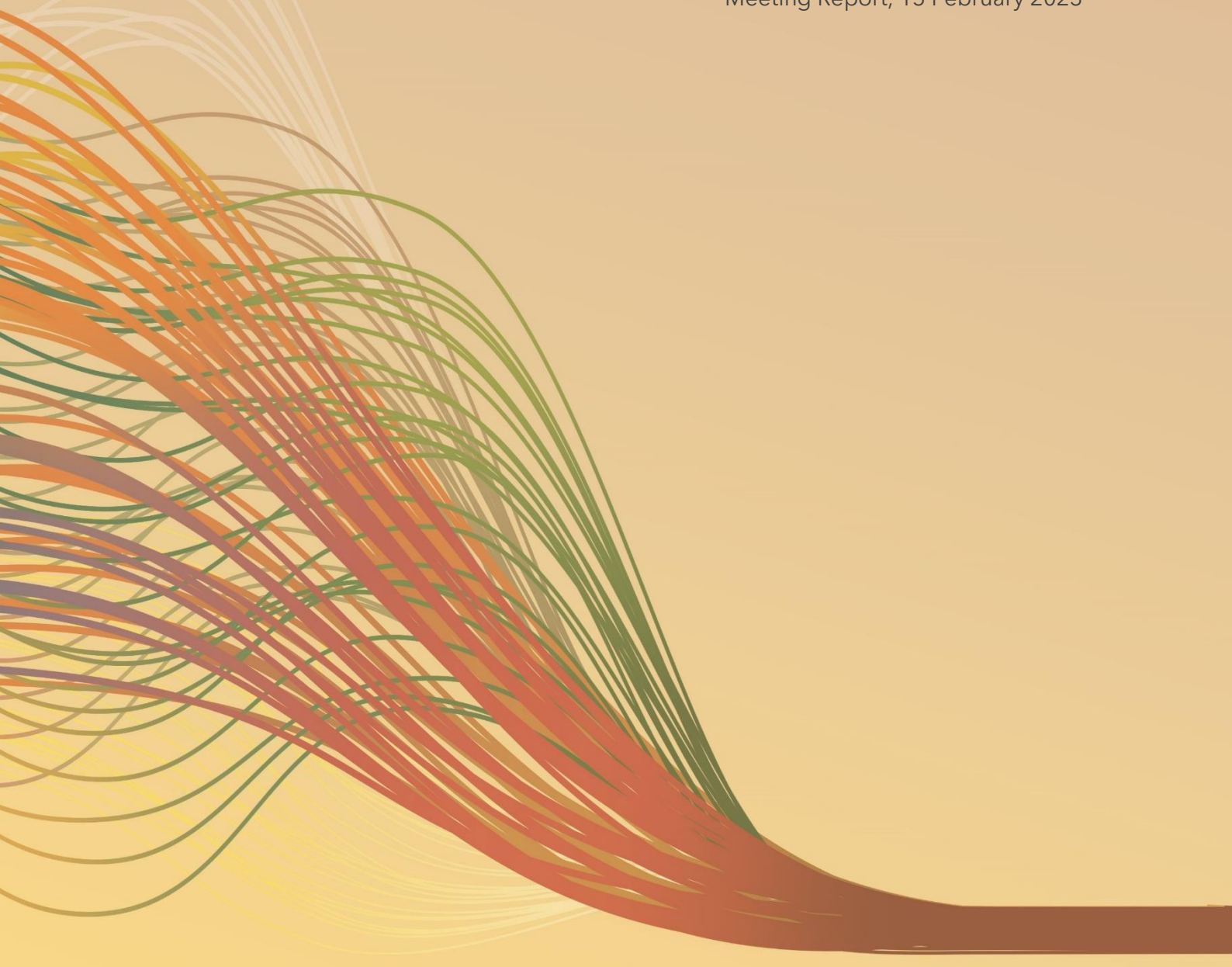
ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

Update on the rollout of COVID-19 tools

Second meeting of the ACT-A Tracking & Monitoring Task Force

Meeting Report, 15 February 2023



ABOUT THE TASKFORCE

The Access to COVID-19 Tools Accelerator (ACT-A) entered a 6-month transition period in October 2022 and a Tracking & Monitoring Task Force was created to maintain key ACT-A Facilitation Council functions. Co-chaired by the United States of America and India with members from former ACT-A Council Working Groups, the Task Force monitors rollout and access to tools, facilitates political engagement, tracks resource use and needs, and maintains the Council's readiness to reactivate, if needed. The Task Force met for the first time on 9 December 2022. The first meeting report is available here.[1] The Task Force met for the second time on 15 February 2023. It will operate to the end of March 2023 in line with the time frame of the ACT-Accelerator's six-month Transition Plan.

[1] Update on the rollout of COVID-19 tools: a report from the ACT-A Tracking & Monitoring Task Force, 14 December 2022, Geneva: ACT-Accelerator (https://www.who.int/publications/m/item/update-on-the-rollout-of-covid-19-tools--a-report-from-the-act-a-tracking---monitoring-task-force, accessed 16 February 2023)

CO-CHAIRS STATEMENT

It is almost three years since the start of the pandemic. Currently, work to integrate the management of COVID-19 into routine health programmes and systems is well underway. It has been more than a year since the Omicron variant was at its peak and more than 70,000 deaths were being reported to WHO each week. Despite a recent surge in COVID-19 cases at the end of 2022, particularly in China, reported mortality remains relatively low in most countries around the globe.

We have learned important lessons from this latest stage in the pandemic. First, our tools have remained largely robust. Secondly, countries' demand for COVID-19 tools has not increased, even during recent surges in cases. Thirdly, with the COVID-19 virus still circulating widely, it remains critically important to ensure priority populations are fully vaccinated and boosted, and that diagnostics and antivirals are available for those at risk.

Since the Task Force last met (9 December 2022), the ACT-A agencies have been working to take forward the three objectives[2] of the ACT-A Transition Plan while remaining prepared to respond to a possible surge in COVID-19 disease and mortality.

At the second meeting of the Task Force (15 February 2023), we received updates on progress with the roll out of new oral antivirals (Transition Plan objective 3) and ACT-A agency institutional arrangements to ensure long-term supply of COVID-19 tools (Transition Plan objective 2).

With regards to the roll out of and access to oral antivirals, we received an update on ACT-A agency support to countries and the status of the supply pipeline. ACT-A partners reported that while there have been significant delays in accessing novel oral antivirals for low- and middle-income countries (LMICs), these products are now available through the partnership, including in generic form. In addition, seven LMICs have started official processes of accelerated regulatory approval for oral antivirals via the WHO Collaborative Procedure, with ~276,000 units ordered via the WHO Partners Platform.

It was noted that there is a gap in access to oral antiviral license agreements to generic suppliers, as they do not apply to Upper Middle-Income Countries (UMICs). Access to antivirals by many UMICS remains limited to their ability to reach agreement with originator companies, however ACT-A lacks visibility on these bilateral agreements.

We were particularly concerned to hear about the slow progress and the lack of visibility on demand and delivery data for oral antivirals. There is a need for industry, countries, regulatory agencies, policymakers, communities and ACT-A agencies to share information in order to get the full picture of what is available, which products have been approved and

[2] The ACT-A Transition Plan objectives include: 1) focusing ACT-A's R&D and market shaping activities to ensure a pipeline for new and enhanced tools; 2) securing institutional arrangements to ensure long-term access to COVID-19 vaccines, tests and treatments; and 3) concentrating ACT-A's delivery work on new product introduction and the protection of priority populations, in support of national and international targets.

the size of the at-risk population in each country, as well as quantities of products that have been procured and delivered. With regards to demand for oral antivirals, it was noted that some generics manufacturers of prequalified products have not been contacted by global procurement agencies or countries to place orders. If demand remains low, manufacturers may not pursue licensing and registration, further limiting product availability.

During the meeting, we also learned about ACT-A partner agencies' plans beyond March 2023 to ensure sustained access to COVID-19 tools based on need once the ACT-A Transition period ends. In addition, each agency provided a high-level update on the implementation status of funds reported in the ACT-A Commitment Tracker.

We welcome the progress presented by ACT-A partners on maintaining readiness, securing sustained access to COVID-19 tools and providing ongoing support to countries. This includes the Gavi Board decision to maintain the provision of doses at no cost to the AMC92 countries, while developing a programme to support countries with COVID-19 vaccination of high-risk populations in 2024-2025 for the consideration of the Board in June 2023. The Global Fund's COVID-19 Response Mechanisms (C19RM) has been extended until the end of 2025, which enables the Global Fund to support both the immediate COVID-19 response and broader pandemic preparedness, while strengthening underlying health systems.

Of the US$24 billion generously committed to date for the ACT-A agencies, the seven core ACT-A implementing agencies have disbursed/implemented 88% of the funding, with an additional 10% allocated and shortly to be implemented. Transparency in reporting is an important element of facilitating ongoing access to key COVID-19 tools.

In our final meeting, planned for 31 March 2023, we will consider the state of play with regards to the rollout of all COVID-19 tools, and hear updates from agencies on plans to maintain readiness to respond to countries' needs for COVID-19 tools and potential surges in disease.

STATUS UPDATE

PROGRESS ON COVERAGE OF COVID-19 TOOLS

This report provides a short summary of the status of the rollout of COVID-19 tools. Further detail is available from the Global COVID-19 Access Tracker and in the ACT-A quarterly reports[3].

Vaccines

With sufficient vaccine supply now available, many countries have made strong progress in recent months, and are taking steps towards the integration of COVID-19 vaccination with routine services. There is still a need for continued focus on reaching high-priority groups, in particular the elderly, and to close coverage gaps. As of 13 February 2023, 13.2bn doses of COVID-19 vaccine have been administered globally.[4]

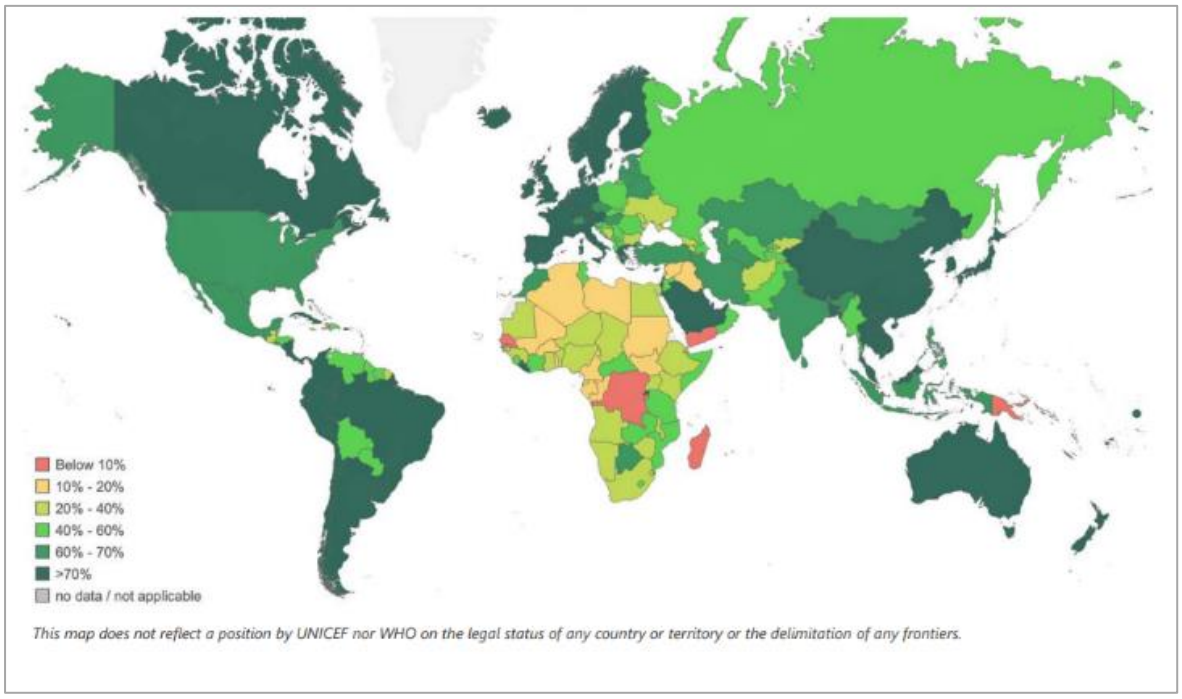
Overall, 65% of people in WHO Member States have completed primary vaccination; this figure rises to 89% of health workers and 81% of adults aged 60+. In low-income countries (LICs), there is 23% overall primary vaccination coverage, 49% coverage of healthcare workers, and 33% coverage of people aged 60+. Seven WHO Member States have less than 10% vaccination coverage (down from eight in Nov 2022).

Figure 1 shows that low coverage persists in most of Africa, some parts of the Eastern Mediterranean Region, as well as Papua New Guinea. Among LICs, nine out of 27 have not yet started a booster programme. Among the 34 priority countries under the COVID-19 Vaccine Delivery Partnership (CoVDP), there is only 2.6% total booster coverage.

COVAX has delivered 1.89bn doses[5] of COVID-19 vaccine in 146 countries, helped more than 40 countries start their vaccination campaigns and doubled coverage in AMC countries in 2022 to 52% average. There has also been an eight-fold increase in primary series coverage across the 34 countries identified for concerted CoVDP support since December 2021.[6]

[3] Impact: ACT-Accelerator; 2023 (https://www.act-a.org/impact, accessed 16 February 2023).
[4] Update on COVID-19 vaccine roll-out, WHO, 13 February 2023 (slide deck)
[5] Information on country-by-country delivery of COVID-19 vaccines is available at the COVID-19 Market Dashboard, UNICEF; 2023 (https://www.unicef.org/supply/covid-19-market-dashboard, accessed 16 February 2023)
[6] COVID-19 Vaccine Delivery Partnership, Update on COVID-19 vaccine delivery, ACT-A Principals Group, 16 February 2023 (slide deck)

Figure 1: Persons vaccinated with complete primary series, per 100 people, as at 13 February 2023



Source: COVID-19 Vaccine Delivery Partnership

Support is still needed to maintain momentum to increase coverage, particularly among the elderly and vulnerable. This includes the introduction of boosters and the integration of COVID-19 vaccination into routine primary health care. Flexible deployment of remaining COVID-19 funding is required to continue vaccinating target populations, but also to support bundling with other health and humanitarian activities and investments in community health systems.

Diagnostics

The global community now has the necessary diagnostics tools available at affordable prices to manage COVID-19. Reflecting on the progress to date, through the support of the ACT-A Diagnostics Pillar and its partners, investments in diagnostics resulted in rapid development, manufacturing, and implementation of SARS-CoV-2 tests. This has improved equitable and timely access to low-cost, quality-assured diagnostics that are central to enabling countries to understand transmission dynamics, create COVID-19 surveillance programmes and implement timely countermeasures to safeguard their people and communities. Through these efforts, from the start of the pandemic in Q1 2020 to Q4 2022, 203.3 million tests have been procured, with 163.4 million delivered to 182 countries in need. Tests are now also affordable, with partners negotiating 30-50% price reductions. Furthermore, investments in local manufacturing and technology transfer are securing global capacity for current and enhanced COVID-19 tests that is less constrained by demand volatility.

During the pandemic, countries leveraged and enhanced existing diagnostics infrastructure in order to detect and anticipate surges, creating capacity can be used for preparedness against future threats. However, throughout the pandemic, testing rates have fluctuated based on the epidemiologic situation, test availability, and changes in national testing policies, with declines experienced globally. Disparities in testing rates according to income level persist, with HICs continuing to test more, at 1.62 tests per day per 1,000 population at the end of Q4 2022 versus LICs at 0.02 tests per day per 1,000 population. Competing national and local priorities, coupled with the underreporting of data (i.e., self-testing data is often not captured in data systems) are some of the key challenges contributing to declining testing rates. If COVID-19 testing is not prioritized or routinized into health systems, the world will be blind to patterns of virus transmission and evolution, which could impact individual patient care and healthcare systems' capacity.

To address these challenges, the ACT-A Diagnostics Pillar partners continue to work together to generate an integrated, holistic approach around COVID-19 diagnostic priorities to maintain and enhance progress for COVID-19 and build preparedness for future pandemic threats. Figure 2 below sets out the Pillar's approach to ensuring equitable access to affordable diagnostic tools and technologies through and after the ACT-A transition period.

Figure 2: ACT-A Diagnostic Pillar Priorities for 2023

Area	ACT-A Diagnostic Pillar Priorities
1. **Local Manufacturing & Regulation**	▪ Continue to ensure availability and supply of accurate, affordable diagnostic tools, through **expanded local manufacturing, tech transfer – including through C-TAP, regulatory improvements** and **support for market entry.**
2. **Research & Development**	▪ **Invest** in the development and rollout of affordable, accessible technologies with a focus on **digital tools, multiplex platforms and surveillance systems**.
3. **'Maintain to Sustain' Testing and Surveillance**	▪ Scale, maintain, improve, and sustain equitable access to testing in countries through the **C19 RM** (*funding extended until December 2025*) **test procurement,** enhancing **decentralized models** of care, improving **health and community systems**, **scaling self-testing,** and **integrating COVID-19 testing into routine care**. ▪ Continue to **update timely global guidance** on testing strategies to minimize severe disease and long-term sequelae, reduce the impact of COVID-19 on health care systems and inform surveillance to enable early detection and assessment of new variants.
4. **Test to Treat**	▪ Collaborate between the diagnostics and therapeutics pillars to **sustain progress around Test to Treat** approaches, including through implementation projects and engagement via in-country advocacy partners..
5. **Sequencing**	▪ **Expand fit-for-purpose sequencing systems**, strengthening the integration of epidemiological and genomic data to guide public health action.
6. **Pandemic Preparedness**	▪ **Prepare for the next threat** by improving rapid detection, development, and deployment of diagnostic tools in support of **health and community systems** (including laboratory systems and diagnostics networks as well as supporting community health workers), **the Health Emergency Preparedness and Response (HEPR) architecture** and the G7 Agenda on the **100-Day Mission (Dx Component)**. In addition, support national Governments to put in place strategies that help them to respond quickly in case of future surges and health threats.
7. **Knowledge Hub**	▪ **Create and launch a diagnostics knowledge hub platform is being developed** 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.

Therapeutics

Regulatory pathways expanded when generic antivirals were prequalified by WHO in September (molnupiravir) and December (nirmatrelvir/ritonavir) of 2022. Procurement agreements are in place for generic products to support more affordable access to oral antivirals across most LMICs. WHO updated its living guidelines "Therapeutics and COVID-19" on 13 January 2023, with operational guidelines also in development.

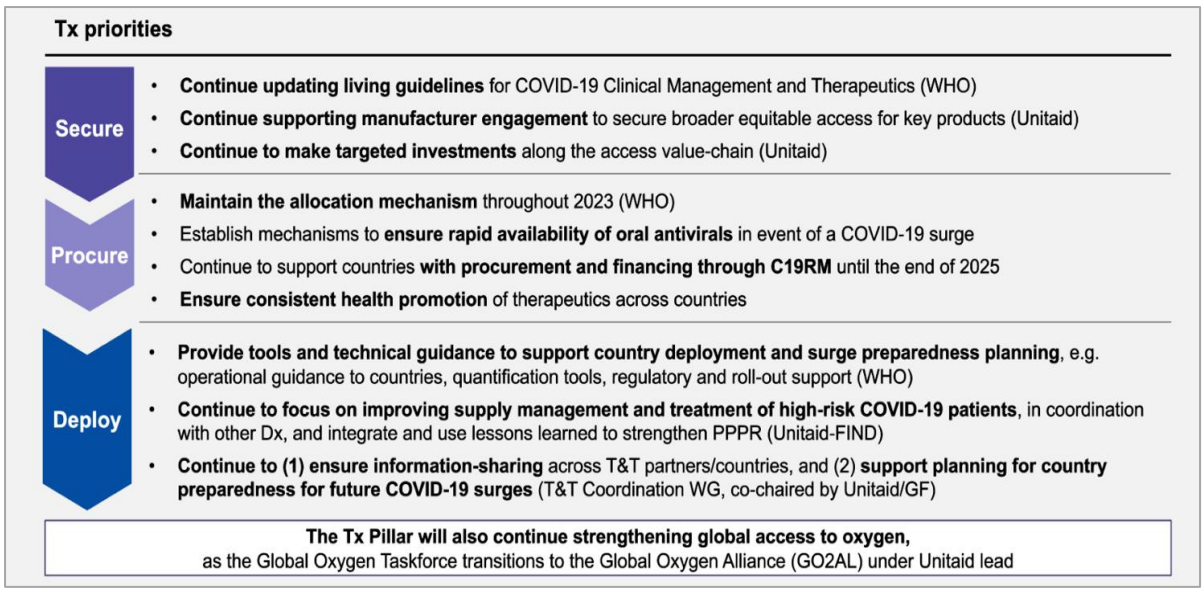
The ACT-Accelerator Therapeutics Pillar has secured enough antivirals to address current demand and will continue working to build resilient systems and markets to address potential COVID-19 surges.

Therapeutics allocated to countries by ACT-A agencies include 315,000 treatment courses of nirmatrelvir/ritonavir (brand name: PAXLOVID), molnupiravir, and tocilizumab. 141,000 units of molnupiravir have been ordered for 22 countries, and 135,000 units of nirmatrelvir/ritonavir have been ordered for 19 countries.[7] Multiple "Test and Treat" pilot programmes of bilateral and other partners have procured around 65,000 treatment courses of molnupiravir for 13 countries and 23,000 courses of nirmatrelvir/ritonavir for 21 countries.[8] Multiple countries are in the process of securing market authorizations of these products, including generic versions which became available through ACT-A mechanisms in Q4 2022.

These therapeutics became available after reported COVID-19 cases started to decline in most countries and as a result, country demand for novel antivirals is low. Another challenge countries face is health seeking behaviour and connections to health care, as sick and at-risk populations need to present for care, be diagnosed and start treatment within the window of five days from the start of symptoms.

The Therapeutics Pillar will maintain efforts to support surge capacity and broader country preparedness plans. Figure 3 below sets out the Pillar's approach to securing, procuring and deploying COVID-19 treatments and medical oxygen.

Figure 3: Therapeutics pillar priority efforts support surge capacity and broader country preparedness plans for 2023



[7] WHO Partners Platform for health in emergencies, Geneva: WHO (https://partnersplatform.who.int/en/ accessed 17 February 2023)
[8]COVID-19 Market Dashboard, Geneva: UNICEF (https://www.unicef.org/supply/covid-19-market-dashboard accessed 17 February 2023)

ENSURING ACCESS TO COVID-19 TOOLS IN THE LONGER TERM

Through the transition period, and as set out in the Transition Plan[9], ACT-A agencies have been adjusting their ways of working and planning for longer-term access to COVID-19 tools. This section of the report relates to the second objective of the ACT-A Transition Plan on securing longer-term institutional arrangements for sustained access to COVID-19 tools (e.g., vaccines, tests, and treatments, including oxygen).

Research and development, policy and regulatory matters

Clinical trials and timely updates of guidance will continue as part of WHO's normative work, along with prequalification of vaccines, therapeutics and diagnostics, and development of other norms and standards, in areas such as medical oxygen and ensuring international standards are available. WHO's access to medicines and health products team will continue to support pricing, procurement and other areas. WHO Regulatory teams will continue to review evidence and provide regulatory approval, as well as oversee the transition of vaccine products from emergency use listing (EUL) to pre-qualification (PQ) status, where requested.

CEPI will continue to invest in innovations for SARS-CoV2 and broadly protective coronavirus vaccines. CEPI is focused on optimization of SARS-CoV2 vaccines for long term use, driving innovations to increase breadth of protection and accessibility in low-resource settings, such as improved thermostability and speed in manufacturing processes. CEPI continues to identify research gaps and coordinate with other funders to invest and remains the only vaccine R&D funder globally that systematically includes equitable access terms in its agreements.

FIND will spur innovation and invest in the development and rollout of affordable, accessible diagnostic technologies and tools, with a focus on digital tools, multiplex platforms and surveillance systems.

Product procurement and market shaping

In 2023, Gavi will maintain free provision of COVID-19 vaccine doses to the AMC92 countries, while developing a programme to support AMC countries with COVID-19 vaccination of high-risk populations in 2024-2025, pending Board approval in June. UNICEF is tendering to meet demand for COVID-19 vaccines for 2024 onwards.

Responding to the shift in priorities in implementing countries, the Global Fund's C19RM has been extended until the end of 2025. The extension enables the Global Fund to support both the immediate COVID-19 response and broader pandemic preparedness, while strengthening underlying health systems.

UNICEF's COVID-19 related long-term agreements remain valid through 2023 (for personal protective equipment), early 2024 (for antivirals), and until 2025 (for oxygen and diagnostics), respectively. UNICEF will look to re-tender and establish contractual agreements, subject to disease evolution and demand from countries.

[9] ACT-Accelerator Transition Plan (01 October to 31 March 2023), 28 October 2022, Geneva: ACT-Accelerator (https://www.who.int/publications/m/item/act-accelerator-transition-plan, accessed 16 February 2023)

Unitaid and FIND are continuing their efforts to ensure the availability and supply of accurate and affordable diagnostics, including next-generation sequencing, through targeted investments and expanded local manufacturing. WHO and partners will continue to enable procurement of tests and support technology transfers – including through the COVID-19 Technology Access Pool (C-TAP) initiative – facilitating market entry and regulatory approval.

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 and regional health agencies (ii) with the Medicines Patent Pool (MPP) and generic manufacturers to support prompt development and PQ submissions for early procurement and introduction in LMICs, and for market resilience including for oral antivirals and (iii) addressing persistent access barriers in LMICs excluded from access plans. Unitaid will also continue to unlock sustainable and equitable oxygen access, through its market shaping expertise, and track record driving product adoption and access at the country level.

Delivery of tools

The WHO Allocation mechanism for vaccines and therapeutics will continue through 2023, with a transition plan envisaged for later in the year.

UNICEF will continue its work integrating the delivery of COVID-19 tools into primary health care, and related advocacy and behaviour change efforts into community engagement mechanisms, as needed. UNICEF will also supply COVID-19 tools within programme scope for preventive and "Test and Treat" solutions, through its diverse portfolio and long-term agreements.

WHO teams working at regional and country levels will continue to support Member States to integrate COVID-19 vaccinations into their routine programmes, working with partners to provide support across areas including technical assistance, programmatic guidance and national immunization strategies. WHO will also continue to enable workforce development to strengthen testing service delivery, including the linkage to the clinical care pathway.

Unitaid is committed to continuing its efforts in supporting countries to enhance their procurement and supply chain systems for COVID-19 tools, ensuring access to generic products, and providing technical assistance to secure long-term resources. In addition, Unitaid will continue its work via the Test and Treat grants promoting decentralized models of care that focus on high-risk populations by advocating for national-level policies and guidelines, providing training and implementing effective case-management strategies.

Unitaid will play a leading role in the Global Oxygen Alliance (GO_2AL) and continue to make investments to boost access to oxygen innovations adapted to LMICs, via support to regional manufacturers.

The extension of Global Fund's C19RM enables investments that take longer to prepare and implement effectively, such as resilient and sustainable systems for health (RSSH) and pandemic preparedness. These include investments in disease surveillance, laboratory networks, community health worker networks and community-based organizations, medical oxygen and respiratory care systems, as well as the rollout of novel therapeutics to scale up test-and-treat programs in case of future COVID-19 surges. The Global Fund will continue to work with ACT-A partners to generate an integrated, holistic approach around

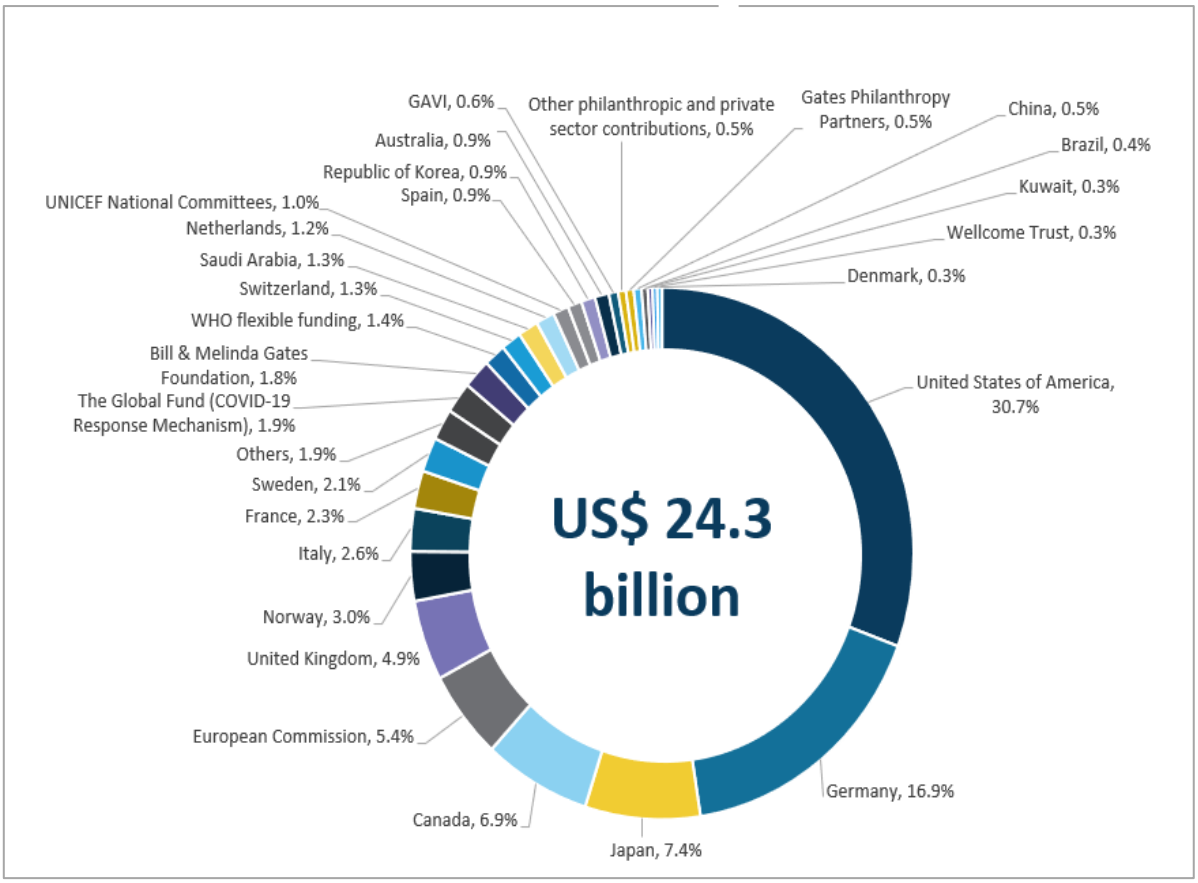
diagnostic and therapeutic priorities to expand progress on COVID-19 and other disease areas, as well as building preparedness for future pandemic threats.

FINANCIAL STATUS

Funds raised

As of 6 February 2023, contributions received since April 2020 total US$ 24bn through the unprecedented generosity of donors to the ACT-A agencies. Of these funds, US$ 4.1million are still pending allocation among the Pillars. The contribution by donor is shown in Figure 4 below. The split by agency, by pillar and by donor is detailed in the ACT-A Commitment Tracker.

Figure 4: Total contributions to ACT-A from April 2020 to 20 February 2023 [10]



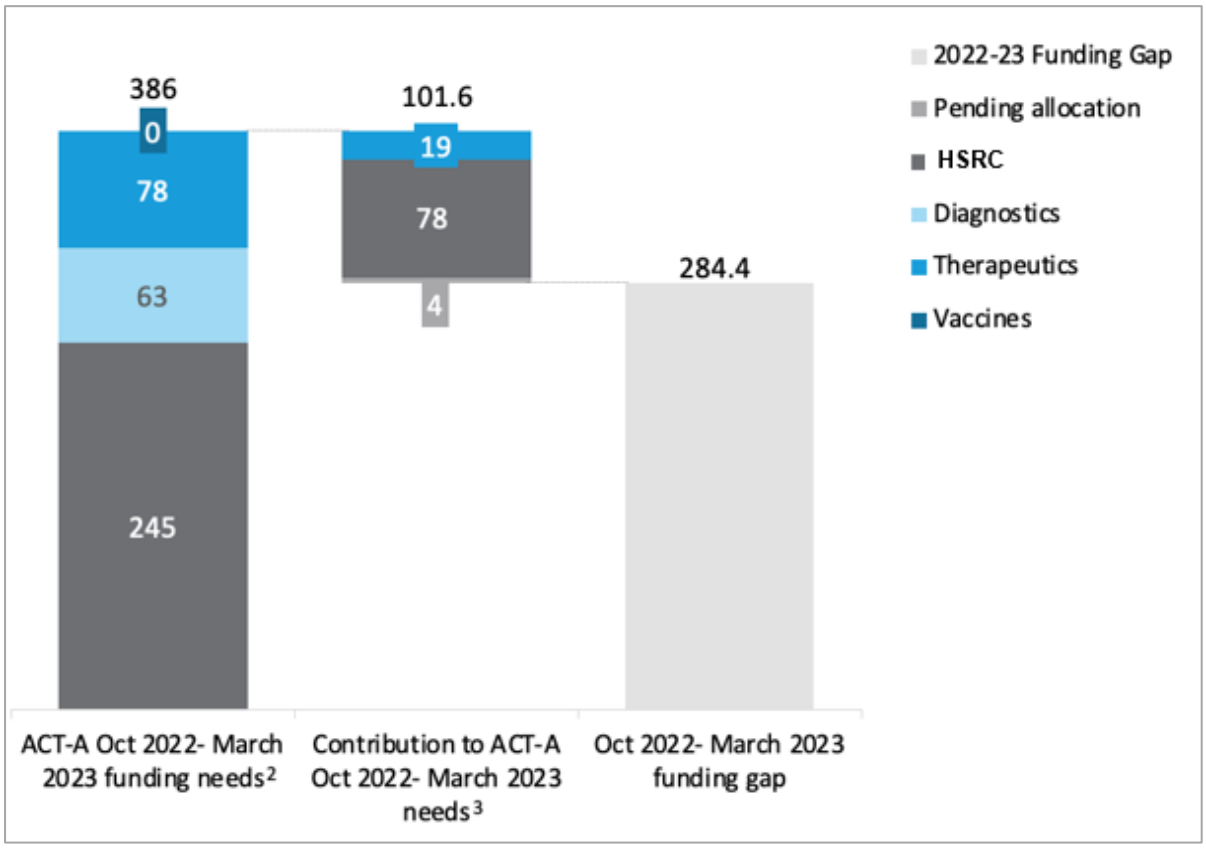
Source: ACT-A Commitment Tracker

[10] Does not include non-gap reducing pledges and contributions (see Commitment Tracker for details of non-gap reducing pledges and contributions).

The funding gap for the transition period

The ACT-A Pillars identified funding needs of US$ 386m to carry out activities of the Transition Plan period. Contributions received since October 2022 have reduced this gap to US$ 284.4m as of 6 February 2023. The funding gaps for the transition period by Pillar are shown in Figure 5 below.

Figure 5: ACT-A Funding gap for transition period (1 Oct 2022 to 31 March 2023) in US$ million[1]



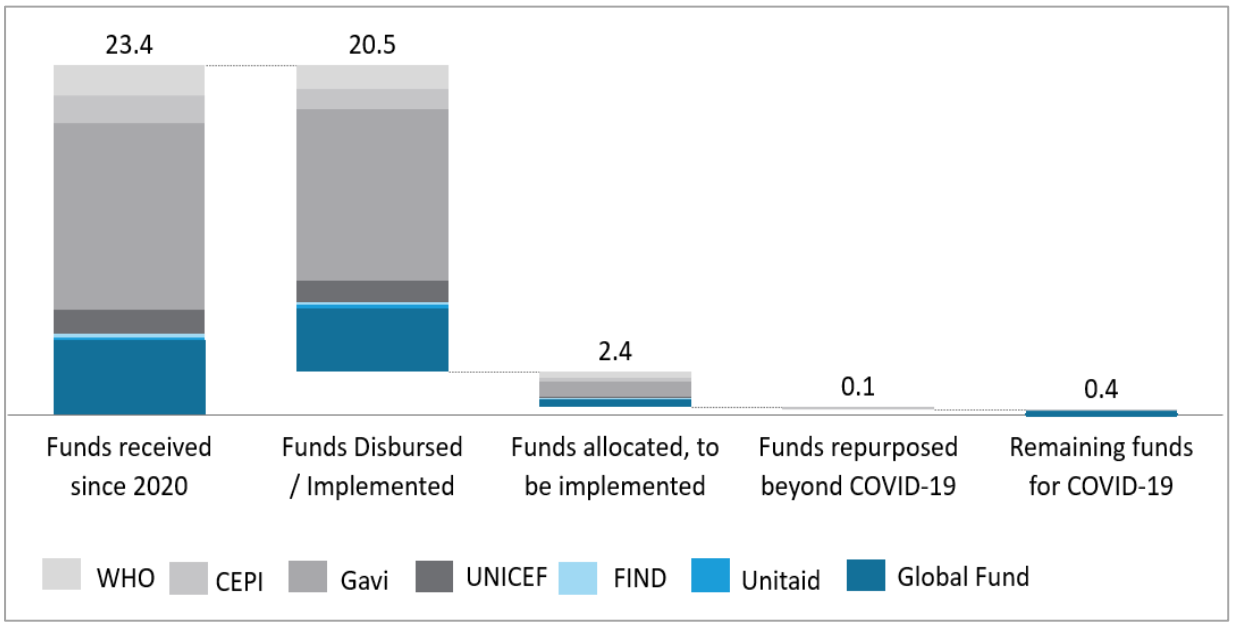
Source: ACT-A Agencies

[1] does not include non-gap reducing pledges and contributions (see Commitment Tracker for details of non-gap reducing pledges and contributions).
[2] As outlined in ACT-Accelerator Transition Plan (1 Oct 2022 to 31 Mar 2023) published on October 28, 2022.
[3] Gap-reducing contributions corresponding to the transition budget financial needs, received during the transition period (1 Oct 2022 to 31 Mar 2023). Not including commitments reported since October 2022 but attributed to the 2021-22 budget (budget period end Oct 2021 to Sept 2022).

Overview of funding implementation

Figure 6 below shows the consolidated financial status of ACT-A funds as of 14 February 2023 from seven ACT-A agencies: CEPI, FIND, Gavi, Global Fund, UNICEF, Unitaid, and WHO. Together these agencies have raised US$ 23.4bn, through the generosity of ACT-A donors. Of the total, US$ 20.5bn (88%) has been implemented or disbursed. US$ 2.4bn (10%) is allocated and to be implemented shortly, while US$ 100m has been repurposed, and US$ 400m, (1.7 %) is pending allocation.

Figure 6 Status of ACT-A contributions, US$ Billion (as of 14 Feb 2023)



Source: ACT-A Agencies