined in Section 3 (pandemic planning scenarios) and Section 4 (pillar plans), critical structures and capacities needed to maintain readiness to reactivate ACT-A partner support in response to a major global surge in COVID-19 will also be maintained during this period.

3 ADAPTING TO AN EVOLVING PANDEMIC: PLANNING SCENARIOS TO REACTIVATE SUPPORT AS NEEDED

This section includes information on the base case and surge scenarios used to inform the development of this transition plan. They were also used by the Pillars to identify which scopes of work to maintain, transition, sunset or keep warm (see section 4) and identify potential funding needs for the six-month transition period (see Section 6).

Given the evolving pandemic, and in recognition that the threat of new concerning variants remains, a base case and two pandemic planning scenarios were used to inform the development of this six-month plan (see Table 3.1). The 'base case' reflects the current epidemiological and response situation, with recurring waves or outbreaks that countries are experiencing at present. This is the case used to inform the development of this transition plan. Two surge scenarios have also been included to facilitate planning and the identification of activities and functions that would need to be 'kept warm' and on standby in case a reactivation of additional ACT-A partner support is needed. This will be guided by the work of the WHO Technical Advisory Group on Virus Evolution, which monitors and assesses the impact of SARS-CoV-2 variants on transmissibility, disease severity, diagnostics, and therapeutics, and determines whether a given variant constitutes a variant of interest (VOI) or a variant of concern (VOC) according to WHO definitions.

Table 3.1: ACT-A Transition Plan base case and surge planning scenarios.⁶

BASE CASE	SURGE SCENARIO 1	SURGE SCENARIO 2
ONGOING OUTBREAKS: countries continue to have recurring waves of COVID-19 as the SARS-CoV-2 virus evolves or immunity wanes. A seasonal pattern of peaks in transmission in temperate zones may also emerge and drive new waves. Available vaccines, tests and treatments remain effective in preventing hospitalizations and mortality and demand for these tools remains relatively stable. Overall, the ongoing outbreaks will have limited impact on the global economy.	 GLOBAL SURGE IN DISEASE: There is a major surge in COVID-19 infections driven by a new, more transmissible variant. Available vaccines, tests and treatments are at least partially effective in preventing hospitalizations and deaths, but health systems are strained due to the large volume of cases. Demand for new and improved COVID-19 tools increases rapidly, constraining equitable access globally. Societies and the global economy may be impacted under this scenario. 	 GLOBAL SURGE IN MORTALITY: major surge in infections and mortality is driven by a new highly transmissible variant that evades current levels of immunity/ protection. There is significant demand for scarce tools as available medical countermeasures do not prevent hospitalization and deaths. In order to ease pressure on health systems, countries may even reintroduce stringent public health and social measures. Societies and the global economy may be heavily impacted under this scenario.

⁶ The 'base case' shown in table 3.1 largely aligns with WHO's 'base case' scenario as reflected in <u>WHO's Strategic Preparedness, Readiness</u> and <u>Response Plan to end the Global COVID-19 Emergency in 2022</u>. Surge scenario 2 aligns with WHO's worst case scenario and Scenario 1 represents an intermediate scenario in which morbidity increases but without a significant associated increase in mortality.

CONSOLIDATION TO SUPPORT THE TRANSITION (BASE CASE)

In the base case, it is assumed that the current epidemiological situation will continue for the foreseeable future. It is also assumed that demand for ACT-A partner support to access COVID-19 tools may oscillate, but not reach a level that will require a substantial increase in procurement and delivery support. In this case, the primary focus for ACT-A agencies and partners will be to support the transition to long-term COVID-19 control, as outlined in Section 2. However, as indicated previously and as reflected in the Pillar transition plans (in Section 4), critical capacities and functions needed to maintain readiness to respond to a major surge in COVID-19 will be maintained under the base case.

RESPONDING TO A MAJOR, GLOBAL SURGE IN DISEASE (SURGE SCENARIO 1)

In the face of a significant global surge in disease, demand for existing, new and/or enhanced COVID-19 tools would increase rapidly. Under this surge scenario, ACT-A partners would likely need to increase their R&D and market shaping activities to enrich product portfolios for vaccines, tests and treatments. ACT-A partners would also need to ramp up their support for large-scale procurement and delivery (including for personal protective equipment and oxygen) to ensure sufficient supply to cover a broader population - geographically and demographically - as per earlier major waves of disease in the pandemic, for example as experienced with the Omicron variant. ACT-A's allocation mechanisms may also need to be reactivated for tools in scarce supply, and support for in-country delivery may need to be increased to expedite the roll out of tools to priority populations.

RESPONDING TO A MAJOR, GLOBAL SURGE IN DISEASE & MORTALITY (SURGE SCENARIO 2)

This represents the WHO's worst-case scenario and would require a full reactivation of ACT-A's work across the entire product value chain to support the development, scaled up production and equitable deployment of available tools such as tests, personal protective equipment (PPE) and oxygen, as well as potentially new vaccines and treatments. In this scenario, which is similar to the context which led to ACT-A's establishment at the start of the pandemic, R&D and market shaping and regulatory activities would need to be increased to facilitate the development and rapid entry to market of new or more effective medical countermeasures. ACT-A agencies would also need to scale back up their support for large-scale procurement of products - many of which would initially be in scarce supply - and in-country delivery to ensure coverage of all affected populations.

4 SUMMARY OF PILLAR TRANSITION PLANS AND PRIORITIES FOR THE NEXT SIX MONTHS

This section provides a summary of Pillar priorities for the next 6 months, taking into account changes in each of the Pillar's operating environment and unique product landscape. Major areas of work and Pillar functions that will be **maintained** (continued during the transition period), **sunset** (discontinued because work is completed or no longer needed), **transitioned** (integrated into the work of one of the ACT-A partner agencies who will take it forward as part of their regular work) or **kept warm** (placed on standby for reactivation in the event needed) are also described.

4.1 VACCINES (COVAX)

The Vaccines Pillar is co-convened by CEPI, GAVI, UNICEF and WHO. Together, the four partners bring a combined expertise across key areas, including: R&D, manufacturing, procurement, shipment, regulatory, policy and country delivery.

CHANGES IN THE VACCINES CONTEXT AND PRODUCT LANDSCAPE

The COVAX partnership was forged during an emergency to provide an end-to-end approach to vaccine development and deployment. It aspires to provide global and equitable access to COVID-19 vaccines. COVAX has achieved unprecedented progress in supporting the development and roll-out of vaccines in low- and middle-income countries. Agreements were signed with 11 manufacturers, and COVAX supply can now meet the needs for vaccinating up to 70% of the population in Advance Market Commitment (AMC) countries and beyond. As of October 2022, 1.8 billion doses were delivered through COVAX to 146 countries, including more than 1.6 billion doses to 87 AMC⁷ countries. Given COVAX's heightened focus on AMC countries in 2021-2022 due to huge inequities in access to vaccines in these countries relative to global production, COVAX has played a fundamental role

in addressing vaccine inequities, providing 80% of vaccines supplied to low-income countries and 37% of those supplied to lower-middle-income countries.⁸

COVAX will continue to support countries to reach their national targets on COVID-19 vaccination with a focus on full coverage of populations in the highest and high-priority use groups.⁹ As of October 2022, 63%¹⁰ of the world population had been vaccinated with the primary series of COVID-19 vaccines and 51% in AMC92 countries. However, primary series vaccine coverage is estimated at only 18% in low-income countries and 24% in Africa. Among the AMC participants reporting on healthcare worker vaccination and vaccination of older populations, 74% and 62% respectively are estimated to have completed primary series vaccination.¹¹ COVAX will continue to support countries in reaching their targets, and in mobilizing booster campaigns for priority populations in line with national targets.

At the same time, the current pervasive perception that the worst of the pandemic is behind us - and limitations in country absorption capacity in some cases - has led to falling vaccine demand from countries as well as lower forward-looking demand expressed by countries. As a result, there has been a reduction in monthly shipments of vaccines from COVAX. This is against the backdrop of a global oversupply of COVID-19 vaccines and sufficient supply through COVAX for all WHO pandemic scenarios.

While the current approach is to support booster campaigns with existing vaccines, the risk of waning protection and emergence of vaccine resistant variants remain. Further evidence is needed on additional booster doses and variant containing vaccines to mitigate those risks. Depending on how the evidence and policy guidance for variant containing vaccines develop, it may have implications for future COVAX R&D, procurement, operations, and delivery activities, particularly if demand for variant containing vaccines outstrips global supply.

⁷ 92 Low- and Middle-Income economies are eligible to get access to COVID-19 vaccines through Gavi COVAX Advanced Market Commitments. ⁸ LMIC figure does not including India and Indonesia, where COVAX provided 9% of doses.

⁹ Global Covid-19 Vaccination Strategy in a Changing World, World Health Organization July 2022 Update.

¹⁰ COVID-19 Vaccine Delivery Partnership Situation Report, October 2022.

¹¹ COVID-19 Vaccine Implementation Analysis & Insights, CoVDP August 2022.

IMPLICATIONS FOR THE WORK OF COVAX

COVAX partners have been reviewing and updating the priorities for COVAX, given this context (see Fig 4.1). The aim is to ensure that COVAX structures are fit for purpose and efficient given the current status of the pandemic but can swiftly respond to any shifts in the pandemic trajectory. Planning has begun to sustain some activities while transitioning or sunsetting others:

- CoVDP¹² and Pillar partners across global, regional, and country level will continue to support the AMC92 countries with concerted efforts targeted at a subset of countries facing challenges in reaching national targets. The focus in the coming months is to achieve optimal protection among highest- and high-risk groups across the AMCs and booster uptake and monitoring, and the longer-term aim is support integration of COVID-19 vaccination into the Expanded Programme on Immunization (EPI).
- Operational teams will shift their processes to be fit for purpose given the current pandemic trajectory. This includes rephasing and reducing existing supply to better match demand patterns

in 2022 and 2023, a shift in demand forecasting and allocation approach given that supply now exceeds demand and planning for the possible procurement of variant containing vaccines (if required).

- An agile approach to allocation will be maintained: To more efficiently address limitedvolume requests and respond timely to country needs in the current context, an agile allocation process has been introduced, in which, ad-hoc country requests are gathered and allocated against available supply in real time. Periodic assessment of the allocation process and the pandemic evolution throughout 2022 will indicate the need to revisit the allocation process to ensure equity in case the demand-supply landscape shifts again.
- Coordination and leadership teams will continue to support delivery and transition efforts while also ensuring that the objectives, frequency, and COVAX coordination support available to partners is appropriately sized to meet demand.

Fig. 4.1: Key COVAX PIllar priorities for Q3/4, 2022 (agreed June 8, 2022	Fig.	4.1: Key COVA	Verify the second se	s for Q3/4, 2022	(agreed June 8, 2022)
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VALUE CHAIN AREA	KEY PRIORITIES	COVAX LEAD(S)
R&D	• Spur innovations ^a on C19 vaccines , especially with potential need to "routinize" them going forward	CEPI/ WHO
Regulatory and Policy	 Policy recommendations on additional booster doses, variant containing vaccines, etc. WHO PQ process for vaccines currently under EUL 	WHO
Procurement	 Rephase existing supply to minimize wastage in 2022 and be able to serve demand in 2023 (and beyond) Secure early access to variant containing vaccines 	Gavi/ UNICEF SD
Delivery	 Provide concerted support for CoVDP-34 countries to reach national target Focus on reaching optimal protection among high-risk groups across the Al Focus on booster uptake and monitoring across AMCs 	
Overall	 Shift COVAX operations to be fit for purpose for near term Plan for programmatic integration of C19 with broader EPI Document and communicate COVAX successes externally Ensure COVAX learnings are embedded in PPR thinking 	PIllar Leadership

^a Innovations to achieve broader variant coverage, increased duration of protection, transmission reduction, easier modes of administration (nasal, patch, etc.), increased temperature stability of mRNA candidates, etc.

¹² Recognizing the urgency of transforming vaccine doses into immunized communities, UNICEF, WHO, and Gavi launched the CoVDP in January 2022, an inter-agency initiative building on existing resources globally, regionally and in-country to accelerate COVID-19 vaccination in countries with the lowest coverage. The CoVDP primarily supports the 34 countries that were at or below 10% coverage in January 2022 and provides urgent, concerted support to a small, rotating list of countries. **Discussions have begun on the need for a possible routine COVID-19 vaccine programme in future**. This has implications for the work of COVAX this year, including in the planning for the transition of COVAX structures into a future model of collaboration on COVID-19 vaccination and preparing for programmatic integration of COVID-19 with broader EPI at the country level. Within COVAX:

- R&D, manufacturing, and marketplace teams will continue to work on incentivizing innovations in COVID-19 vaccines especially with the likely need for vaccines that are suitable for routine COVID-19 vaccination going forward.
- Policy teams will continue to develop recommendations to guide COVID-19 vaccination including on guidance on additional booster doses, variant containing vaccines, and on the programmatic integration with broader EPI. Vaccines currently under EUL will also need to achieve full WHO PQ status for use going forward.
- Operational teams will refine and integrate processes (e.g. on demand planning, allocation etc.) as needed to best serve the possible future

routinized COVID-19 vaccination programme as well as embed applicable learnings from COVAX into broader routine immunization.

Efforts have also begun to ensure COVAX achievements and lessons learned are incorporated into the future pandemic preparedness and response (PPR) architecture. This includes documentation and recommended next steps for many of the innovations, key learnings, processes and partnerships integral to the COVAX experience for broader PPR discussions. At the same time, the pandemic is not over and COVAX will continue to adapt to the changing needs, including through a transition to a more regular and integrated way of working to continue to address COVID-19 (as mentioned above).

SUMMARY OVERVIEW OF ADJUSTMENTS TO BE MADE TO COVAX SCOPES OF WORK

Table 4.1 provides an overview of COVAX transition plans and adjustments to be made to specific scopes of work during this period.

	Workstream	Overview	Adjustments to COVAX scopes of work	Transition Strategy
1	R&D and Manufacturing	Investment in R&D for COVID-19 vaccines and support for manufacturing, including for regional diversification.	Transition	Transitioned into partner processes , with continuing operational discussions through existing bilateral channels between partner organizations.
2	Deal & Portfolio Strategy	Management of advance purchase agreements with manufacturers, unblocking of issues, and resolution of supply issues, including through the One Deal team.	Maintained	Maintained at increased levels, especially around rephasing and reducing existing supply contracts to better serve demand patterns going forward and planning for the procurement of variant containing vaccines (if required).

Table 4.1: Summary overview of COVAX transition plans (October 2022 to March 2023).

	Workstream	Overview	Adjustments to COVAX scopes of work	Transition Strategy
3	Operations	Support for end- to-end operations, including allocation, demand planning, downstream product operationalization, procurement logistics and shipping, and data and analytics.	Maintained	Maintained at reduced levels, in line with country demand/need, with potential to scale back up in case of epidemiological changes. Operational processes will be streamlined to ensure they are fit for purpose for reduced volumes, including adaption of allocation processes to suit demand and supply situation. In the longer term, the aim is for COVID-19 vaccine operations to be integrated into a routine-like future COVID-19 vaccine programme (under discussion) and/or "kept warm" as part of a broader PPR structure (also under discussion).
4	Delivery support	Country engagement, readiness, and support for provided through the COVID-19 Delivery Partnership.	Maintained	Maintained at increased levels for targeted goals and countries, to accelerate countries reaching their national targets for the full vaccination of priority populations. Delivery support is expected to continue to scale up, including through integration with routine immunisation and other PHC interventions, before shifting to a more targeted approach (e.g., for booster campaigns, humanitarian situations, etc.). In the longer term, the aim is for COVID-19 delivery support to be integrated into broader EPI and routine primary care services.

	Workstream	Overview	Adjustments to COVAX scopes of work	Transition Strategy
5	Policy, Strategy and Programme Design	Development of policy, regulatory, and programmatic guidance, including SAGE, the global COVID-19 vaccines strategy, and future COVID-19 vaccine programme design.	Maintained	Maintained at increased levels across partners, to design a possible routine COVID-19 vaccine programme going forward. This includes a refresh of the Global COVID-19 vaccine strategy, evolving SAGE, programmatic and regulatory guidance, as well as the design of a Gavi Alliance COVID-19 Vaccine programme (Gavi 5.1).
6	Leadership and Coordination	Delivery of coordination meetings - including the COVAX Coordination Meeting, the Pillar Leadership Team, Workstream Conveners – and cross-partner coordination mechanisms, including the Strategic Coordination Office.	Maintained	Bespoke Pillar activities will be maintained at reduced levels in line with both the movement into more regular ways of working and reduced operational activities, while ensuring sufficient support for delivery and transition activities. In the longer term, the aim is for COVID-19 vaccine operations to be integrated into the future COVID-19 approach (see above). For CoVDP specifically, the work is also being tracked and monitored through the Gavi Alliance COVID-19 Vaccination Delivery Support Temporary Steering Committee.
7	Resource Mobilization	Cross-partner coordination of resource mobilization activities, including on dose donations.	Kept warm	Kept warm for the eventuality that additional COVAX- specific funding and RM is required, likely due to a shift in the current pandemic or in broader PPR approach. Otherwise integrated into business-as-usual partner processes for both a possible COVID-19 vaccine programme and broader PPR engagement activities.

4.2 DIAGNOSTICS

The Diagnostics Pillar is co-convened by FIND and Global Fund with WHO providing leadership. The Diagnostics Pillar works alongside 50 global health partners to scale-up equitable access to COVID-19 diagnostic tools and resources.

CHANGES IN THE DIAGNOSTICS PILLAR CONTEXT AND PRODUCT LANDSCAPE

Diagnostics are an essential tool to combat

COVID-19 and were the first tools deployed via ACT-A through the leadership of the ACT-A Diagnostics Pillar to support the global COVID-19 response. Diagnostics enable countries and the global community to understand transmission dynamics and implement timely countermeasures, including nonpharmaceutical interventions, vaccines, and newly emerging treatment options. Moreover, recent modelling efforts show that, when linked to timely treatment, the proportion of deaths averted increases with increasing testing rates. However, in the current pandemic context, the global community faces challenges regarding the continued prioritization of COVID-19 diagnostics.

Despite the evolving pandemic and recent increase in cases, hospitalizations and deaths, there is a growing sense of COVID-19 fatigue. The exhaustion of health workers and the public, coupled with competing national and local priorities, has exacerbated the challenges and further reduced the already-suppressed demand for testing, screening and diagnosis of SARS-CoV-2. Most notably, testing rates have fluctuated over time based on the epidemiologic context but are now on a continued downwards trajectory. The alarming decline in reported testing rates has continued throughout the pandemic, with low-income countries testing at an average of .03 tests per day per 1,000 population at the end of August 2022,¹³ while the WHO surveillance test target is 1 test per 1,000 population per week¹⁴- the minimum testing rate required for timely identification of new variants. Testing is not only important for surveillance but also critical to limit the spread of the virus. Without sufficient use of diagnostic tools and resources, the world risks undoing the hardearned public health gains achieved. Furthermore,

without adequate diagnostics, we cannot ensure that people everywhere have timely or equitable access to effective therapeutics and are blind to patterns of virus transmission and evolution that current therapies and vaccines may not cover.

Reflecting on the progress to date, through the support of the ACT-A Diagnostics Pillar and its partners in-country and globally, significant strides have been made to scale up equitable access to COVID-19 diagnostics to save lives. From the start of the pandemic in Q1 2020 to August 2022, 177.67m tests were procured, and 141.22m tests were delivered for countries in need¹⁵. Additionally, over the course of the pandemic, partners have negotiated price reductions of approximately 30-50%. PCR tests were priced between \$20-30 and are now less than \$10, while quality assured Ag RDTs (both professional use and self-tests) were initially priced at \$5 and are now between \$1 to \$2. Furthermore, investing in laboratory systems and strengthening national surveillance systems, including laboratory and genomic surveillance, has allowed countries to be better prepared for new waves of COVID-19 and serve as a platform for resilient pandemic preparedness. The global community has the necessary diagnostics tools and resources available at affordable prices to respond to COVID-19 and has never been in a stronger position to fight this pandemic. Looking forward, to achieve scale, sustainability, and continued preparedness, the global community, with support from the ACT-A Diagnostics Pillar, needs to continue partnering to deliver on key diagnostics priorities.

The ACT-A Diagnostics Pillar is the first of its

kind, prior to the ACT-Accelerator, there had been limited convening of partnerships in the diagnostics space in an end-to-end manner across a range of organisations at the global, regional, and country level to deliver on public health priorities. The Diagnostics Pillar is composed of 5 Working Groups, each addressing various aspects of the diagnostic value chain to ensure availability of low-cost and high-quality diagnostic tools and resources. Working Groups are led by agencies with expertise in the space and membership is drawn from an array of technical specialists, with civil society represented on each Working Group (see Fig 4.2).

¹³ FIND Test Tracker – 01 July 2022 Data <u>https://www.findDiagnostics.org/ COVID-19-19/test-tracker</u>.

¹⁴ https://www.who.int/publications/ii/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-

interim-guidance.

¹⁵ WHO COVID-19 Global Supply Chain Dashboard.

Fig 4.2: ACT-A Diagnostic Pillar working groups.



In addition to the Working Groups, there are two overarching coordination forums. The Coordination Committee comprised of Working Group leads and convening organisations to provide a smaller forum to discuss key issues related to the Pillar; and the larger Partnership meeting consisting of all Pillar partners and funders as a forum for information sharing and wider engagement. Beyond these regular structures, the Pillar also convenes ad-hoc forums or specific technical initiatives including joint sessions across Working Groups on cross-cutting issues (such as multiplex platforms or self-testing); country engagement sessions at the global and regional level to engage on concrete diagnostics priorities; and the ACT-A Diagnostics Modelling Consortium supporting on diagnostic modelling efforts.

The Working Groups of the Pillar play a central role in priority setting, information sharing, intervention design, periodic monitoring and disseminating insights from work while operational and programmatic management of projects is managed by each agency. Working Group engagement is conducted via regular meetings or via partner membership in other coordinating bodies, such as the Global Fund C-19 Technical Advisory Group. The ACT-A Diagnostics Pillar recognizes a continued need to focus on COVID-19 diagnostics, and as the pandemic evolves, new and meaningful approaches and narratives to address diagnostics needs will need to evolve in parallel. To inform this process, the Diagnostics Pillar has extensively consulted with Working Group leads and key stakeholders, including civil society representatives, to gather feedback on effectively prioritizing diagnostics activities moving forward. In addition, a survey was designed and shared broadly across the Pillar to support these efforts.

Input from the consultations and Pillar survey were used to develop a comprehensive transition plan that prioritizes the activities and structures required to ensure continued successful impact for diagnostics and to provide a mechanism to scale back as needed. Additionally, alongside finalizing the Diagnostics Pillar activities, the Pillar has begun working on a knowledge management platform to ensure learnings and resources for diagnostics generated throughout the pandemic are accounted for and can be utilized by partners and countries over the long term.

IMPLICATIONS FOR THE WORK OF THE DIAGNOSTICS PILLAR

The ACT-A Diagnostics Pillar is shifting from an acute response to long term COVID-19 management with a focus on scale and sustainability. The continued efforts are aligned with the need for a stronger, inclusive, equitable and coherent health emergency preparedness, response, and resilience (HEPR) architecture.¹⁶ As such, efforts will continue to be undertaken to achieve the following diagnostic priorities:

- 1. Manufacturing and Regulation: Ensure availability and supply of accurate, affordable diagnostic tools, through expanded local manufacturing, tech transfers, and support for market entry and regulatory approval.
- 2. Scale to Sustain Self Testing: Scale, improve and sustain equitable access to testing through procurement, strengthening diagnostic systems including expanding decentralized models of care, scaling self-testing in both the public and private sectors, and integrating COVID-19 diagnostics into the overall health system, especially communitybased settings, thereby enhancing comprehensive patient-centered care (i.e., integrated testing, bidirectional screening).
- 3. Test to Treat: A joint approach has been developed with the Therapeutics (Tx) Pillar, with work already underway, and expected to continue at relatively high intensity for the next 6-9 months. Addressing diagnostics barriers is key to enable effective roll-out of therapeutics, and the two Pillars (Diagnostic and Therapeutics) will therefore focus on further strengthening their collaboration. Policy, training, and financing have all been barriers to scaling-up diagnostic usage in-country, and indeed testing rates persistently remain low across many LMICs. Continuing to address these barriers remains critical to support outpatient treatment scale-up. The COVID-19 epidemiological situation continues to fluctuate. Therefore, to ensure that effective diagnostics and therapeutics reach populations most in need, the ACT-A Diagnostic/Therapeutic Pillars' joint efforts will be agile to support countries to

effectively offer appropriate services to reflect different epidemiological scenarios. In particular, this means increasing test-and-treat health literacy and establishing and refining test-andtreat programs that can be i) targeted at high-risk populations between waves and ii) scaled to meet increased demand during more intense waves as appropriate.

- 4. Research & Development: Investing in leaping forward the development and roll out of affordable, accessible technologies with a focus on digital tools, and multiplex platforms (i.e., multiplex molecular POC respiratory assays). In addition, the Pillar plans to continue working with partners to determine how to collaboratively address challenges related to regulatory approvals, technology, human resource capacity, etc. in this space post the COVID-19 pandemic.
- 5. Genomic sequencing: Expanding fit-for-purpose genomic sequencing systems, strengthening the integration of epidemiological and genomic data to guide public health action for COVID-19 management as well as regional and global emergency preparedness, readiness and response.
- 6. **Preparing for the next threat** by improving rapid detection, development and deployment of diagnostic tools.
- 7. Knowledge Management: Creation of a knowledge management platform to ensure learnings and resources for diagnostics generated throughout the pandemic are stored in an accessible, user-friendly format relevant for stakeholders at the global, regional, and country levels. Furthermore, the creation of this platform provides an opportunity to leverage learnings from the pandemic and transpose these to other disease areas and other diagnostic challenges.

¹⁶ https://www.who.int/publications/m/item/10-proposals-to-build-a-safer-world-together---strengthening-the-global-architecture-for-health-emergency-preparedness--response-andresilience--white-paper-for-consultation--june-2022.

SUMMARY OVERVIEW OF ADJUSTMENTS TO BE MADE TO PILLAR SCOPES OF WORK

The ACT-A Diagnostics Pillar will maintain its existing structures and will continue supporting ongoing funded activities over the next 6 to 9 months.

Moreover, whenever applicable, working groups will coordinate activities by holding joint meetings across the diagnostics value chain to collaborate, problem solve, and share learnings to maximize impact. The ACT-A Diagnostics secretariat team will also continue to support the work of working group leads and create settings for leads and key partners to consistently meet in order to discuss how activities can be better coordinated and supported across working group priorities. Strong engagement and collaboration with civil society organizations will also continue during and after the transition period.

	Activities / meetings	Overview	Adjustments to Pillar scopes of work	Transition strategy
1	ACT-A Diagnostics Partnership Meeting	Monthly large group sessions with members from all Diagnostics Pillar partner organisations. The meetings cover updates on progress across working groups and alignment on goals and priorities of the Diagnostic Pillar overall.	Maintain	Continue to maintain monthly sessions, with the aim to reduce intensity and cadence of coordinating meetings over time.
2	ACT-A Diagnostics Coordination Committee	Monthly small group sessions with Diagnostics Pillar Working Group Leads, Key Partners and CSOs covering updates on working groups, problem-solving challenges, and key bottlenecks.	Keep warm	Move from monthly cadence to meet on an as need basis.

Table 4.2: Summary overview of the ACT-A Diagnostic Pillar's transition plans (October 2022 to March 2023).

	Activities / meetings	Overview	Adjustments to Pillar scopes of work	Transition strategy
3	Joint/Special Sessions on Diagnostics	As needed, topic- specific, large group sessions with all Diagnostic Pillar Partners with an open invite to the wider ACT-A partnership. Dedicated time to update or problem solve on priority topics. (i.e., multiplexing, decreasing testing rates), etc.	Keep Warm	Setup meetings when needed to reflect priorities and collec- tive objectives of Diagnostic Pillar partners.
4	Diagnostics Knowledge Management Platform	Development of a Knowledge Management platform to ensure learnings and resources for diagnostics generated throughout the pandemic are stored in an accessible, user- friendly format relevant for stakeholders at the global, regional, and country levels.	Maintain	The Knowledge Management platform is currently under development and will be worked on over the transition period. The goal is to have the platform accessible to the diagnostics community, while also serving as a platform for users to share, innovate, reuse, collaborate, and learn from everyone's collective experiences.
5	Modelling Consortium	Ad hoc meetings to develop and review models designed to determine diagnostics tools impact and resource- requirements.	Keep warm	Setup meetings if needed and when requested by Diagnostic Pillar partners to support coordination of modelling efforts.

	Activities / meetings	Overview	Adjustments to Pillar scopes of work	Transition strategy
6	Advocacy and CSO Engagement (ACT-A Civil Society Platform)	Monthly meetings held between the Diagnostics Pillar and CSOs to share updates on progress across working groups and alignment on goals and priorities of the Pillar overall.	Maintain	Continue to maintain cadence over the transition period.
7	Research & Development of Tests and Digital Tools	Promote development of the right tests for the right use cases, including incorporation, where appropriate, of fit-for-purpose and innovative digital/data solutions.	Maintain	 Specific activities within this working group will continue. Activities include: WHO PQ team will continue to ensure efficient EUL and prequalification mechanisms for critical diagnostics. WHO technical team will continue to lead on global policy development. CTAP¹⁷ to continue over long term. Strengthen local capacity and technology transfers for the development and deployment of SARS-CoV-2 tests and POC respiratory assays. Support digital solutions and data reporting tools. Cross cutting initiatives will be worked on in collaboration with the Market Readiness and Country Support Working Groups.

	Activities / meetings	Overview	Adjustments to Pillar scopes of work	Transition strategy
8	Market Readiness Working Group	Drive availability of innovative tests through market shaping and integrated delivery models, including projects that enable evidence-based implementation and scale up of diagnostics across LMICs.	Maintain	Specific activities aligned with the overall objective of this working group will continue by individual partners to enable successful market shaping from both supply and demand sides, linking closely with the R&D, Country Support Working Group and Diagnostics Consortium for COVID (UN COVID-19 Supply Chain Consortia).
9	Diagnostics Supply Consortium	Ensure equitable provision of critical and affordable COVID-19 diagnostics globally.	Maintain	WHO will continue to lead coordination of this group, including collation and dis- semination of procurement and supply data. This group will closely link with the R&D, Country Support Working Group and the Market Readi- ness Working Group. Activities include assessment of molecu- lar testing footprint, coordina- ted forecasting, supply chain bottleneck reviews, etc.
10	Procurement	Procurement of diagnostic tests and resources.	Maintain	Continued procurement of tests by Dx Consortium partners.

	Activities / meetings	Overview	Adjustments to Pillar scopes of work	Transition strategy
11	Country Support Working Group	Ensure availability and in country adoption, implementation and scale up of the right tests for the right use cases.	Maintain	Implementation projects are underway in partnership with countries. Global Fund will continue to work with countries to implement C19RM awards adapted to countries that support building health systems' capabilities. Country implementation projects including advocacy, training, testing using decentralized models of care, self-testing, and test and treat projects (working closely with the Therapeutics pilar) will continue until project completion in 2023.
12	Genomic Surveillance Working Group	Strengthen integrated genomic surveillance within routine surveillance systems and market access to sequencing.	Transition	As part of the <i>Global genomic</i> <i>surveillance strategy for</i> <i>pathogens with pandemic</i> <i>and epidemic potential</i> , 2022-2023, WHO is convening a Partners Coordination Group that focuses on global programmatic aspects that facilitate strategy implementation. All Global Surveillance Working Group members will now meet and transition to the Partners Coordination Group which will enable coordination of SARS- CoV-2 sequencing efforts within a broader ecosystem.

4.3 THERAPEUTICS

Co-convened by Unitaid, Wellcome and the Global Fund with WHO leading on product assessment, regulatory and access & allocation work.

CHANGES IN THE TX PILLAR CONTEXT AND PRODUCT LANDSCAPE

COVID-19 therapeutics are becoming available and roll-out of COVID-19 test-and-treat initiatives for those at highest risk of severe disease is now the priority. Oral antivirals can prevent hospitalization and save the lives of patients most at risk of developing severe COVID-19. This is especially valuable in lowand middle-income countries (LMICs), where average vaccination rates are still low.¹⁸ Since March 2022, WHO treatment guidelines include recommendations for novel oral antivirals for patients with non-severe COVID-19 at highest risk of hospitalization, in addition to other medicines, and oxygen, recommended for patients with severe or critical COVID-19.¹⁹

ACT-A Therapeutics (Tx) Pillar partners have made significant progress laying the groundwork to increase the availability of priority therapeutics

in LMICs. When there was a global shortage of medicines to treat hospitalized COVID-19 patients, ACT-A partners secured supplies of tocilizumab to support countries with unmet needs.²⁰ More recently, ACT-A partners secured supply agreements with MSD and Pfizer for up to 13 million treatment courses of originator oral antivirals.²¹ Partners also supported the process to ensure broad access to oral antiviral generics: The Medicines Patent Pool (MPP) secured voluntary licensing agreements with MSD and Pfizer; signed sublicensing agreements with generics manufacturers^{22,23} and; supported generic product submissions to the WHO Prequalification Program.^{24,25} UNICEF established over 10 conditional supply agreements with generic manufacturers for the supply of molnupiravir with large supply capacity.²⁶

In parallel, COVID-19 has catalysed rapid changes to the oxygen landscape, with unprecedented funding for oxygen becoming available to address the huge surge need by countries but also offering opportunities for countries to strengthen their overall oxygen systems and close basic gaps that pre-existed before COVID-19. Available financing and strategic planning coupled with large procurement efforts have delivered oxygen equipment at unprecedented levels. Donors have mobilized more than US\$800 million in grant financing to help LMICs avert oxygen shortages, mostly through the Global Fund and the World Bank. Through the work of the Tx Pillar's Oxygen Emergency Taskforce, LMICs are now prioritizing oxygen with nearly 20 countries developing long-term national oxygen roadmaps. The Taskforce has also helped shape the oxygen market. Industrial companies are now engaging with multilateral partners and Ministries of Health and for the first time and i) made commitments to improve their capacity in LMICs and ii) agreed to price reductions for bulk liquid oxygen and filled cylinders to meet demand surges.

Although these advancements represent a pivotal milestone in the COVID-19 response, challenges to effectively roll-out therapeutics remain.

Recent evolutions of the COVID-19 pandemic, such as the emergence of new variants, and periods of low incidence in many countries, have significantly impacted the public's risk perception and healthseeking behaviour. This is despite the fact that transmission levels remain high even in areas with widespread vaccination. Accordingly, testing rates remain concerningly low in LMICs²⁷ and this limits i) potential Tx uptake and ii) visibility on the emergence of future variants. Furthermore, relatively complex treatment eligibility criteria for novel antivirals (high-risk patients, within five days of symptom onset) pose additional challenges in contexts with already stretched health systems. In addition, the Tx Pillar work has been impacted by several factors including price transparency, intellectual property and regulatory barriers. These, in addition to ensuring that voluntary licenses for generic manufacturing cover the broadest geographical scope, have slowed

²⁵ ACT-A Therapeutics Pillar Market Discussion (Manufacturing and Pricing), April 2022.

¹⁸ As of March 2022, of the more than 10 billion COVID-19 Vx doses given out worldwide, only 1% have been administered in low-income countries (<u>link</u>).

¹⁹ Therapeutics and COVID-19: living guideline (link).

²⁰ Joint Statement from Unitaid and the WHO (on behalf of the ACT-A) regarding availability of tocilizumab, August 2021 (<u>link</u>).

²¹ For molnupiravir, UNICEF signed a supply agreement with MSD in December 2021 for up to 3 million treatment courses (<u>link</u>). For nirmatrelvir/ritonavir, UNICEF signed a supply agreement with Pfizer for 4 million treatment courses in March 2022 (<u>link</u>), and the Global Fund has signed an agreement with Pfizer in September 2022 (link).

²² MPP Molnupiravir page on VL and sublicensing (link).

²³ MPP Nirmatrelvir/Ritonavir page on VL and sublicensing (<u>link</u>).

²⁴ WHO PQ Tracking June 2022, "Status of COVID-19 Medicines and APIs (<u>link</u>).

²⁶ UNICEF enters supply agreements for COVID-19 oral antiviral generic medicine Molnupiravir (<u>link</u>).

²⁷ Low-income countries testing at an average of just 5 tests per day per 100,000 people – far from the goal of 100 per day (link).

the Pillar's ability to roll-out Novel Antivirals (NAVs). In addition, while significant investment has been made in oxygen, it has mostly been for procurement of certain types of equipment, leaving other crucial needs underfunded. More attention and resources must be dedicated to human capital to install, optimize, and maintain equipment, market shaping to improve oxygen affordability and sustainability and demand generation.

IMPLICATIONS FOR THE TX PILLAR'S WORK

The Tx Pillar is transitioning towards a longerterm COVID-19 management strategy, focusing on supporting countries to set up test-and-treat programs to prepare for future surges and other health threats. The current epidemiological situation for COVID-19 is still in flux. Therefore, whilst it is critical to ensure that existing Tx reach populations most in need, ACT-A Tx's work will focus on enabling countries to effectively deal with different epidemiological scenarios going forward. In particular, this means working to establish and refine test-and-treat programs now, with the aim of being used either for i) targeted test-and-treat for high-risk populations between waves or ii) test-and-treat at broader scale during waves. A joint approach will be developed with the Diagnostic (Dx) Pillar, with work already underway, and expected to continue at relatively high intensity for the next 6-9 months.

For oxygen, there will be a transition of the ACT-A Oxygen Emergency Taskforce to a more sustainable and representative Global Oxygen Alliance. The Alliance is expected to drive global advocacy, mobilize financing, and support countries with technical cooperation, capacity building and demandgeneration, to ensure that investments in oxygen systems made during the COVID-19 crisis are sustained.

This shift requires ACT-A Tx Pillar partners to increase their strategic emphasis on downstream activities. As one aspect of that shift, the Tx and Dx Pillars have set up the Test-and-Treat Country Support Coordination Group. At the second Global COVID-19 Summit in May 2022, ACT-A partners and the US Government announced over \$120mn in additional support to setup test-and-treat programs.²⁸ The Coordination Group (which includes BMGF, CHAI/Duke, the Global Fund, UNICEF, FIND, Unitaid, USAID, and WHE/HSRC) meets regularly, sharing information and intelligence, to ensure complementarity of programs, avoid duplication of efforts, and link pilot test-and-treat programs to larger-scale financing and procurement via C19RM, UNICEF, and the WHO Partners Platform.

The Tx Pillar is committed to strengthening communication with country stakeholders so as to more prominently address countries' priorities. Existing communication fora will be bolstered (e.g., joint WHO/GF/UNICEF country briefing calls and agency-specific updates), and new dedicated channels may be created (e.g., open webinars), to provide and receive inputs from country stakeholders, including communities and CSOs. Acknowledging the key role of communities and civil society, the Tx and the Dx Pillars are also supporting test-and-treat health literacy, advocacy and community engagement efforts to increase access to and uptake of COVID-19 testing and therapeutics²⁹ in 19 countries.

SUMMARY OF ADJUSTMENTS TO THE TX PILLAR'S WORK

The ACT-A Tx Pillar has re-organized its activities in line with its renewed focus on downstream activities to close the access gap in LMICs for WHO-recommended treatments and enhance country preparedness. In May 2022, The Global Fund joined Unitaid and Wellcome as a co-convenor of the ACT-A Tx Pillar, reflecting the increased focus on downstream activities where Global Fund plays a key role. To streamline activities, the Tx Pillar re-organized along four main workstreams that focus on 1) securing, 2) procuring, and 3) deploying therapeutics, and 4) oxygen. The new structure reflects the Tx Pillar's shift of focus, as the "upstream" scopes of work (previously "Rapid evidence assessment" and "Market preparedness workstreams") are merged under a single workstream with decreased levels of activity (the new "Secure" workstream), while the country preparedness work is scaled up to a dedicated workstream with increased activity (the new "Deploy" workstream), focused on coordinating financing and technical assistance across countries.

WHO will continue to update guidelines and provide quality assurance for existing and emerging Tx. Products and corresponding manufacturing (and clinical) site(s) that meet WHO recommended standards, will continue to be included in the list of medicinal products that are considered to be acceptable for procurement by ACT-A partners and others. Treatment guidelines will continue to be updated as evidence on the use of products becomes increasingly available. WHO will also continue to play a key role in safety, efficacy and quality assurance,

²⁸ The Global Fund, United States and Unitaid Launch "Test-and-Treat" Programs at Second Global COVID-19 Summit (<u>link</u>).
²⁹ FIND and Unitaid invested US\$2 million to support advocacy for COVID-19 test-and-treat approaches in low- and middle-income countries (<u>link</u>).

for example through its Prequalification process and Collaborative Registration system (including pharmacovigilance).

The ACT-A Tx Pillar will continue to support national and global efforts to increase access and affordability of products for treatment of COVID-19. Tx partners will continue to promote equitable access for current and new products (incl., broad-spectrum antivirals), to strengthen the COVID-19 treatment formulary and create more resilient markets in preparation for potential future outbreaks.

The Oxygen Emergency Taskforce will maintain a coordination role during the ACT-A transition period. The Taskforce is scoping ways to transition its architecture and functions from an emergency pandemic model to sustainable endemic model to address all priority oxygen access use cases and realize maximum impact of ongoing and new investments, to support countries in developing oxygen strategies and ensuring long-term plans and resources to maintain and further scale oxygen, and to strengthen health systems and future pandemic preparedness. Taskforce members are discussing the formation of a Global Oxygen Alliance and working on a structure that is centered on country engagement.

Tables 4.3 and 4.4 provide an overview of adjustments to be made to specific Tx PIllar scopes of work. The lead agency in each workstream will continue to work closely with other Tx Pillar members in line with the partners' expertise.

	Workstream	Overview	Adjustments to Pillar scopes of work	Transition strategy
1	Secure	Facilitate R&D, market entry, and enable supply at scale of new treatments.	Keep warm	Wellcome, BMGF and Unitaid will maintain involvement in current clinical trial platforms generating evidence on treatment regimens for COVID-19, with no additional studies in the horizon.
			Keep warm	WHO will continue to continue track the pipeline to identify potential priority products, and new evidence on use of current products, to enable early market and country preparedness.
			Maintain	WHO will continue to lead updates to COVID-19 treatment guidelines and clinical management guidelines.
			Keep warm	Unitaid will continue to lead engagement with manufacturers for equitable access, including with (i) originators as novel products are identified as high priority by WHO (ii) with MPP and generic manufacturers to support prompt development and PQ submissions for early procurement and introduction in all low and all middle-income countries and (iii) addressing persisting access barriers in countries excluded from access plans.

Table 4.3: Summary overview of the ACT-A Therapeutic Pillar's transition plans (October 2022 to March 2023).

	Workstream	Overview	Adjustments to Pillar scopes of work	Transition strategy
2	Procure	Ensure equitable allocation, procurement, & delivery of Tx.	Maintain	WHO, UNICEF and Global Fund will continue to support countries in navigating trade-offs between products, factoring in product availability (timing), price, and efficacy.
3	Deploy	Support country preparedness and scale-up uptake of Tx across L/MICs.	Maintain	Unitaid, Global Fund, UNICEF, WHO/WHE/ HSRC will continue to support countries on test- and-treat strategies adapted to current context; and, together with FIND, will increase coordination efforts of test-and-treat country support activities ³⁰ , until at least Q1 2023, as partners deploy their programs adapting to changes in epidemiology.
			Maintain	Unitaid/FIND (also under Dx Pillar) will maintain the support to communities' test-and-treat health literacy and advocacy strategies for test-and-treat approaches. Projects launched in June 2022 and range in duration from 6 to 18 months.

Table 4.4: Summary overview of the ACT-A Therapeutic Pillar's transition plans for the Oxygen Taskforce (October 2022 to March 2023).

Workstream	Overview	Adjustments to Pillar scopes of work	Transition strategy
1	Investment coordination/strategy development.	Transition	WHO and UNICEF in close collaboration with NGOs will continue to identify priority countries and O2 sources to address short- and long-term needs, mapping priority countries and support the development of national O2 roadmaps post COVID-19.
		Maintain	USAID will maintain funders coordination leadership via the Donor coalition.

³⁰ A "COVID-19 test-and-treat Country Support Coordination" working group has been developed, chaired by Unitaid and the Global Fund, meeting on a bi-weekly basis.

Workstream	Overview	Adjustments to Oxygen Taskforce scopes of work	Transition strategy
2	Oxygen generation repair and market shaping.	Mantain	Unitaid, PATH and UNICEF keep monitoring needs & ongoing interventions for oxygen generation repairs (for COVID-19 and beyond through the EAG) and resolving bottlenecks in the supply of PSAs (e.g., spare parts, etc.).
		Sunset	USAID will no longer coordinate funds' allocation and technical interventions as these efforts will transition to broader donor coalition.
3	Liquid market shaping.	Transition	Unitaid, USAID, CHAI and UNICEF maintain the coordination of agreements on liquid oxygen and service offerings to improve pricing, services for countries and capacity. However, partners will transition market shaping investments into a permanent sustained market for liquid medical oxygen.
		Sunset	Support partners to identify and address country gaps / bottlenecks. Outcomes and achievements of ongoing work to shape the liquid oxygen market and scale up supply will be reported and disseminated across countries and partners for broader adoption.
		Maintain	Unitaid, USAID, CHAI and UNICEF will expand support to countries to identify and address country gaps/bottlenecks of broader oxygen needs, including for health emergencies. Bolster efforts that address key challenges to scaling up liquid oxygen in low resource settings and improve country capacity. Utilize research to guide and incentivize further action from liquid oxygen companies and to ensure access is embedded in business practices for the long-term. Monitor actions over the long-term to promote accountability.

Workstream	Overview	Adjustments to Oxygen Taskforce scopes of work	Transition strategy
4	Advocacy and Communications	Transition	Every Breath Counts will continue to lead i) coordinated advocacy to mobilise long-term resources and funding for national O2 programmes and strengthening O2 systems, ii) advocacy and media outreach across countries, donors and funders for COVID-19 but increasingly transitioning to other critical O2 use cases including RMNCAH, HSS/UHC/PHC, and future PPR efforts.

4.4 HEALTH SYSTEMS & RESPONSE CONNECTOR (HSRC)

Co-convened by WHO, The Global Fund, UNICEF, and the World Bank with support from the Global Financing Facility.

CHANGES IN THE CURRENT HSRC CONTEXT AND LANDSCAPE

The Health System and Response Connector acts as the transversal pillar of ACT-A, aiming to work closely with vertical product pillars (vaccines, diagnostics, and therapeutics) to focus on country demand and delivery. The HSRC aims to ensure that all countries have the necessary technical, operational, and financial resources to accelerate the translation of new COVID-19 tools into national response interventions to stop transmission and save lives - further ensuring that health systems are strengthened, that decision-makers have up-to-date and reliable health information/data, and that healthcare workers are protected through effective Infection and Prevention Control (IPC) and PPE measures (including adequate water, sanitation, and hygiene at primary health care and community level).

HSRC country engagement has highlighted the growing sense of COVID-19 fatigue in countries which, coupled with competing national priorities (including health, socio-economic, and humanitarian priorities) further reduces already suppressed demand for COVID-19 tools. Given that all COVID-19 tools are delivered through one common health system at facility and community levels, an integrated model for COVID-19 delivery should be supported at country level particularly to ensure uptake of tools. However, each country's unique context must be carefully considered as the starting point for supporting an integrated COVID-19 response. Achieving equitable outcomes will thus require more concentrated support in countries which have the greatest needs.

IMPLICATIONS OF THIS CHANGING CONTEXT FOR THE HSRC'S WORK

Given the evolving context, HSRC activities will be transitioned to individual agencies while keeping warm some selected activities that would need to be reactivated in case of a surge scenario (see Table 4.5). In line with the WHO SPRP 2022, transitioning COVID-19 response into routine health systems as part of broader national plans involves five core components (which will be underpinned by cross-cutting aspects such as digital health technologies, connectivity and data management, biosafety and biosecurity etc.).

- 1. Collaborative surveillance
 - » Integrating COVID-19 surveillance with systems for surveillance of influenza and other respiratory pathogens
 - » Expanding genomic sequencing capacity to increase global coverage
 - Maintaining and strengthening transmission trend surveillance of cases, deaths, and hospital admissions
 - Maintaining and strengthening of monitoring of national health service capacities for COVID-19 case management and essential health services
- 2. Community protection
 - Fully vaccinating the most vulnerable and using an optimal schedule of vaccines including boosters
 - » Expanding social listening systems to facilitate and improve immunization strategies
 - » Applying context-specific public and social measures to reduce risk of spread of the virus where required by the prevailing epidemiological situation
- 3. Safe and scalable care
 - Strengthening early recognition, triage, safe patient flow, and diagnostics to provide timely treatment and resuscitation
 - Addressing gaps in infection prevention and control, including improved access to WASH in healthcare facilities
 - » Restoring essential health services that have been disrupted due to COVID-19

- 4. Access to countermeasures
 - » Monitoring variants and adjusting countermeasures as needed
 - » Scaling manufacturing platforms and expanding agreements for technology transfer
 - » Supporting vertical pillars coordinate procurement (and allocation) and strengthen in-country supply chains to ensure equitable access
- 5. Emergency coordination (incl. budgeting)
 - » Integrating COVID-19 into broader health systems and health security strategies and plans
 - » Supporting coordinated planning, costing, and financing
 - Strengthening monitoring and tracking against delivery targets

SUMMARY OVERVIEW OF ADJUSTMENTS TO BE MADE TO HSRC SCOPES OF WORK

The HSRC's strategy for the ACT-A Transition period (October 2022 – March 2023) aims to (1) transition planning, financing and M&E activities as well as key technical areas to various existing initiatives, (2) merge overlapping activities with other ACT-A Pillars to reduce duplicative efforts, and (3) remain adaptable and flexible to support countries resolve identified technical, financial, and operational bottlenecks and address any immediate COVID-19 needs.

It should be noted that sunsetting an HSRC workstream does not mean that all ongoing support to countries will cease, but rather that activities will continue to be led by agencies with clear mandates to lead these activities as part of their regular work. HSRC partners will be available to provide support on these topics as required.

A breakdown of the transition strategy for each workstream is provided in Table 4.5.

	Workstream	Overview	Adjustments to HSRC scopes of work	Transition strategy
1.1	Consolidated planning & financing	Building capacity and supporting countries in identifying and budgeting their needs, mobilizing resources (incl. domestic financing), determining, and addressing gaps through holistic national plans.	Transition	WHO to lead remaining planning and financing activities.
1.2	Implementa- tion monitoring & tracking	Building monitoring and evaluation capacity and support tracking at national and subnational levels of building blocks of health systems readiness and response and monitoring of implementation against delivery targets.	Transition	WHO to lead monitoring & tracking activities.
2.1	Scale-up of vaccine delivery	Supporting the Vaccines Pillar in addressing vaccine delivery bottlenecks.	Transition	HSRC support to be merged with vertical pillars – potential to continue CoVDP-HSRC missions.
2.2	Scale up of testing for surveillance	Supporting the Diagnostics Pillar in addressing diagnostics and other public health and social measures delivery bottlenecks.	Transition	HSRC support to be merged with vertical pillars.

Table 4.5: Summary overview of the HSRC's transition plans (October 2022 to March 2023).

	Workstream	Overview	Adjustments to HSRC scopes of work	Transition strategy
2.3	Scale up of clinical care pathways	Supporting the Therapeutics Pillar in addressing clinical care bottlenecks.	Transition	HSRC support to be merged with vertical pillars.
3.1.1	Health workforce	Supporting countries in scaling up surge workforce to deliver COVID-19 tools.	Transition	Future activities to be led by agencies and existing initiatives (e.g., Community health workforce initiative led by UNICEF and USAID).
3.1.2	RCCE	Leveraging communities and other in-country stakeholders to combat misinformation and create demand for COVID-19 tools.	Keep warm	Keep warm to respond to specific requests from countries, address decreasing demand for COVID-19 tools and to increase demand for Essential Health Services.
3.1.3	Health logistics	Providing guidance and operational support to countries for in-country health logistics.	Transition	HSRC support to be merged with vertical pillars.
3.1.4	Country adoption of policies & guidelines	Providing end to end support to rapidly translate new evidence into technical guidance and implementation at local level.	Transition	WHO to lead future workstream activities.
3.2	Essential health services	Supporting countries to maintain essential health services.	Transition	Work to continue at individual agency level (including the World Bank, GFF) established programs such as the Primary Health Care Accelerator.

	Workstream	Overview	Adjustments to HSRC scopes of work	Transition strategy
3.3	Infection Prevention & Control	Supporting countries in protecting their health workforce through effective IPC and improving access to basic WASH and PPE at healthcare facilities.	Keep warm	Kept warm to respond to specific requests from countries – PPE procurement to be led by UNICEF and The Global Fund and the World Bank, access to WASH to be led by UNICEF and WHO.
Settings	Acute situations	Coordinating partner efforts to dynamically identify acute situations and push for immediate response.	Transition	WHO to lead future workstream activities.
Settings	Fragile, Conflicted and Vulnerable settings	Coordinating comprehensive COVID-19 response in fragile, conflicted, and vulnerable states.	Transition	WHO and UNICEF to lead future workstream activities.

5 COORDINATING ACT-A'S WORK & PARTNERSHIPS IN THIS NEXT PHASE

This section provides an overview of changes to be introduced in the setup and ways of working across the ACT-A partnership to consolidate and streamline functions where appropriate and ensure continued coordination and support is provided, while maintaining readiness to surge in the event needed.

MAINTAINING ACT-A COORDINATION SUPPORT FUNCTIONS

The ACT-A Hub will continue its core coordination functions to facilitate synergies across the ACT-A partnership. This includes supporting cross-Pillar coordination meetings (e.g., Principals Group calls), supporting the WHO Special Envoys to the ACT-A, facilitating the development of joint products (e.g., joint ACT-A Agency statements, joint talking points), supporting engagement with key partners including CSOs and Industry representatives, and tracking and reporting on the overall ACT-Accelerator work and financing status (e.g., via the commitment tracker³¹). The Hub will provide secretariat support to the Tracking and Monitoring Task Force of senior Council members that will continue work in this next phase (see below). The Hub will also continue to convene monthly meetings of the agency Resource Mobilization and Communications leads to year end and potentially into 2023 should there be sustained interest or need.

CONSOLIDATING AND SHARPENING THE FOCUS OF THE ACT-A COUNCIL

The **ACT-Accelerator Facilitation Council**, co-hosted by WHO and the European Commission and cochaired by South Africa and Norway, has provided crucial political leadership and advocacy and advice in support of ACT-A's agenda.

As ACT-A agencies work towards greater efficiency and sustainable approaches in this period, the work of the ACT-A Council members will also be consolidated to focus on monitoring impact, tracking resources, and maintaining readiness to reactivate the full high-level Council, if needed. To achieve this, the ACT-A Council, which will have met 12 times by the time of publication of this plan, will go into a 'stand-by mode' and will meet as a full group only if needed. Elements of the work of the Council, the Tracking and Accelerating Progress Working Group (TAP WG) and Financial and Resource Mobilization Working Group (FinRM WG) will be consolidated into a new ACT-A Tracking and Monitoring Task Force (see Fig 5.1). The Tx & Dx Working Group, as was the case for the Vaccines Manufacturing Working Group, ceased its activities in October 2022 once its mandate and final report were delivered.

Key Council functions that will be maintained by the **ACT-A Tracking and Monitoring Task Force** include: (i) monitoring progress in the rollout of and equitable access to vaccines, diagnostics and new oral antivirals, including through Test and Treat strategies; (ii) maintaining coordination and facilitating political engagement, as needed, to support the work of ACT-A partners; (iii) tracking resource use and needs (e.g. via the ACT-A Commitment Tracker); and (iv) maintaining Council and ACT-A stakeholder readiness to reactivate, as needed, in response to major surges of COVID-19.

The Tracking and Monitoring Task Force will brief WHO Member States and other stakeholders on ACT-A's work during the next 6-months through WHO COVID-19 briefings or other fora.

OPTIMIZING COORDINATION BETWEEN ACT-A PRINCIPALS & PILLAR CO-CONVENERS

The **Principals Group** comprises the Principals of the co-convening agencies and representatives of key partner constituencies (e.g. CSOs and industry). Principals Group meetings provide a forum for sharing information, discussing key developments and challenges, and aligning strategy and cross-Pillar priorities.

The Principals met weekly from the start of the pandemic until June 2021 when the cadence of

³¹ The ACT-A Commitment Tracker, which provides transparent reporting on funding commitments made between donors and ACT-A agencies against ACT-Accelerator Pillar budgets, will be updated on a monthly basis until the end of 2022, and thereafter on an as needed basis and if agencies agree to provide inputs.



Fig 5.1: Consolidating and maintaining Council functions during the transition period.

meetings was shifted to fortnightly. At that time, on alternating weeks, the **ACT-A Agency Leaders** began meeting to address inter-agency coordination issues.

In September 2022, the cadence of both the Principals Group and ACT-A Agency Leaders meetings was adjusted again to monthly and twice monthly respectively. During the transition period, both meeting fora will be supplemented with ad hoc or additional meetings as needed.

SUSTAINING CORE COORDINATION FUNCTIONS TO MAINTAIN CSO AND COMMUNITY ENGAGEMENT

The **Platform for ACT-A Civil Society and Community Representatives** will focus on the following four key areas during the period October 2022 to September 2023:

Convening: The Platform will continue its role of convening and mobilizing civil society and community representatives who remain engaged in the workstreams, Pillars and the working groups of the Facilitation Council that remain active in the next phase of ACT-A's work. This includes coordination, information gathering and intelligence sharing across remaining streams of work and with broader civil society and communities.

Knowledge Management: The Platform will focus on distilling the key lessons learnt from ACT-A as reflected in the external evaluation and in the internal review of the Platform through legacy documents, blogs, podcasts, policy briefs and our social media channels including our website.

Future COVID responses: The Platform will continue engaging and advocating with lead agencies to ensure the full and meaningful inclusion of civil society and communities in governance and in organization's long term COVID-19 response as work transitions into the core strategy of organizations; as well to ensure that the sustained focus on inequalities between and within countries is prioritized in the future COVID responses.

Future PPR mechanisms: The Platform will continue to engage in the creation of new pandemic prevention, preparedness and response mechanisms, including the counter measure platform. We will work to ensure lessons learnt from our engagement in ACT-A inform the design of future PPPR mechanisms and for the full and meaningful participation of civil society and communities in governance and decision-making structures.

6 MAINSTREAMING ACT-A FINANCING DURING THE TRANSITION PERIOD

This section summarizes the status of funds pledged in support of the ACT-Accelerator since its formation in April 2020 and gives an updated view of funding needs for ACT-A PIllars and agencies for the six-month transition period. These updated figures reflect the 'base case' described in Section 3 and take into account changes in the overall operating environment (e.g., availability of new or enhanced tools), demand for tools from countries, and available resources.

TOTAL FUNDS PLEDGED IN SUPPORT OF ACT-A (SINCE APRIL 2020)

By end September 2020, donors had pledged a total of US\$ 23.7 billion to the ACT-Accelerator (see Fig 6.1). This includes: US\$ 16.1 billion for Vaccines, US\$ 1.7 billion for Therapeutics, US\$ 1.4 billion for Diagnostics, US\$ 2.3 billion for the Health Systems Response Connector and US\$ 2.2 billion currently being allocated between Pillars.³²

Fig 6.1: Total donor pledges and commitments to ACT-A during the period April 2020 to September 2022.



Source: ACT-A Commitment Tracker as of 03 October 2022

³² All financial commitments can be accessed at <u>https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker</u>.

ACT-A FUNDING NEEDS FOR THE BASE CASE

A new ACT-A budget has not been developed for this transition plan as many scopes of work under the 2021-2022 ACT-A strategic plan are being carried forward and implemented during this period, and ACT-A Agencies are integrating a lot of COVID-19 costs into their ongoing work and programmes. However, in recognition that the pandemic has evolved considerably since the last strategic plan and budget was released in October 2021, and hence the operating environment for ACT-A and its Pillars, an exercise was undertaken with the ACT-A Pillars to identify any funding gaps for the next six months.

The exercise adjusted the financing gaps to reflect realities of the current pandemic situation, the current demand for COVID-19 countermeasures, and available or expected resources. As discussed with the ACT-A Facilitation Council Finance and RM Working Group (FinRM), the exercise focused on needs of ACT-A agencies. Using a common set of assumptions about the epidemiological situation and existing tools, the Pillars identified a funding gap of US\$ 386 million for ACT-A Pillars and agencies (See Annex 1 for details).

Going forward, the ACT-A Hub will continue to coordinate the monitoring and tracking of ACT-A financing during the transition period (i.e. via the ACT-A commitment tracker). ACT-A partner agencies will, however, primarily utilize their regular RM processes and networks to address financing gaps. The new ACT-A Tracking and Monitoring Task Force will provide an important forum for maintaining a coordinated approach to tracking financing requirements and pledges and facilitating resource mobilization for ACT-A if needed in this next phase.

FINANCING ACT-A ACTIVITIES IN THE EVENT OF AN EMERGENCY SURGE

Given that SARS-CoV-2 continues to circulate and evolve, there continues to be a risk that a new, more serious and/or more transmissible variant may emerge. ACT-A Agencies and the FinRM Working Group and concurred that providing estimates of the resources required under the two surge scenarios described in Section 3 could be counterproductive. The major uncertainties around essential assumptions for costing a response to such scenarios – related to factors such as the effectiveness of tools, severity of disease, at-risk populations, etc. - result in a very wide range of potential costs. That said, building on the ACT-A experience, it was recognized that if a new, significant and more deadly variant emerges, which evades current countermeasures, tens of billions of dollars could be rapidly required to mount an effective emergency response on a global scale.

7 NEXT STEPS AND LOOKING TO THE FUTURE

This section summarizes next steps for taking forward the ACT-A Transition Plan. It also describes how in parallel, lessons learned from ACT-A's work will inform ongoing WHO Member State and other processes, that are deliberating what a future pandemic countermeasures platform needs to look like.

TAKING FORWARD & REPORTING ON IMPLEMENTATION OF THE TRANSITION PLAN

This transition plan will cover the period October 2022 to March 2023. The need to extend, adapt or supplement this plan will be considered in Q1 of 2023 (or sooner if there is a major surge in cases and/or deaths) in discussion with the ACT-A Agencies, Council Co-Hosts and Co-Chairs, and implementing partners, taking into account the evolving epidemiological and response situation.

Regular briefings on ACT-A's work during this period will be provided in relevant fora (e.g., WHO COVID-19 Member State Briefings, G20) by ACT-A Agencies and members of the newly established Tracking & Monitoring Task Force. As indicated in Section 5 (coordination functions), a report addressing implementation of activities covered in this six-month plan will be published in May 2023. Other monitoring and accountability tools such as the GCAT and ACT-A financial commitment tracker will also be maintained, with some (e.g., the commitment tracker) being updated on a less frequent basis (monthly instead of fortnightly).

FEEDING KEY ACT-A LEARNINGS INTO OTHER PROCESSES LOOKING AT THE FUTURE GLOBAL HEALTH ARCHITECTURE FOR PPR

It is widely recognized that the ACT-Accelerator was a ground-breaking initiative that was instrumental in advancing access to COVID-19 tools during the pandemic. ACT-A partner experiences - including findings from the recently completed <u>external</u> <u>evaluation of ACT-A</u> - are already being considered in WHO Member State processes, board-level discussions of ACT-A partner agencies, G20 and other fora. These learnings have informed and will continue to inform the development of a new pandemic instrument, pandemic financing, and core capacities needed for a future pandemic countermeasures platform.

This transition plan is anchored in the current pandemic and COVID-19, and does not provide specific recommendations about how to address other pandemic threats. However, in recognition that discussions on how to better prepare for the next pandemic are ongoing, ACT-A partners have compiled some key learnings and reflections based on their experiences with COVID-19 over the last 2.5 years. These have been included in an addendum to this plan.



ANNEX 1 ACT-A PILLAR & AGENCY FUNDING GAPS UNDER THE BASE CASE

Table A.1: Assumptions used to cost the Transition Plan base case.

BASE CASE

ONGOING OUTBREAKS

Continued evolution of SARS-CoV-2 but existing tools remain effective



NUMBER OF CASES

< 10 m new cases per week (max. peak after BA.4/BA.5 variants became dominant)^a



SEVERITY

Same severity as Omicron & subvariants (i.e. current situation)



TOOLS

RDT/PCR tests effective (to date)

Current vaccines and antivirals effective

EOI for 17m antivirals in Q3 2022 (limited demand for testing)

VACCINES

Existing portfolio/supply sufficient to complete existing programs and provide additional boosters to highest risk groups



DIAGNOSTICS

Limited demand for tests

Need to expand local manufacturing and country capacity to deploy qualityassured diagnostics tools



THERAPEUTICS

Limited demand for treatments



Continued investment in oxygen production capacities

HSRC

Limited demand for PPE

New activities to transition COVID into health systems and health security plans



^a Peak in 3rd week of July 2022.

	R&D, product assessment	Procurement	Agency technical assistance & delivery support	Tota
Vaccines	US\$ 0m	US\$ 0m	US\$ 0m	US\$ 0m
	Ongoing R&D projects covered for the next 6 months	Ongoing programs & additional boosters for highest risk groups covered by existing portfolio/ supply	Covered by existing funding or expected funds in the pipeline ^a	
Diagnostics	US\$ 4m	US\$ 70m	US\$ 4m	US\$ 78n
	Self testing and point-of-care respiratory R&D projects	Test procurement and sequencing of positives	Support countries to deploy and scale diagnostic tools	
Therapeutics	US\$ 1m	US\$ 51m	US\$ 11m	US\$ 63n
	R&D and other activities	Procurement for oxygen (US\$40m for Unitaid and US\$ 11m for UNICEF)	UNICEF for technical assistance	
HSRC	US\$ 0m	US\$ 70m	US\$ 175m	US\$ 245n
	No R&D projects in the next 6 months	UNICEF PPE procurement	UNICEF (US\$ 150m) & WHO (US\$ 25m) for cross-cutting technical assistance (incl. RCCE & EHS)	
Total	US\$ 5m	US\$ 191m	US\$ 190m	US\$ 386m

Table A.2: ACT-A Pillar & Agency funding gaps under the base case.

^a Need of US\$ 80m for UNICEF on vaccine rollout is potentially covered by funds in the pipeline.

ACT-A co-convening partners:



Working with goverments, civil society and industry