ACT-Accelerator Investment Case

Invest now to change the course of the COVID-19 pandemic

26 June 2020

Foreword and notes

This document is intended for countries, foundations, and civil society. It provides a consolidated overview of the Access to COVID-19 Tools (ACT) Accelerator, its goals, and the investments that partners have calculated are required to carry out its mission.

Emergency responses are dynamic by nature. The ACT-Accelerator will regularly adjust its investment needs and update this document as understanding of COVID-19 epidemiology and additional data on the ACT tools become available. For more detailed analysis on the ACT investments for its work in diagnostics, therapeutics and vaccines, please refer to the costed plans of the relevant 'pillar'. At the time of publication, the investments required for the Health Systems Connector pillar were still under development.

Why invest in the ACT-Accelerator?

No-one is safe until everyone is safe.

There is no time to waste in the fight against COVID-19. Millions of people have been infected, hundreds of thousands of people have died, and every month the global economy loses an estimated US$375 billion. Faster and more effective progress on the tools to protect, test and treat is vital. And once developed, these tools must be fairly shared among those most at risk from the disease.

Launched on 24 April 2020, at an event co-hosted by the Director-General of the World Health Organization, the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation, the Access to COVID-19 Tools (ACT) Accelerator brings together governments, health organizations, scientists, businesses, civil society, and philanthropists. They have joined forces to speed up the end of the pandemic by supporting the development and equitable distribution of the tests, treatments and, vaccines the world needs to save lives, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 in the medium term.

Success will depend on scientific endeavour and innovation collaborating and being funded at unprecedented levels. It will be based on the principles of fairness and speed – so that all safe, effective tools to fight COVID-19 can be deployed equitably, not just to those who can pay the most.

To achieve this, the ACT-Accelerator aims to develop essential health products for the fight against COVID-19 and to ensure they are distributed equitably through a rapid and ambitious programme of work to develop, test, bring to market, procure and distribute new diagnostics, drugs and technologies, while taking steps to help ensure health systems can deliver these tools to the people who need them.

ACT-ACCELERATOR

Total investment needed

US$ 31.3 BILLION

Vaccines

CEPI

Gavi The Vaccine Alliance

$18.1 BILLION

Needed for next 18 months

2 billion

doses globally by the end of 2021

Therapeutics

Unitaid Innovation in Global Health

wellcome

$7.2 BILLION

Needed for next 12 months

245 million

therapeutics courses in Low and Middle-Income Countries by mid-2021

Diagnostics

FIND Because diagnosis matters

The Global Fund

$6 BILLION

Needed for next 12 months

500 million

tests in Low and Middle-Income Countries by mid-2021

Health Systems Connector

THE WORLD BANK

Strengthening health systems to make sure essential COVID-19 tools reach the people who need them

The Global Fund To Fight AIDS, Tuberculosis and Malaria

The ACT-Accelerator will deliver new tools for the whole world.

World Health Organization

What will the ACT-Accelerator achieve?

The ACT-Accelerator partners will collaborate under four pillars that will help produce the key tools needed to achieve a step change in the pandemic response and that will benefit the whole world.

- The first, **Vaccines** pillar, led by CEPI, Gavi and the WHO, is speeding up the search for effective vaccines for all countries. At the same time, it is supporting the building of manufacturing capabilities and buying supply, ahead of time, so that 2 billion doses can be distributed fairly in the places of greatest need, worldwide, by the end of 2021.
- The second, **Therapeutics** pillar, convened by the Wellcome Trust and UNITAID, aims to develop effective new therapeutics, and to ensure the manufacture, procurement, and distribution of 245 million courses of these treatments to low and middle-income countries (LMICs) by mid-2021.
- The third, **Diagnostics** pillar, convened by the Global Fund and FIND, focuses on developing new simple, affordable, high-quality and rapid diagnostics to detect infection and contain disease spread, with 500 million of these tests reaching people in low and middle-income countries by mid-2021.
- The final, **Health Systems Connector** pillar, led by the World Bank and the Global Fund, is working to ensure that these tools reach the people who need them.

Cross-cutting all of this work, and fundamental to the goals of the ACT-Accelerator, is the **Access and Allocation workstream** that is led by WHO and is developing the principles, frameworks and mechanisms needed to ensure the fair and equitable allocation of these tools. Although the tools developed will benefit the whole world, the ACT-Accelerator pillars will also purchase and deliver them to low and middle-income countries.

Products will be introduced through a three phase timeline over an 18 months period:

Phase 1
consists of rapidly scaling up diagnostics and identifying viable new products for large-scale use. Activities range from R&D to market and country preparedness

Phase 2
consists of introducing these new products to complement existing solutions, and while ensuring market preparedness and sufficient manufacturing capability

Phase 3
is the period in which the response will transition to use these new products as the primary intervention, and will include large scale procurement of products and equitable delivery

While these phases appear sequential, it is crucial that market preparedness, manufacturing and delivery work begins in parallel with research and development, to ensure the new tools can be deployed as early as possible.

Across the **Diagnostics**, **Therapeutics,** and **Vaccines** pillars, critical needs span the whole value chain from Research & Development, Market Preparedness & Manufacturing, to preparing for Procurement & Delivery.

Research & Development

Current rapid diagnostic tools often have suboptimal performance and despite encouraging success on new therapeutics, we are still lacking sufficient effective treatments for COVID-19. Although there is a very large portfolio of over 200 vaccine candidates, development is still at an early stage and many of these candidates may fail. The challenges ahead are considerable and success is not guaranteed. Finding, producing, and providing appropriate and equitable access to diagnostics, therapeutics, and vaccines means that large investments will have to be made at a level of risk not normally considered by international public finance.

However, the extreme urgency and importance of this work, with potentially millions of lives at stake, makes accepting such risks both defensible and necessary.

The Diagnostics, Therapeutics and Vaccines pillars are concentrating R&D efforts on the following activities:

- **Vaccines:** ensuring the most promising vaccine candidates get the funding that they need, when they need it, and that regulatory conditions are in place to allow the safest and most seamless passage from early stages of development through to licensure and use.
- **Therapeutics:** supporting the repurposing of existing therapeutics and development of new antibody and antiviral therapies, and ensuring that products will be available widely, especially in low and middle-income countries that often face other threats (e.g. Tuberculosis, Malaria, HIV).
- **Diagnostics:** given the performance of many first generation Rapid Diagnostic Tests, accelerating the development of high performing, affordable antigen rapid diagnostic tests, and creating robust digital, data, and analytics solutions.

Market Preparedness & Manufacturing

While the development and deployment of innovative products is essential, it will not be enough. Effective tools often fail to be made available evenly across populations. This inequity poses a risk to global public health and economic development. All tools to address COVID-19 must be available to all.

For this to happen, we must simultaneously and urgently prepare markets to accelerate implementation as soon as new or enhanced products are available, and to enable delivery of the new COVID-19 tools to those who need them most. Consequently, Market Preparedness & Manufacturing activities include:

- Creating mechanisms to aggregate demand across countries
- Designing market interventions to make products available and affordable
- Securing manufacturing and production capabilities
- Working out allocation strategies to ensure equitable and transparent access
- Providing regulatory support, including for regulatory approvals
- Building a large-scale inventory and manufacturing reservation to ensure affordable pricing in preparation of procurement

- Diversifying supply chains by fostering innovative licensing agreements on technology and know-how transfers, as well as strengthening local production
- Setting up adequate supply systems including cold chain capacity
- Creating risk sharing mechanism to secure investments

As readiness of production capacity and regulatory approvals are ensured, market preparedness & manufacturing will enable rapid and effective scale-up.

Procurement & Delivery

Even if low cost, repurposed, off-patent products were found to be effective in the areas of diagnostics, therapeutics, or vaccines, the already stretched health budgets of many countries would not on their own be able to bear the cost of making these products available to all who need them.

Support to these countries and populations, for both product procurement and delivery activities, will be provided to reach the following targets:

- **Vaccines:** the delivery of 2 billion doses by the end of 2021. The ACT-Accelerator's vaccines pillar has created a Global COVID-19 Vaccine Facility through which countries can work together to share risk by accessing a wide portfolio of vaccine candidates. At the same time, countries can optimize their chances of accessing the number of doses they need, whether by financing procurement themselves or through official development assistance (ODA). The pillar is currently investing in vaccine production capacity across several candidates so that, upon regulatory approval, doses can be made available immediately.
- **Therapeutics:** the procurement and delivery of 245 million courses of therapeutics, across all levels of COVID-19 disease severity, for populations in low and middle-income countries over the next 12 months.
- **Diagnostics:** the procurement and deployment of 500 million tests over the next twelve months to low and middle-income countries, 85 million of which will be deployed over the next 6 months to cover immediate needs in such areas.

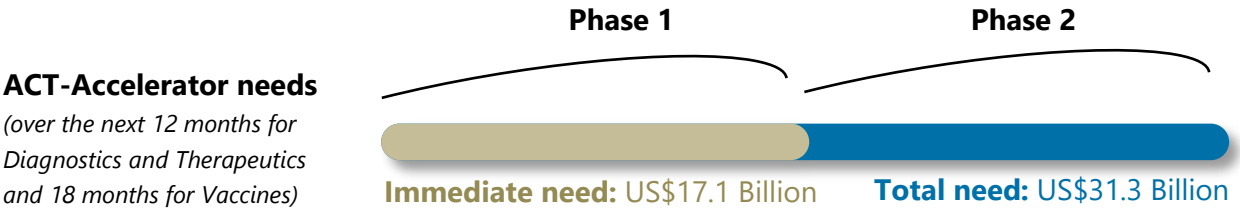
How much support does the ACT-Accelerator need?

This section provides a consolidated view of the investment needs across the Diagnostics, Therapeutics and Vaccines pillars. The financial needs for the Health Systems Connector are in the process of being calculated and will be released in the near future.

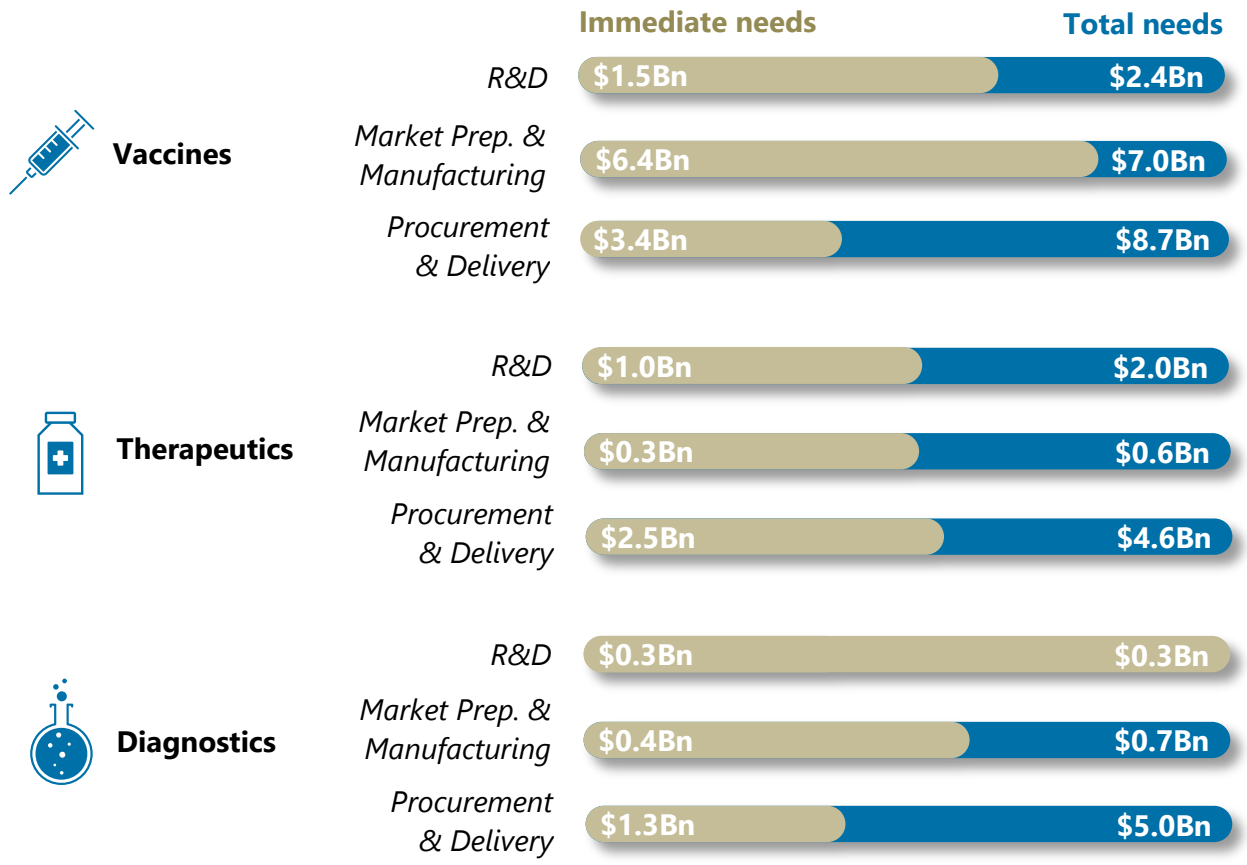
As uncertainties in the ACT product pipeline are addressed, and as more epidemiological data becomes available, the assumptions that underpin these investment needs will be refreshed and the requirements updated.

Required investments

A total of US$31.3 billion is needed for the work of the ACT Diagnostics, Therapeutics and Vaccines pillars. These needs have been developed through pillar-specific scenarios and assumptions that are detailed in their respective plans and investment cases. The total needs have been calculated over a 12 months period for the Therapeutics and Diagnostics pillars, and 18 months for the Vaccines pillar.



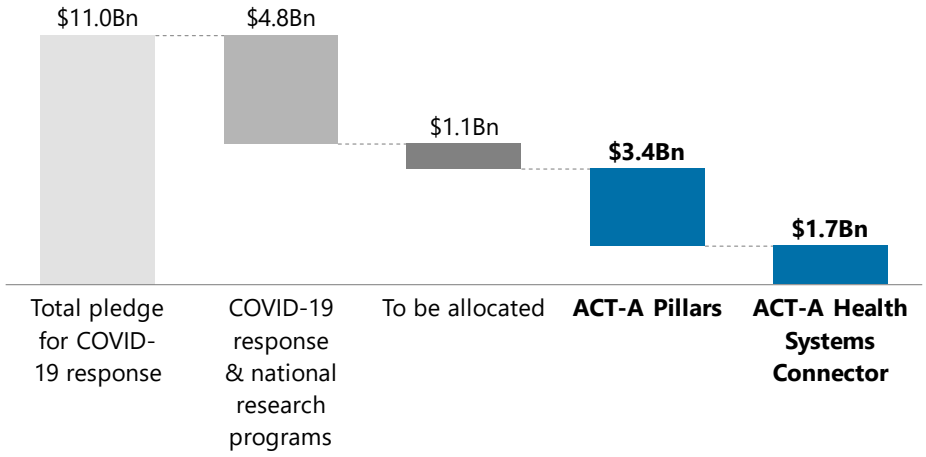
The 'immediate needs' represent the critical investments required within the next six months to meet the ACT-Accelerator targets. These needs can be broken down into the major activities of each pillar as follows:



NOTE: assuming safe and effective vaccines are developed in the near future, ACT's current estimate for the delivery of 2 billion doses of vaccine by the end of 2021 is up to US$18.1 billion, with 950 million of those doses procured by self-financing high and upper middle-income countries through the COVAX Facility. These numbers will be updated as understanding of the technology that the successful vaccine candidates will be based on, and the number of doses required to protect people from COVID-19, improves.

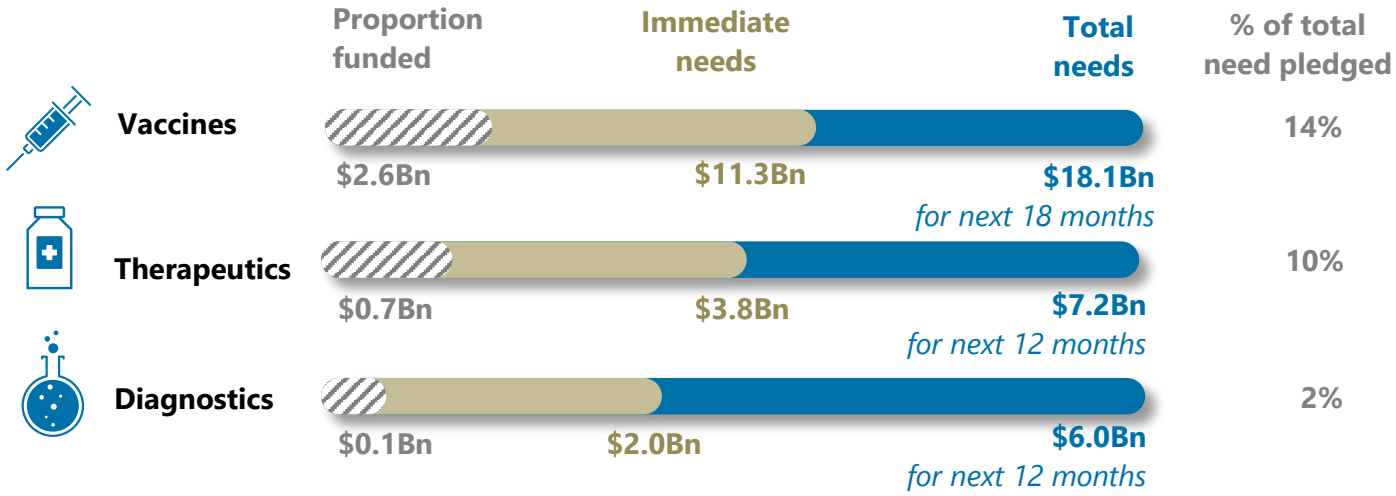
Financing & funding gaps

Since the launch of the ACT-Accelerator on 24 April 2020, many governments, foundations, companies and individuals have signaled their commitment and made financial pledges to end COVID-19. To date, these pledges total US$11 billion[1] of which **$3.4 billion is for the 3 'product pillars'** and **$1.7 billion for the Health Systems Connector**, with the balance for COVID-19 response activities.



Breakdown of commitments from the 4 May 2020 European Commission-led pledging event

These generous pledges represent 11% of the total investment needed for ACT Diagnostics, Therapeutics and Vaccines:



In summary, the diagnostic, therapeutic and vaccine pillars of the ACT-Accelerator will need an additional US$27.9 billion, including US$13.7 billion to cover immediate needs (i.e. $17.1 B required - $3.4 B pledged). Fortunately, there is growing recognition of the benefits of collaborating through ACT, our most promising hope of a successful global effort to end the virus.

[1] An additional $567m was contributed to the COVAX AMC facility on 4 June 2020

Accountability

When the ACT-Accelerator was launched, a number of donors came together to form a Facilitation Group. This arrangement will soon transition into a Facilitation Council, composed of representatives from founding member countries of the ACT-Accelerator and governments from the global North and South, and with participation of international organizations, private philanthropy, and civil society. Membership is currently being determined. The Council will provide the pillars with support and guidance on key strategic, policy, and financial issues to ensure delivery, financing, and equitable access. The Council will also monitor the activities of the ACT-Accelerator pillars and communicate progress to a broad range of interested stakeholders.

An ACT-Accelerator 'Hub' is hosted by WHO, supports the Council and enables the work of the partners in each pillar, recognizing the interlinked nature of treatment, testing and vaccination, and the critical role of health systems. Formal governance of the work of the pillars is provided by the Boards and governing bodies of the partner organizations that lead the work of each pillar.

Donors have full oversight on the allocation of their pledges. Co-conveners are accountable for the workplans and investment cases of each pillar. Grant management and financial reporting to donors will be managed by the receiving entity.

Next steps

We must continue to build on the momentum and promise of the ACT-Accelerator by rapidly addressing the most immediate financial needs of each pillar, to enable them to deliver their full impact.

Upcoming milestones:

- the next pledging event to include ACT activities will be held on 27 June 2020, led by Global Citizen and hosted by the European Commission.
- this Investment Case will be updated as needed in the early fall of 2020, as the first ACT-Accelerator milestones for product development are achieved and more epidemiological data becomes available.