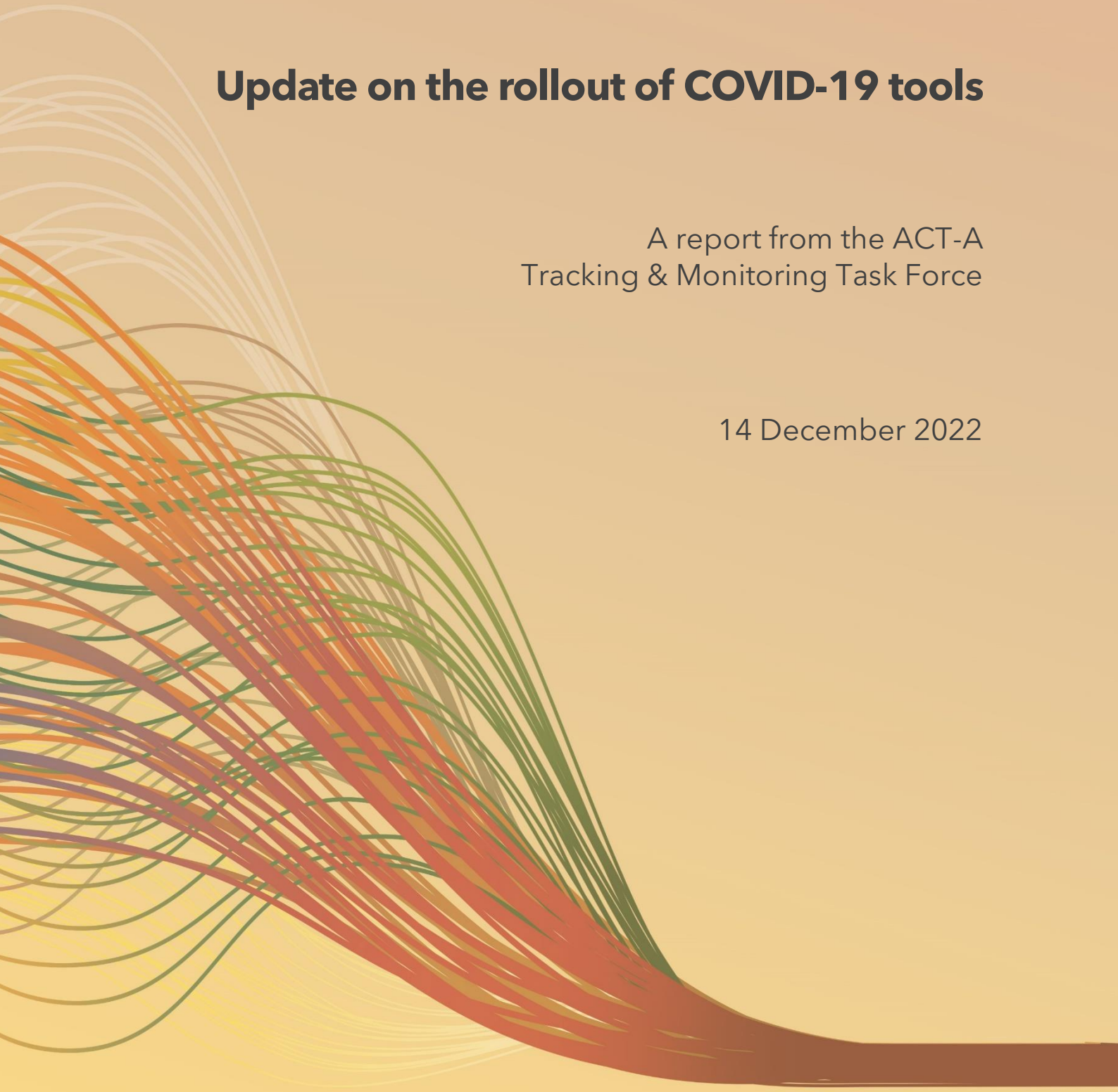
ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Update on the rollout of COVID-19 tools

A report from the ACT-A
Tracking & Monitoring Task Force

14 December 2022



ABOUT THE TASKFORCE

Access to COVID-19 Tools Accelerator (ACT-A) entered a 6-month transition period in October 2022, ACT-A's Facilitation Council was put on 'stand-by' and a Tracking & Monitoring Task Force was created to maintain key 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 reactive, if needed. The Task Force met for the first time on 9 December 2022 and will operate during the period October 2022 to end March 2023 in line with the time frame of the ACT-Accelerator's 6-month transition plan.

CO-CHAIRS STATEMENT

Almost three years since the start of the COVID-19 pandemic, SARS-CoV-2 continues to evolve and spread. Unlike in the previous stages of the pandemic, effective tools to protect, detect and treat COVID-19 now exist. Many countries are experiencing recurring waves of infection, albeit with lower mortality. COVID-19 will be with us for the long-term and many countries have already transitioned or are in the process of transitioning to long-term control measures. Facilitating equitable and sustained access to COVID-19 vaccines, tests, and treatments will be crucial in this transition period and beyond.

As countries adapt to living with COVID-19, increased attention is also being given to the need to address other pressing health priorities. Sustaining momentum and engagement in responding to COVID-19 will be challenging, but it is still necessary for two reasons:

- Equitable access to COVID-19 vaccines, tests, and treatments remains essential, especially in countries with low vaccination coverage. Access to oral antivirals and vaccines for individuals at highest risk of severe disease is key to reducing the still unacceptably high mortality rate.
- The transition period presents an opportunity to build on the progress made so far and to strengthen global health systems for the future.

Key actions for countries, ACT-A and partners include:

- Rapid authorization of new WHO prequalified COVID-19 oral antivirals. ACT-A agencies and partners are supporting LMICs to introduce these new treatments, including their availability for authorized populations.
- Prioritizing vaccination of at-risk populations, including Health Workers and the elderly, especially in countries with low vaccination coverage.
- Maintaining momentum to secure long-term supply arrangements for access to COVID-19 tools during and beyond the transition period

Maintaining readiness and securing longer-term institutional arrangements and sustainable supply strategies will be key as the world integrates COVID-19 work into routine public health programs and continues to monitor and evaluate the effectiveness of COVID-19 tests, treatments and vaccines. This includes considering the need for regular COVID-19 vaccinations or updates to the composition of COVID-19 vaccines and therapeutics to respond to emerging variants.

As outlined in the ACT-A Transition Plan, to maintain readiness ACT-A partners will continue R&D and market shaping activities to ensure a pipeline for new and enhanced COVID-19 tools. As the multiple variants of COVID-19 have shown, there are risks for the effectiveness of COVID-19 vaccines and treatments with continued evolution.

As we heard at our first Task Force meeting, many countries have started to transition to long-term COVID-19 control, and ACT-A agencies are supporting the mainstreaming of current COVID-19 emergency work into routine public health programmes. It is concerning that still 50% of HCWs and 65% of the elderly population in LICs are not yet fully vaccinated. Furthermore, the lack of data to monitor the rollout of new oral antivirals provides an

incomplete picture to fully understand the readiness of countries to tackle future COVID-19 surges.

ACT-A partners are working to secure longer-term institutional arrangements for sustained access to COVID-19 tools. This includes support for distributed manufacturing and generics production, with procurement based on country priorities and demand a crucial component. We look forward to further discussing the longer term COVID-19 institutional arrangements of ACT-A agencies in our Taskforce meeting in February 2023.

Low testing rates around the world make it challenging to reach target patients and evaluate the progress of the pandemic. Targeted testing strategies should be used to help link patients to treatment and help individuals know what action to take, should they test positive.

During the transition period, the Task Force will:

- Continue to monitor the status of COVID-19 tools and ACT-A financing,
- Examine in detail the roll-out of vaccines and of "Test & Treat" strategies with a focus on vaccinating at-risk populations and facilitating access to new oral antivirals.
- Monitor long-term arrangements for sustained access to COVID-19 tools, notably sustainable supply strategies by ACT-A pillars and the integration of COVID-19 control into national health programs

STATUS UPDATE

ACT-A SUPPORT DURING THE TRANSITION PERIOD

ABOUT THE TRANSITION PLAN & PILLAR PRIORITIES

The ACT-Accelerator Transition Plan (October 2022 to March 2023) sets out the priorities for ACT-A's work in the six-month period after the end of the ACT-A 2021-2022 Strategic Plan & Budget. It adjusts ACT-A's ways of working and activities to optimize efficiencies and adapt to the new phase of the pandemic.

The overarching objective of ACT-A's work in the transition period 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 translates into 3 priorities:

- Focusing ACT-A's R&D and market shaping activities to ensure a pipeline for new and enhanced COVID-19 tools
- Securing longer-term institutional arrangements for sustained access to COVID-19 tools (e.g., vaccines, tests, and treatments, including oxygen)
- Concentrating ACT-A's delivery work on new product introduction and protection of priority populations, in support of national and international targets.

Priorities of the Vaccines pillar in the transition period:

- Shift towards the established model structures for operations and delivery support wherever possible, leveraging pre-existing partner processes
- Continue to support R&D into COVID-19 vaccine innovations, expanding and scaling tech transfer and supporting partners and regional bodies on manufacturing
- Support primary vaccination and booster dose programmes through existing agreements and donations
- Support additional booster dose programmes to reach highest priority, healthcare workers and high-risk populations
- Supply paediatric doses if countries request them and as long as supply is available
- The Gavi Alliance board have approved in principle a COVID-19 program for 2024 and 2025. During 2023, the Gavi secretariat will work with Gavi Alliance partners on the design and transition of this program.
- Strengthen pandemic preparedness incorporating the lessons of COVAX to support a strong, future collaboration model for PPR

Priorities of the Diagnostics pillar in the transition period:

- Ensure availability and supply of accurate, affordable diagnostic tools
- Scale, maintain, improve, and sustain equitable access to testing in countries through the Global Fund C19RM (extended until 2025)
- Work with the Therapeutics pillar to support countries to set up scalable test-and-treat programs
- Expand fit-for-purpose sequencing systems, strengthening the integration of epidemiological and genomic data to guide public health action
- Invest in the development and launch of affordable, accessible traditional and new diagnostics platforms (e.g., multiplex molecular POC respiratory assays)
- Prepare for the next threat by improving knowledge, rapid detection, development, and deployment of diagnostic tools in support of health and community systems

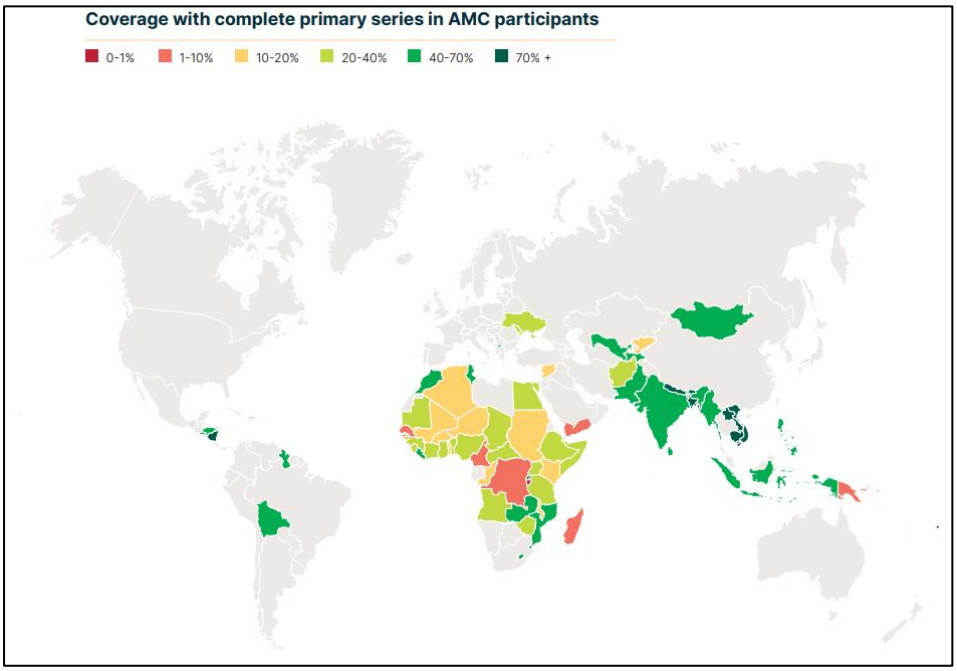
Priorities of the Therapeutics pillar in the transition period:

- Track the pipeline to identify potential new products, monitor new evidence on use of current products, and engagement with manufacturers for equitable access
- Update COVID-19 treatment guidelines and clinical management guidelines
- Ensure countries' rapid access to available therapeutics, and support them to navigate trade-offs between products, factoring in efficacy/safety, product availability (timing) and price differences (originators and generics)
- Ensure markets can respond to potential future surges.
- Increase the number of countries covered by generic manufacturing licensing agreements
- Work closely with countries to implement test and treat strategies targeted to high-risk populations, and build sufficient capacity to rapidly respond to potential future surges
- Support to communities' advocacy strategies for test-and-treat approaches
- Sustain O2 investments made during COVID-19 to build a healthy O2 market in the long term

PROGRESS ON COVERAGE OF COVID-19 TOOLS

Vaccines

As of December 2022, almost 13 bn doses have been administered globally of which almost 2 bn doses were supplied through COVAX. Only eight countries remain below 10% coverage, among which many are facing humanitarian emergencies. Although 64% of the world's population has been vaccinated with a primary series, significant disparities exist between regions and income groups. The average vaccination rate in low-income countries has improved to 22%. Overall, countries have, on an average, vaccinated 83% of their health care workers (HCW) and 79% of their elderly population. While there has been progress in low-income countries, still 50% and 56% of HCWs and elderly population remain unvaccinated, leaving large segments of at-risk populations vulnerable. COVAX is playing a crucial role in equitable access, delivering almost 75% of all doses used by low-income countries, as of December 2022.



Source: COVID-19 Vaccine Delivery Partnership, Situation Report, October 2022

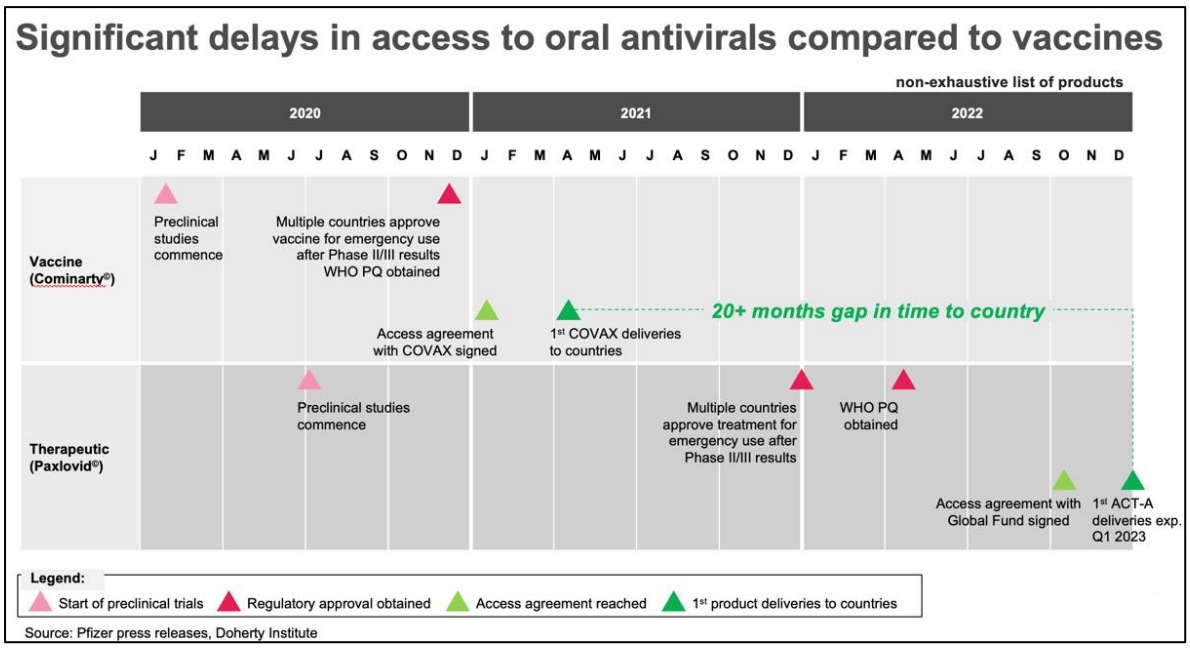
Diagnostics

Testing policies across the world have continued to change with the evolving pandemic and testing rates have dropped significantly over the course of 2022. With more decentralized testing due to Antigen rapid diagnostic tests (Ag-RDTs), reported testing numbers are low. Few low-income, low-middle income and upper-middle income countries reached the 100 tests per 100k population per day target during the acute phase of the pandemic. Testing as part of integrated surveillance remains crucial to understand the evolution of the virus and to aid in research and rollout of new oral antivirals.

The ACT-A Diagnostics Pillar has procured 185.5m tests for 182 countries. ACT-A and partners have also negotiated price reductions of approximately 30-50% over the course of pandemic and secured RDT manufacturing capacity to ensure sufficient supply of tests for LMICs, regardless of demand volatility. 34 SARS-CoV-2 diagnostic tools have been authorized by WHO for emergency use listing (EUL), including 3 Ag-RDT self-tests, 11 Ag-RDT professional use tests and 20 molecular tests. Of 190 WHO Member States, 77% have SARS-CoV-2 sequencing capabilities and 22% have access to timely sequencing through an international referral mechanism, enabling the world better prepared for future threats.

Therapeutics

The access to new lifesaving COVID-19 antivirals molnupiravir and nirmatrelvir & ritonavir (Paxlovid) in low and low-middle income countries is expected to increase due to adequate global supply. Affordable, generic options are available and additional generics are in the pipeline for WHO prequalification. The long delay in securing supplies for low and low-middle-income countries will make it challenging to introduce these new therapies, hence an intensified effort is needed to engage countries and support scale up of test and treat strategies.



There were significant delays in some Tx access, with key products reaching countries 20 months after vaccines. Source: Therapeutics Pillar

Sublicensing agreements have been signed with 23 generic manufacturers in 10 countries for molnupiravir and 38 manufacturers in 13 countries for nirmatrelvir & ritonavir (Paxlovid). Supply agreements were secured for Paxlovid with acceptable access conditions, and Paxlovid generics are expected in Q1 2023 at a fraction of the original access price.

The ACT-A Therapeutics pillar is supporting test and treat pilots in 29 countries, with US$ 70m of additional funding. ACT-A partners have procured COVID-19 medicines worth US$ 25.2m In addition, US$ 190m was awarded by the Global Fund to countries for therapeutics and other supportive hospital equipment. Furthermore, ACT-A has supported significant oxygen investments during COVID-19 to build a healthy medical oxygen market in the long term, which is essential to protect the most vulnerable and maintain readiness.

A more detailed account of pillars' achievements since the beginning of the pandemic can be found in the ACT-Accelerator Outcomes Report, 2020-22, published in December 2022.

ISSUES REQUIRING SPECIAL ATTENTION

Therapeutics partners are facing several challenges in getting antivirals to patients, primarily related to low demand, policy & regulatory challenges, procurement, and community engagement.

- Low diagnostic rates make it challenging to reach target patients.
- Some national governments are reluctant to approve new treatments and include them in national guidelines before cost-effectiveness studies can be concluded, and those studies would ideally be informed by pricing and availability of lower cost or generic products, where those are available. Especially in countries where cases are declining, investment in COVID-19 has been more limited, in part due to competing priorities, low testing rates, uncertain funding options, supply delays, and uncertain evolution of the pandemic.
- Availability of originator stocks was delayed for nirmatrelvir & ritonavir because of negotiations and shelf-life issues. Regulatory processes are ongoing with support from WHO for countries that are moving forward with rollouts using innovator products and will continue for the transition to generics.
- Lack of product familiarity may require efforts to educate local stakeholders on drug profiles and use cases.

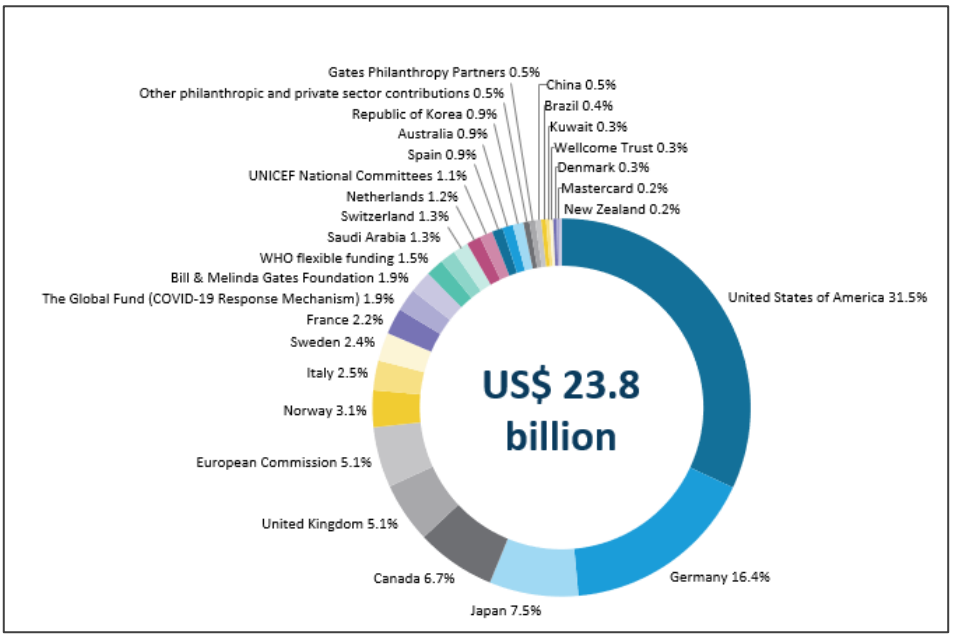
While substantial progress has been made against ACT-A Diagnostics priorities, partners have also raised ongoing challenges regarding testing.

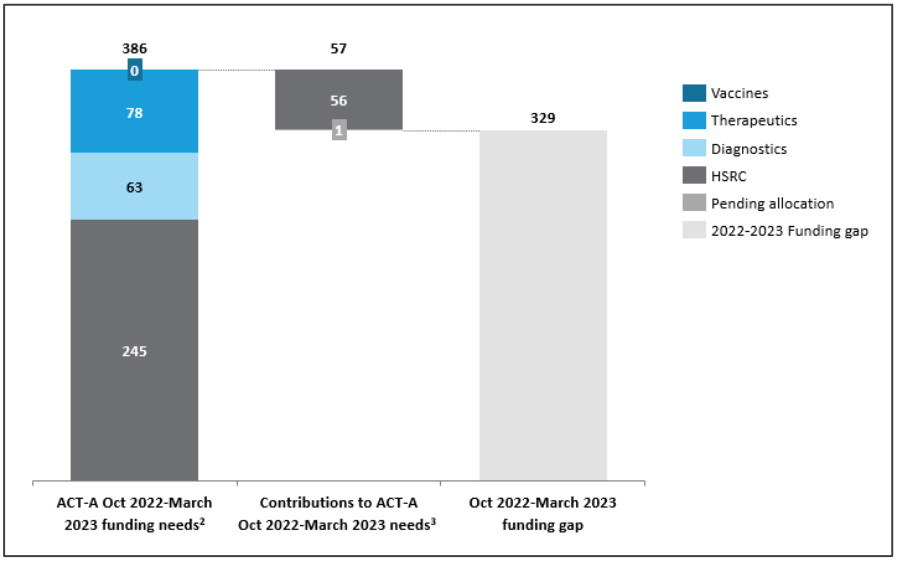
- The lack of locally-produced diagnostic tests in LIC/LMIC settings hinders the ability to monitor and detect pathogens of concern effectively.
- Regulatory bodies need to be adequately supported to respond under the strict timeline requirements of a pandemic.
- COVID-19 fatigue, limited diagnostic literacy and the lack of integration of COVID-19 surveillance into health system has contributed to declining testing rates and the deprioritization of diagnostics for COVID-19. Diagnosis and care can be brought closer to communities, including through more meaningful engagement of communities and country stakeholders.
- Addressing the test-to-treat approach is a structural problem as well as a technical one since diagnostics and therapeutics are often considered different markets with independent stakeholders.
- The ongoing need for building strong national laboratory programs and sequencing capacities, which enables visibility on changes in existing and the emergence of new pathogens.
- New diagnostic technologies, like digital tools and multi-pathogen tests, together with existing diagnostic systems, will need continued investment and advocacy.

FINANCING STATUS

FUNDS RAISED

As of 14 November 2022, contributions received since April 2020 total US$ 23.8 billion. Among these funds, US$ 1.1 billion received in the 2021-2022 budget cycle are still pending allocation between Pillars. The split by agencies and Pillars is detailed in ACT-A Commitment Tracker.



FUNDING NEEDS FOR THE TRANSITION PERIOD

In ACT-A transition plan, as of October 1, 2022, the Pillars identified funding needs of US$ 386m to carry out activities of the Transition Plan period. Contributions received since from the United States and Canada have reduced this gap to US$ 329m as of November 2022. Details can be found in ACT-A Commitment Tracker. The next update of the tracker will be published ahead of the Task Force's second meeting.