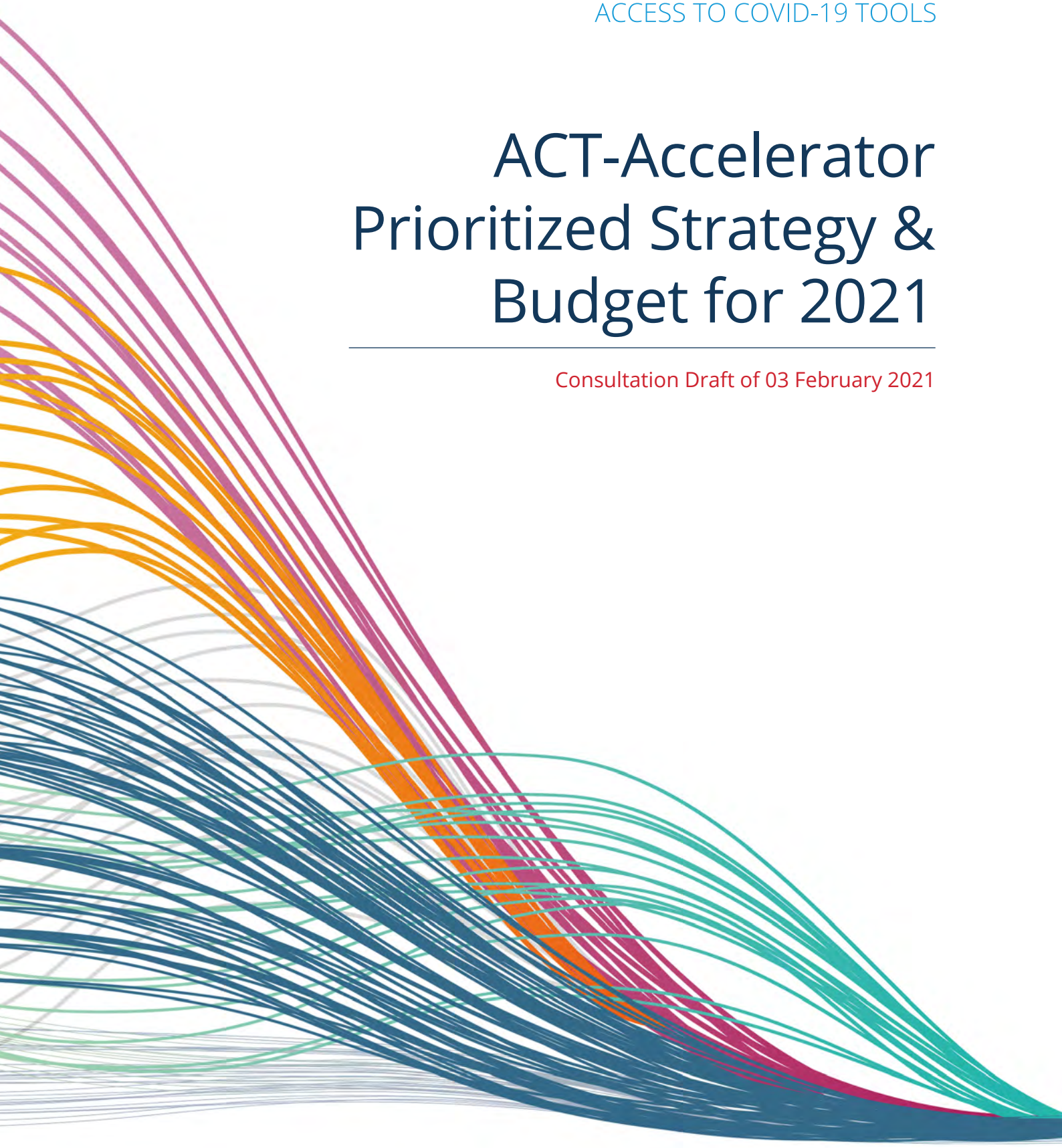
ACTaccelerator
ACCESS TO COVID-19 TOOLS

# ACT-Accelerator Prioritized Strategy & Budget for 2021

Consultation Draft of 03 February 2021



Gavi The Vaccine Alliance · CEPI · Bill & Melinda Gates foundation · World Bank Group · World Health Organization · wellcome · FIND Because diagnosis matters · The Global Fund · Unitaid

**Working with governments, civil society and industry**

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Consultation Draft of 03 February 2021

The Access to COVID-19 Tools (ACT) Accelerator strategy and budget is periodically updated to reflect the evolving epidemiological situation, knowledge of COVID-19, COVID-19 products and pipeline, and financing requirements. The ***ACT-Accelerator Prioritized Strategy & Budget for 2021*** supersedes the ***ACT-Accelerator: Status Report & Plan*** and ***ACT-Accelerator: Economic Investment Case & Financing Requirements***, published in September 2020, and the ***ACT-Accelerator Urgent Priorities & Financing Requirements*** published in November 2020.

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# 00

# ACRONYMS USED IN THIS DOCUMENT

| | |
|---|---|
| **Ag** | Antigen-detecting |
| **ACT** | Access to COVID-19 Tools |
| **AMC** | Advance Market Commitment |
| **APA** | Advance Purchase Agreement |
| **CEPI** | Coalition for Epidemic Preparedness Innovations |
| **EUL** | Emergency Use Listing |
| **FIND** | The Foundation for Innovative New Diagnostics |
| **GDP** | Gross Domestic Product |
| **HICs** | High-income Countries |
| **HSC** | Health Systems Connector |
| **IP** | Intellectual Property |
| **IMF** | International Monetary Fund |
| **LICs** | Low-income Countries |
| **LMICs** | Low- and middle-income Countries |
| **mAbs** | Monoclonal Antibodies |
| **MPA** | World Bank's Multiphase Programmatic Approach |
| **NDVP** | National Deployment Vaccination Plan |
| **ODA** | Official Development Assistance |
| **PCR** | Polymerase Chain Reaction |
| **PPE** | Personal Protective Equipment |
| **SFP** | Self-Financing Participants in the COVAX Facility |
| **SM NAV** | Small Molecule Novel Antivirals |
| **SRA** | Stringent Regulatory Authority |
| **R&D** | Research & Development |
| **RDT** | Rapid Diagnostic Test |
| **UMIC** | Upper middle-income Countries |
| **VIRAT** | Vaccine Introduction Readiness Assessment Tool |
| **VRAF** | Vaccine Readiness Assessment Framework |
| **WHO** | World Health Organization |

# 01

# ACT-ACCELERATOR IS EVOLVING IN A RAPIDLY CHANGING WORLD

**The evolving context for ACT-Accelerator:**

1. **We have entered the 'era of COVID-19 vaccines'**
2. **Viral variants are emerging with increasingly concerning characteristics**
3. **The international collaboration in responding to the COVID-19 pandemic is increasingly fragmented and underinvesting in global solutions**

The world continues to deal with an unprecedented threat, which extends far beyond a global health crisis. We are facing an economic, humanitarian, security and human rights crisis. Dire challenges have been unfolding, and countries have spent trillions on the consequences of COVID-19. As of late January 2021, COVID-19 has tragically claimed more than 2 million lives and infected over 100 million people worldwide.[1] Many countries are experiencing a resurgence in cases, often more extreme than previous waves, putting immense strains on health systems. New and more transmissible variants of the virus are taking hold in many geographies. We need to do much more and act much faster to save lives, stabilize health systems and restore global economic momentum.

The Access to COVID-19 Tools (ACT) Accelerator, launched in April 2020, is a global solution for expediting the end of the COVID-19 pandemic. This collaboration of leading public health agencies has accelerated the development of COVID-19 tests, treatments and vaccines and is positioned to rapidly scale and ensure equitable access to a new generation of COVID-19 tools. ACT-Accelerator has transformed our ability to tackle COVID-19 on a global scale: vaccines are poised to roll-out worldwide, low-cost high-performing antigen rapid diagnostic tests (Ag-RDTs) can now detect transmission anywhere, and affordable therapy for severe disease can save lives in any setting. How quickly these tools can be made available to all who need them will depend in large part on the ability of ACT-Accelerator partners to continue to finance these activities. The original 2020-2021 budget estimate in September 2020 for ACT-Accelerator was US$ 38.1 billion. Cost adjustments and donor commitments since then have reduced the funding gap for 2021 to US$ 27.2 billion (see Appendix C).

The arrival of vaccines in particular has brought great optimism; however, with a limited vaccine supply, an evolving virus that could neutralize current COVID-19 tools, and a rapidly changing global situation, navigating one of the biggest public health efforts in human history requires a refresh of the ACT-Accelerator plan[2,3], financing requirements, and investment case[4]. We must continue to build towards a strong global, integrated, and

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[1] WHO Coronavirus Disease (COVID-19) Dashboard. Geneva: World Health Organization; 2020 (https://covid19.who.int/, accessed 1 February 2021).
[2] ACT-Accelerator: Status report & plan, September 2020 – December 2021. Geneva: World Health Organization; 2020 (https://www.who.int/docs/default-source/coronaviruse/act-accelerator/status-report-plan-final-v2.pdf, accessed 13 January 2021).
[3] ACT-Accelerator: Urgent priorities & financing requirements at 10 November 2020. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/urgent-priorities-financing-requirements-at-10-november-2020, accessed 20 January 2021).
[4] ACT-Accelerator: An economic investment case & financing requirements, September 2020 – December 2021. Geneva: World Health Organization; 2020 (https://www.who.int/docs/default-source/coronaviruse/act-accelerator/economic-investment-case-final-v2.pdf, accessed 13 January 2021).

agile response, and deliver on the full potential of the tools we have now. In parallel, we need to ensure research and response mechanisms evolve as the virus and the pandemic characteristics continue to change. This evolving context for a refreshed ACT-Accelerator strategy, priorities and budget for 2021 is summarized in three big shifts:

1. **We have entered the 'era of COVID-19 vaccines',** and are moving from a phase where COVID-19 vaccines were an uncertainty and a scientific endeavour to a phase where they are a reality, in huge demand, and with the race on to accelerate, scale and ensure their equitable access. The first safe and efficacious vaccines for COVID-19 have received approvals for emergency use listing (EUL) by WHO and/or stringent regulatory authorities (SRAs), and more than 50 countries have started vaccination. More vaccine candidates are expected to follow soon, and manufacturing is being scaled at unprecedented speed. The world now has a reliable tool at hand to prevent the disease and protect the most vulnerable populations. Throughout 2021, supply constraints are predicted to become less pressing quickly given the higher than expected success rate of vaccine candidates and the progress in manufacturing scale-up and roll-out. Nevertheless, key challenges remain. The global demand for vaccines is immense and in some settings risks crowding out demand for other tools, even while manufacturers struggle to meet this demand and initial vaccine availability is very limited.

2. **Viral variants are emerging with increasingly concerning characteristics,** reminding us that speed matters and that we need to continually assess our portfolio of tools to ensure they remain fit-for-purpose. Thus far, three variants of concern have been detected, and others are under investigation. Evidence is still being gathered, but these variants of concern are thought to contribute to the increase in virus transmission we are now seeing globally. In addition, these and future variants may raise questions about the accuracy and efficacy of current COVID-19 tools and pose even greater risk to health systems. Our best answer to these risks is to decrease the circulation of the virus as fast as we can across the globe, as new mutations can originate in any geography, and quickly spread globally. It continues to be vital for ACT-Accelerator and the world to monitor these changes very closely, invest further in scaling up diagnostic testing and sequencing to enhance global surveillance, especially in LICs and LMICs, as well as bolster investments in delivery systems and research and development (R&D) where gaps are occurring, and provide rigorous product assessment for the world while ensuring regulatory activities allow for rapid global adoption.

3. **The international collaboration in responding to the COVID-19 pandemic is increasingly fragmented and underinvesting in global solutions.** The ACT-Accelerator collaboration was founded based on the principle of global solidarity and with an exceptionally strong multilateral commitment (governments, manufacturers, regulators and others). Yet, the slow translation of this commitment into full funding for all needs and investment in and collaboration with multilateral solutions is costing lives and impeding progress, e.g. ACT-Accelerator has a funding gap of US$ 27.2 billion to meet the minimum ambition to address the pandemic. At the same time, we are confronted with an escalation in the number and reach of bilateral deals for key products – particularly vaccines - that further pressure global collaboration and solidarity.

While these shifts pose substantial challenges, ACT-Accelerator is well-equipped to respond, having learned substantially since its launch in April 2020. At that time, very few COVID-specific tools were available to countries in the fight against this threat. Since then,

significant progress in the development and scale-up of new tools and strategies against COVID-19 has been made. Thanks in large part to the unprecedented collaboration across agencies and organizations, and the support of many countries and donors, the world has developed an initial critical portfolio of tools to fundamentally change the course of the pandemic, however needs are continuously changing as the pandemic evolves.

As we advance, ACT-Accelerator is positioned to further strengthen the **three lines of defense** established against COVID-19, each of which is essential to an effective and integrated response to overcome this pandemic. One line of defense, new vaccines, can now dramatically reduce the disease burden and protect the highest risk and highly exposed populations. Another line of defence is testing to identify and isolate cases. The development and scale-up of rapid diagnostics have reinforced this line, thereby informing the application of countermeasures that break transmission, reduce case counts, and enable surveillance for all cases including early detection of variants and targeting of interventions across regions to limit resurgence of the virus. The final line of defense, treating the ill, has been advanced with the identification of the first the effective therapeutic for severe disease (dexamethasone) and acceleration of availability of medical oxygen, providing a vital clinical care pathway with effective treatment options to save lives.

Additionally, the **critical enablers** for further accelerating equitable access and ultimately ending this pandemic are in place, or are rapidly being finalized. These include accelerated regulatory processes, issuance of technical guidance for testing and treatments as well as genomic sequencing, and mechanisms for equitable allocation (e.g. the COVAX Facility, procurement for LICs and LMICs – such as the COVAX Advance Market Commitment to secure doses for 92 low- and middle-income countries and economies, volume guarantees).

# 02

# ACT-ACCELERATOR IS MAKING A REAL DIFFERENCE

A global solution is essential to overcome the biggest public health crisis in human history, even more so with the rapidly evolving global landscape and the emergence of new variants. ACT-Accelerator is this solution, which aims to expedite the end of the pandemic through acceleration of the development of and global equitable access to COVID-19 tools.

ACT-Accelerator has played a critical role in enabling and supporting the scientific progress that has allowed us to enter the era of COVID-19 vaccines and position the world for equitable access to this vital product. COVAX, the Vaccines Pillar of ACT-Accelerator, accelerated the development and production of vaccines through investments in a broad portfolio, currently including 11 candidates across 4 technology platforms. It set up the COVAX Facility, a global mechanism to procure and distribute doses in record time. There are now 98 higher-income economies that have signed up to the COVAX Facility as self-financing members, joining 92 low- and middle-income economies whose participation is supported by the Gavi COVAX Advance Market Commitment (AMC). Based on current projections, COVAX is on track to hit its target of 2 billion doses of vaccine supply in 2021 having assembled a promising portfolio of vaccine candidates and is laying the groundwork for additional doses to be secured through cost-sharing supported by multilateral financing, and donor contributions. The COVAX Facility will distribute doses through an equitable and fair allocation mechanism.[1] To support this, ACT-Accelerator has facilitated agreement around an allocation framework, creating a Joint Allocation Taskforce (WHO-Gavi taskforce) and an Independent Allocation of Vaccine Group, for transparent governance of the allocation process. COVAX partners have also made tremendous progress on other enablers critical for delivering vaccines, especially in issuing standard indemnification and liability language and a no-fault compensation mechanism for all AMC economies, and accelerated regulatory activities. Despite substantial challenges, COVAX made it possible for the first vaccine introductions in LICs and LMICs to likely take place within 10 weeks from introduction in most HICs.

ACT-Accelerator has fast-tracked R&D, independent assessment, emergency use listing and manufacturing scale-up for diagnostic testing, enabling access to easier-to-use, accurate and more affordable tests, such as well-performing Ag-RDTs. Expediting the introduction of these Ag-RDTs reduced the cost of the test for LICs and LMICs to US$ 5 by September 2020, and further to US$ 2.50 in 2021. ACT-Accelerator and its partners have procured more than 40 million molecular and Ag-RDTs for LICs and LMICs to provide better access and improve equity in those geographies. Three Ag-RDTs have WHO EUL and through a new set of R&D agreements that include technology transfer and manufacturing scale-up, ACT-Accelerator aims to make over 250 million Ag-RDTs available every year to LICs and LMICs for less than US$ 2.50 each. Supply chains are being improved through regionalized manufacturing and plans for technology transfers enabled by strategic investments and partnerships

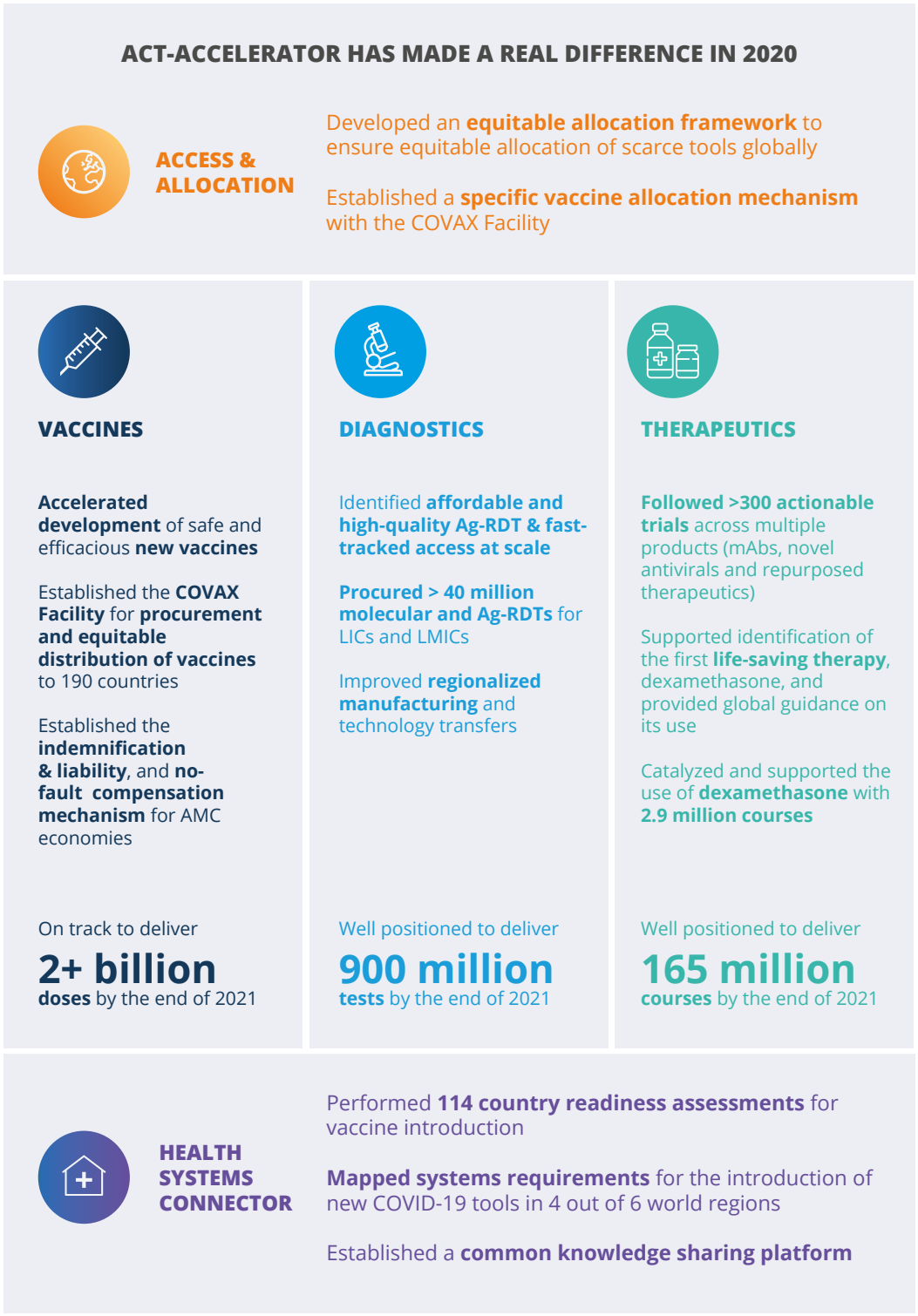
[1] ACT-Accelerator : Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility, September 2020. Geneva : World Health Organization ; 2020. (https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility, accessed 18 January 2021).

with key developers and manufacturers. Further development of tests that use nasal sampling, which is less invasive than current nasopharyngeal swabbing, and enhanced test performance is also being supported. ACT-Accelerator systematically assesses a wide range of products in multiple environments and provides information to countries on what works and does not work; develops policy and implementation guidance, training tools and technical assistance to support countries in the launch of new products; strengthens country capacity by rapidly repurposing and expanding existing infrastructure for COVID-19 and supports countries to put in place effective 'test, trace and isolate' strategies as part of their national response plans; and deploys catalytic funding for governments to optimally implement tests and integrate them into health systems.

Medical oxygen and corticosteroids, including dexamethasone, are life-saving therapies for hospitalized patients. ACT-Accelerator plays a vital role in identifying and integrating these effective treatments with good clinical care to treat those severely affected. Up to 2.9 million courses of dexamethasone have been secured through an advance purchase commitment for LICs and LMICs. ACT-Accelerator continues to actively work on the research agenda for monoclonal antibodies (mAbs) with reserved capacity for LICs and LMICs, small molecule novel antivirals (SM NAV) and repurposed therapeutics.

ACT-Accelerator protects and strengthens health systems to facilitate the rapid uptake of new tools. It equips health care workers with personal protective equipment (PPE) to safely deliver essential health services, and helps countries identify and address key bottlenecks for the effective deployment and use of COVID-19 tools. Thus far, system requirements for the delivery of COVID-19 tools have been mapped in four out of six world regions, and country readiness assessments for the roll-out of these tools exceeded the target of 100 country assessments in 100 days, with 114 performed as of February 2021. The Health Systems Connector has also established a common knowledge platform for countries to share the country-level knowhow and best practices of health systems strengthening to respond to COVID-19. These insights are critical to enable and accelerate the roll-out and optimization of the use of ACT-Accelerator tools across the globe.

***Figure 1 -*** *ACT-Accelerator's key achievements*



# 03

# IN 2021, ACT-ACCELERATOR IS DRIVING FOR EQUITY AND SCALE IN THE DELIVERY OF ESSENTIAL TOOLS WHILE MANAGING EMERGING VIRAL RISKS

**ACT-Accelerator's 4 Strategic Priorities for 2021:**

1. **Rapidly scale-up the delivery of 2+ billion doses of vaccines**
2. **Bolster R&D, evaluations & regulatory pathways to optimize products and address variants**
3. **Stimulate rapid and effective uptake of the utilization of COVID-19 tests, treatments and PPE**
4. **Ensure a robust pipeline of essential tests, treatments and PPE**

## Key strategic priorities for ACT-Accelerator in 2021

In 2021, ACT-Accelerator and the global COVID-19 response have the opportunity to move from being reactive to proactive, to gain back control and ultimately overcome the pandemic. The recent critical shifts described above require adjustment of the ACT-Accelerator priorities to achieve its goals of accelerating the development and equitable access of COVID-19 tools. Given the continuous evolution of the virus, epidemiology and global landscape, ACT-Accelerator will remain flexible and agile in addressing and adjusting its priorities over the course of the year. ACT-Accelerator will drive for equity in the delivery and continuous improvement of essential COVID-19 tools, to be achieved by focusing on four main priorities for 2021:

**1. Rapidly scale-up the delivery of 2+ billion doses of vaccines through COVAX to the most high risk and highly exposed populations globally**

To end the pandemic, people everywhere, particularly the most vulnerable populations, must have urgent access to the vaccine. This is critical for equity, achieving global health security, and getting our economies back on track. COVAX is making significant strides towards addressing some of the vaccine inequities, with the first LICs and LMICs introductions likely to happen within 10 weeks of the introduction in most HICs, an unprecedented achievement despite the challenges presented. Further work will be needed, and COVAX aims to:

- Deliver vaccine doses to all of COVAX's 190 participating and eligible economies in 2021, targeting at least 20% of their population to allow protection of those at highest risk, including health workers and people over 65 years of age. This coverage is possible thanks to COVAX's portfolio of vaccine candidates, which based on latest forecasts is on track to hit its target of supplying 2 billion doses of vaccines in 2021 (of which at least 1.3 billion are for AMC economies) that have been secured into delivered volumes. In preparing for 2022, ACT-Accelerator aims to increase vaccine coverage, outperforming the 20% target of 2021.

- Continue to foster agreements with vaccine manufacturers and governments by reducing the complexity of vaccine access and delivery, through a joint negotiation process for COVAX countries, and by continuing to reduce process complexities for manufacturers (e.g. harmonizing regulatory standards, indemnification and liability, labelling and procurement mechanisms).

- Continue supporting vaccine development in the wake of new variants and vaccine trajectory to continue improving access to countries.

- Enhance country readiness for the deployment of vaccines by providing support on norms, guidance and policies, supporting capability building, ensuring technical assistance and cold chain equipment are available in AMC92 countries, and providing catalytic support for in-country delivery alongside domestic funding and support from Development Banks and other partners.

- Facilitate rapid regulatory review of priority products while maintaining rigorous assessment, by fostering efficient and harmonized processes, e.g. with regards to submissions, labelling and clinical data, and fostering reliance on EUL/prequalification for the introduction of new tools.

- Put tools in place to operationalize the allocation of vaccines based on the allocation principles. This will finalize the development and deployment of equitable allocation mechanisms.

**2. Respond to emerging variants and programmatic needs by driving the R&D agenda, product evaluation and regulatory pathways for new and modified tests, treatments and vaccines**

The emergence of new viral variants requires that ACT-Accelerator and the world are prepared for a scenario where some of the tools that have already been developed or are under development (e.g. mAbs) may no longer be fully adequate. As a result, tools may need to be modified or new ones must be developed to combat these variants. Additionally, the world faces considerable programmatic challenges (e.g. need for ultra-cold chain, multiple doses for vaccines) in the delivery of some COVID-19 tools, which may be overcome in the future if tools can be optimized. These aspects emphasize the need for sustained, strengthened and focused R&D efforts, and rapid regulatory processes. ACT-Accelerator aims to expand R&D investments to optimize tests, treatments and vaccines for programme use and efficacy against variants:

- Support the accelerated development of vaccines that offer clear programmatic benefits (e.g. single dose vaccines, more thermostable options, easier administration) and prepare for the development of new vaccines in case virus variants arise that the current vaccines and vaccine candidates are not efficacious against.

- Accelerate evaluation studies to assess potential impact on performance of existing diagnostic tests, ensuring they remain accurate in the detection of the known and emerging virus variants, and support development of specific tools for accelerated novel variants detection. At the same time, catalyze the availability of low-cost digitally connected diagnostic tests and sequencing solutions.

- Support and monitor R&D efforts on novel antivirals and repurposed therapeutics to expand the therapeutics portfolio, with consideration of new and emerging virus variants. Risk mitigation by pushing the R&D agenda will be especially vital in case vaccines are challenged by the new variant or in regions with suboptimal roll-out.

**3. Enhance and catalyze the utilization of COVID-19 tests, treatments and PPE in LICs and LMICs**

New innovations in technologies have not been fully translated into appropriate scale-up and access. Availability of financing has been a significant limiting factor, other factors include clarity around use cases and limited countries' readiness of implementation of the existing tools (e.g. Ag-RDTs, PPE, medical oxygen, dexamethasone). ACT-Accelerator aims to:

- Engage in a concerted manner with countries and relevant regional stakeholders, including civil society, to operationalize roll-out of tests and treatments and prepare scale-up including closing any supply gaps, while fostering the correct use of available products and addressing health system bottlenecks.

- Support policy guidance and the rapid development of integrated technical and clinical guidance and policy support for new products.

- Support integrated country plans and enhance country readiness – for example, through targeted technical assistance and provision of readiness tools for vaccines – and procurement, training and technical assistance to ensure optimal and successful uptake of the best COVID-19 tools for each country. ACT-Accelerator supported the roll-out of 124 country readiness assessments (including 64 AMC countries) for vaccine distribution. Findings of these assessments are feeding into various partners' existing country projects and platforms, such as the World Bank's Multiphase Programmatic Approach (MPA).

- Fund the scale-up of diagnostic tests, including PCR and Ag-RDTs, in LICs and LMICs where testing is occurring at a fraction of HICs. Testing is essential for tracking the evolving epidemic and helps inform country containment strategies, especially in the context of emerging variants. .

**4. Ensure a robust pipeline of essential tests, treatments and PPE to support broader access in LICs and LMICs and protect vital health infrastructure**

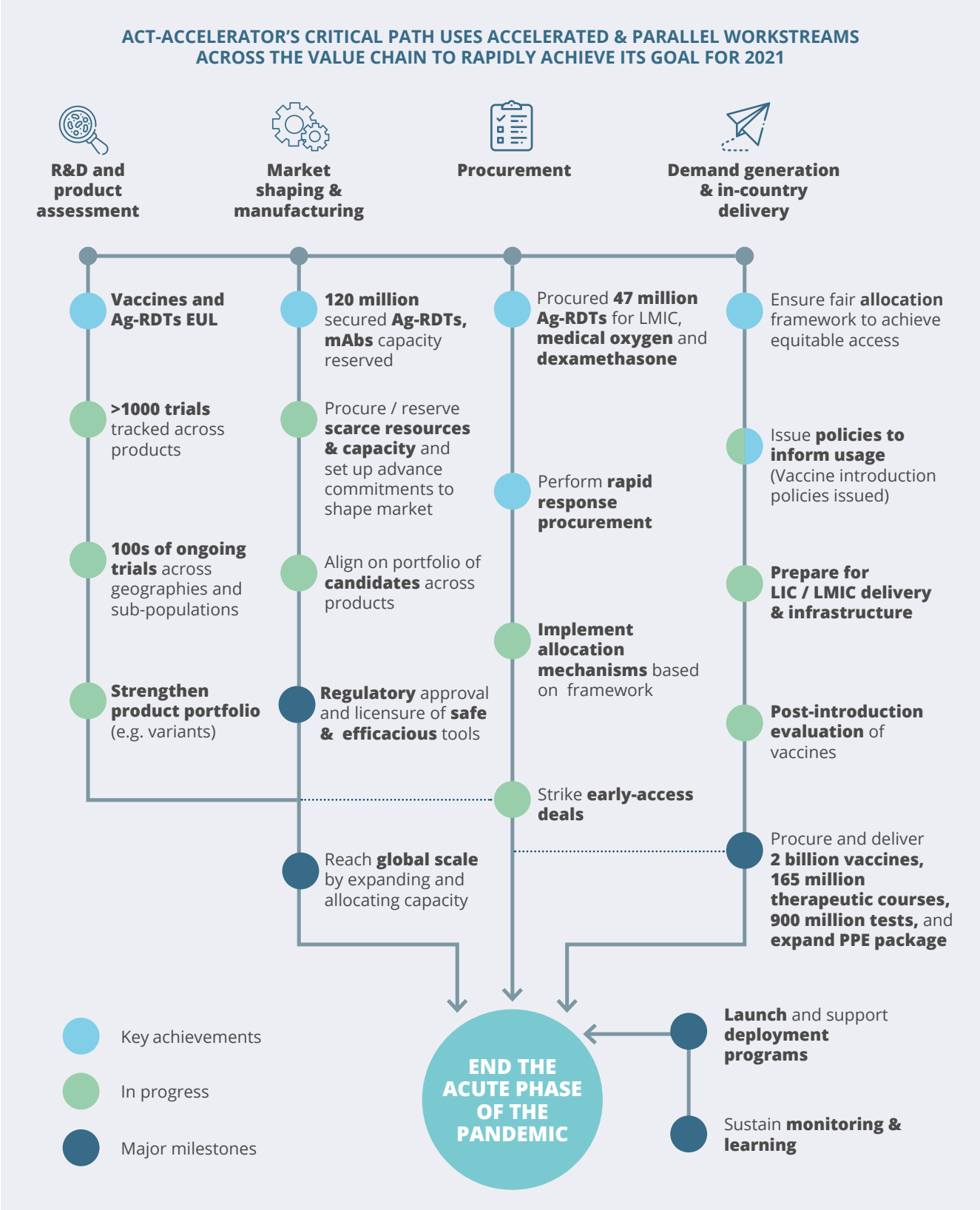
There is a need to generate demand and procure for quality and effective tests and treatments in order to reduce transmission and save lives. ACT-Accelerator aims to:

- Raise the initial target of the supply of diagnostic tests for 2021 with 400 million tests on top of the 500 million initially plan, to a total of 900 million over a period of 12 months, aiming to expand equitable access to quality lower-cost molecular tests, Ag-RDTs, self tests and sequencing solutions, reducing by one third the gap in testing rates between LICs/LMICs and HICs. Molecular tests and Ag-RDTs will remain instrumental to address clinical needs and identify and contain hotspots; and genomic sequencing solutions are critical to monitor and rapidly detect novel variants across regions.

- Ensure access to quality clinical management, including medical oxygen, corticosteroids such as dexamethasone, and other therapeutics if proven efficacious (i.e. prophylactic, treatment for early and mild cases, and treatment for severe and critical cases). The target procurement in 2021 is 165 million therapeutic courses (e.g. corticosteroids/ dexamethasone, repurposed therapeutics and small molecule novel antivirals), subject to evidence supporting use case and product availability. This is a lower quantity than initially planned, due to delayed product availability and an expected decrease in severe cases with increasing vaccine coverage and efficacy.

- Roll out the delivery of the full package of quality PPE for health workers in LICs and LMICs that are projected to be in direct contact with persons with COVID-19, to enhance safe clinical management.

***Figure 2 -*** *ACT-Accelerator's critical path to achieve its objectives for 2021*



# Pillar-specific adjustments and refreshed priorities for 2021

## Vaccines

**Several recent key shifts affect the priorities for COVAX, including overwhelming demand, increasing bilateralism, and the emergence of virus variants of concern.**

The recent and rapid resurgence in COVID-19 cases and emerging virus variants has led to an overwhelming and immediate demand for vaccines globally, with governments facing extreme pressure to secure a portion of the limited supply of vaccines. As a result, we are experiencing a troubling shift from multilateralism to bilateralism. While a limited number of bilateral deals encourage R&D and market development, a proliferation of bilateral deals could threaten equitable access.

At the start of the COVAX Facility, "high bar" expectations of governments for vaccine approval and reliance on SRAs was anticipated. Yet, in the face of a resurgence of cases, and scarcity in vaccine supply, increased willingness of countries to authorize use in anticipation of future approvals by more stringent regulatory authorities was seen. At the same time, there has been an evolution from a state of uncertainty regarding the probability of success for vaccines' efficacy to seeing high success rate for frontrunner vaccines. Given this success and the number of vaccine manufacturers dedicated to their production, supply constraints are not expected in the long-term.

The world is experiencing variable transmission, with emerging virus variants. The virus variants call for ACT-Accelerator and the world to prepare for a scenario where some developed vaccines may no longer provide adequate protection against new viral strains.

**For 2021, COVAX has ambitious goals for improving access and delivery while ensuring vaccine safety, efficacy and quality.**

COVAX's objectives for 2021 are three-fold:

1. Ensure timely delivery of COVID-19 vaccines at scale. COVAX supports countries in the delivery of vaccines by:

    - Delivering 2 billion doses for global access through the COVAX Facility in 2021; ACT-Accelerator aims to increase the vaccine coverage for 2022, exceeding the target for 2021 of 20%;

    - Providing norms, guidance, policies and tools for all countries worldwide, including approach towards readiness assessment and national planning, such as the Vaccine Introduction Readiness Assessment Tool and Vaccine Readiness Assessment Framework (VIRAT/VRAF2.0[1]), and National Deployment Vaccination Plans (NDVPs[2]);

    - Ensuring technical assistance (in-country, global and regional level) and cold chain equipment are available in AMC92 countries;

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[1] WHO, UNICEF, World Bank Group. COVID-19 vaccine introduction readiness assessment tool. 21 September 2020. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/336188, accessed 26 January 2021).
[2] WHO, UNICEF, Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines. Interim guidance. 16 November 2020 (https://www.who.int/publications/i/item/WHO-2019-nCov-Vaccine_deployment-2020.1, accessed 25 January 2021).

- Providing catalytic support for in-country delivery, alongside domestic funding and support from Development Banks and other partners;
- Supporting capacity building (e.g. cold chain, training, planning, pharmacovigilance).

2. Ensure equitable access and fair allocation of COVID-19 vaccines for products that are already available. Current market dynamics are leading to inequitable access (in terms of both quantities and timely access) to vaccines. COVAX aims to mitigate these inequities through:
   - Implementing a fair allocation mechanism[3];
   - Raising and providing funds to cover procurement of vaccines for AMC countries;
   - Reducing the complexity of vaccine access and delivery, through a joint negotiation process for COVAX countries, and by reducing process complexities for manufacturers. These process complexities include standardizing regulatory processes, indemnification and liability, labelling and procurement mechanisms.
3. Accelerate the further development of safe, efficacious and programmatically-optimized vaccines to address new risks through:
   - Investment in additional vaccine candidates. While many frontrunner candidates are proving highly efficacious, it is critical to keep investing in the next generation of vaccines, that should be efficacious against new variants of the virus, as well as have better fit-for-purpose operational profiles, e.g. single dose, more thermostable, easier administration. Additionally, initiate development of broadly protective beta coronavirus vaccines;
   - Coordination of trials (e.g. Solidarity trials) to advance the knowledge base on the efficacy and safety of different vaccine candidates used in different combinations;
   - Development of a smart vaccination (digital) certificate;
   - Perform post-introduction evaluation of vaccine.

As a result, all participating economies will have access to doses in the first half of 2021, with first deliveries anticipated to begin in the first quarter of 2021, contingent upon regulatory approvals and countries' readiness for delivery. This will allow all COVAX's 190 participating and eligible economies to access doses to protect vulnerable groups in the first half of 2021, targeting up to 20% population coverage by the end of the year. At least 1.3 billion doses will be made available to the 92 economies eligible for the Gavi COVAX AMC.

COVAX strongly stresses the prioritization of **safety, efficacy and quality**. Countries served through the COVAX facility will gain access to products that adhere to the established regulatory process.

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[3] ACT-Accelerator: Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility; September 2020. Geneva; World Health Organization; 2020. (https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility, accessed on 18 January 2021).

## Diagnostics

**Diagnostic testing has a more critical role to play in the COVID-19 response than ever before.**

The roll-out of vaccines and emergence of novel variants across the globe underscore the immediate need for more equitable access to testing. The role of testing is essential to the control of COVID-19. Testing to address clinical needs and manage outbreaks will remain critical. Current underutilization of diagnostic tests is contributing to the low degree of control over the pandemic and to increased mortality and morbidity as a result of ineffective test, treat and isolate strategies in some countries, particularly in lower-resourced settings. The higher transmissibility of novel variants will also require increased testing for early detection and containment of such variants.

Additionally, testing remains critical for surveillance and enhancing accuracy and knowledge of real-time epidemiology across regions. Several variants of concern have been detected thus far with widespread community transmission globally, along with other variants under investigation. Current capacity for genomic sequencing of the virus is limited, particularly in LMICs, leading to significant gaps for the detection of novel variants. This puts global health security at risk.

A portfolio of well-performing regulatory-approved diagnostic tests already exists in the market. However, significant funding is urgently needed to meet the increasing demand from countries with the aim of further driving the price down and to ensure continued availability of effective diagnostics despite the emergence of variants, particularly LMICs that cannot afford these tests.

**For 2021, the Diagnostics Pillar will secure equitable access to testing, support country uptake and deployment, and strengthen the product portfolio with R&D investments in low-cost easy-to-use quality tests.**

The Diagnostics Pillar aims for all countries to be able to deploy affordable, quality and rapid point-of-care tests that are easy to use. Support will be provided to LICs and LMICs to put in place effective test, trace and isolate strategies to contain the outbreak and minimize disruption of core health services, as well as to strengthen and sustain country capacity to operationalize diagnostic tools and ready for scale-up.

The key priorities for the Diagnostics Pillar for 2021 are three-fold:

1. Secure equitable access to new and existing tests.

   Diagnostic testing in UMICs[1], LMICs and LICs is occurring at a 15% rate[2] of what is taking place in HICs. To reduce this gap, in 2021 ACT-Accelerator aims to procure 900 million tests (including PCR and Ag-RDTs), instrumental for effective test, trace and isolate measures, and sequencing for early detection of variants of concern..

2. Stimulate rapid and effective uptake in countries.

   In addition to mitigating the access gap, ACT-Accelerator aims to strengthen and expand testing infrastructure capacity in over 50 countries (e.g. repurpose existing testing infrastructure and scale-up country laboratory networks). This would be complemented by an effort to build capabilities and support countries with testing roll-out (e.g. train laboratory technicians and healthcare workers, create technical

[1] Excluding China
[2] Most recent rolling 7-day averages per 100,000 population. Source: FIND test tracker (as of 12 January 2021).

assistance networks to help countries understand how tests differ and how to best deploy them, explore new delivery models with operational research), as well as with tailoring and integrating testing within their national response strategies for rapid detection and containment, and economic and social activities (e.g. schools, workplaces).

3. Drive development and at-scale availability of affordable, transformative, digitally-integrated tests.

   ACT-Accelerator will invest in the development of well-performing lower-cost Ag-RDTs, easy-to-use self-tests, multi-pathogen testing with effective, patient-centric and ethical digital connectivity solutions to support the COVID-19 response, as well as point-of-care diagnostic platforms for decentralized roll-out and specific tools for the detection of novel variants (e.g. sequencing solutions). In order to ensure use of sensitive and specific tests, increase affordability and mitigate supply chain risks, ACT-Accelerator will evaluate the performance of an additional 50 diagnostic tests to understand the potential impact of novel variants, foster regional production (including in LMICs), and engage in market interventions to lower the cost of tests and make them more widely available.

## Therapeutics

**Safe and effective therapeutics of assured quality are essential in 2021 to support the unvaccinated and those at high risk of severe disease.**

Therapeutics play a critical role in the COVID-19 response. It is estimated that up to 70 million people in LICs and LMICs[3] may contract COVID-19, even with the planned roll-out of vaccines. It will be essential to ensure the availability of effective therapeutics once evidence of benefit has been established and quality and safety have been assured. Fit-for-purpose therapeutics will need to be accessible for a broad population (including non-high-risk populations and those not yet vaccinated), as 80% of cases are expected to occur in these groups.

**For 2021, the Therapeutics Pillar will prioritize research for effective treatments, support for countries to optimize clinical care and introduce new tools, and procurement of available therapeutics, including medical oxygen.**

Emerging novel variants appear to reduce the efficacy of several front-running mAbs. Intensified research efforts are urgently needed to understand the impact of emerging virus variants and to support the development of a portfolio of effective therapeutics, including combination therapy. Therapeutics with upcoming clinical readouts must be deployed rapidly if proven effective (i.e. SM NAVs and repurposed therapeutics). In parallel, work is needed to ensure optimal use of therapeutics that can be leveraged today such as corticosteroids (e.g. dexamethasone) and medical oxygen.

The key priorities for the Therapeutics Pillar for 2021 are:

1. Intensify research efforts to develop the clinical pipeline across all promising asset classes, and broaden the portfolio of effective tools, including combinations of therapeutics.

   - Support existing candidates in ongoing phase 2/3 trials.

[3] Estimation made taking into account different estimations of infected and symptomatic rates for LICs (2.35%), LMICs (2.1%) and UMICs (2.15%, excluding China).

- Proactively accelerate repurposed therapeutics, including antivirals, with meta-analyses of promising therapies and targeted support on evidence generation in existing platform trials (e.g. ANTICOV).

- Expand the portfolio of therapeutic tools to integrate additional compounds and combinations of therapeutic products. Specifically, identify promising alternative therapeutic candidates (with high potency, resistance to variants) and advance them into late-stage studies.

2. Ensure market readiness and access for proven therapeutics, supporting countries in optimizing clinical care.

   - Support market interventions such as voluntary licensing, technology transfers, regulatory and policy processes, as relevant.

   - Support dissemination of clear policy and regulatory guidance to accelerate the availability of safe and efficacious products.

   - Initiate operational research to support optimized clinical care, including medical oxygen and test-treat-isolate approaches (jointly with the Diagnostics Pillar).

3. Drive successful uptake and scaled procurement of available therapeutics, including medical oxygen.

   - Procure medical oxygen and 165 million treatments, including repurposed therapeutics and dexamethasone.

   - Bridge gaps in use of existing products (i.e. dexamethasone and oxygen) and apply key learnings to roll-out efforts for future therapeutics.

   - Provide visibility on country demand and mobilize resources to support adequate and timely supply of therapeutics.

   - Support procurement and country allocation for at-scale deployment of proven products as available, utilizing tools such as advanced purchase agreements to secure 2022 supply; maintaining flexibility on procurement budgets across asset classes will be important to anticipate changes in clinical development.

## Health Systems Connector

**Health systems enable the uptake and delivery of COVID-19 tools in countries.**

The Health Systems Connector (HSC) focuses on cross-cutting aspects of health systems and capacities to enable the rapid uptake and delivery of COVID-19 tools as they become available. These include responding to country demands, building capacities and infrastructure where weaknesses have been identified to strengthen the health system for effective deployment of COVID-19 tools (vaccines, therapeutics, and diagnostics), and the (non-product) system investments that are required to complement the new tools. HSC also aims to ensure access to sufficient supplies of essential PPE in LICs and LMICs to protect frontline health care workers and to enhance the capacity of health systems to save lives.

**For 2021, HSC will help identify health system bottlenecks and respond to country demands in accessing and utilizing COVID-19 tools.**

Countries are expected to face major implementation challenges in ensuring access and uptake of COVID-19 tools. Bottlenecks in key areas of health systems, such as financing, data, workforce, clinical care, and supply chain, limited engagement with communities in the COVID-19 response, as well as access to key commodities such as PPE, remain limiting factors to effective deployment and use of COVID-19 tools in many countries. Support is urgently needed for countries with weak health systems to address needs identified in country response plans and ensure the use of available financing mechanisms to include PPE and other tools into national health systems for the protection of all health care workers.

The key priorities for HSC for 2021 are three-fold:

1. Contribute to the identification of key health system bottlenecks to the uptake of COVID-19 tools in countries.

   As a complement to the vaccine readiness assessment, HSC is supporting the application of a series of assessment and monitoring tools (e.g. assessments for facilities, disruption of essential services, health capacity and frontline readiness). These assessments help identify health system bottlenecks and weaknesses to be addressed and inform the development of country plans to aid in the delivery of COVID-19 tools and the systems that support them.

2. Support countries to address the health systems bottlenecks or weaknesses identified to optimize the uptake of COVID-19 tools.

   HSC responds to country needs for addressing identified health systems bottlenecks and weaknesses, taking a country-context approach of translating global knowledge for local problems. In this response, HSC delivers guidance, products and tools, while providing technical support to countries to strengthen their capacities to deploy and use COVID-19 tools effectively. This includes support to community systems and responses. HSC also facilitates the rapid sharing of knowledge and best practices through knowledge platforms.

3. Accelerate availability of PPE as a high priority commodity.

   A critical area for HSC support is ensuring adequate access of PPE for all health care workers to protect those on the frontline, including by addressing issues related to quality control and standards, security of supply and access, environmental impact and disposal, product innovation and local production and procurement.

# 04

# DELIVERING ON ACT-ACCELERATOR 'S PROMISE REQUIRES US$ 27.2 BILLION IN 2021

## ACT-Accelerator funding gap across Pillars

Reflecting on the refreshed strategic priorities outlined in the previous section, and taking into account available resources, ACT-Accelerator Pillars have recalculated their funding gaps for 2021 (see also Appendix C). US$ 27.2 billion is required by the end of 2021 for ACT-Accelerator to deliver on its full promise. This can be broken down by Pillar, as shown in **Table 1**.

Details of 2021 funding gaps across the value chain by Pillar, with an overview of the deliverables and responsible agencies, are detailed in Appendix D.

***Table 1 -*** *ACT-Accelerator funding gap for 2021, by Pillar, as of January 2021 – in US$ billion*

| Pillar | Q1/Q2 2021 | Q3/Q4 2021 | Total 2021 |
|---|---|---|---|
| Diagnostics | $ 1.9 B | $ 7.0 B | **$ 8.9 B** |
| Therapeutics | $ 1.4 B | $ 1.8 B | **$ 3.2 B** |
| Vaccines | $ 7.8 B | $ <0.1 B | **$ 7.8 B** |
| Health Systems Connector | $ 3.2 B | $ 4.3 B | **$ 7.4 B** |
| **TOTAL** | **$ 14.2 B** | **$ 13.1 B** | **$ 27.2 B** |

## ACT-Accelerator funding gap across strategic priorities

**Table 2** provides a view of the 2021 financing gap by strategic priority outlined in 'Key strategic priorities for ACT-Accelerator in 2021' of Section 03.

1. **Rapidly scale-up delivery of 2+ billion doses of vaccines through COVAX to the most high-risk and highly exposed populations globally: US$ 6.4 billion.**

   The COVAX Facility will invest funds to reserve doses for the AMC; ensure global, fair and equitable allocation; support country readiness and equitable delivery of vaccines for LMICs; and provide global, regional and country-level technical support and expertise.

***Table 2 –*** *ACT-Accelerator funding gap, by strategic priority, as of January 2021 – in US$ billion*

| Strategic priorities | Q1/Q2 2021 | Q3/Q4 2021 | Total 2021 |
|---|---|---|---|
| 1. Rapidly scale-up the delivery of 2+ billion doses of vaccines through COVAX to the most high risk and highly exposed populations globally | $ 6.4 B | $ < 0.1 B | **$ 6.4 B** |
| 2. Respond to emerging variants and programmatic needs by driving the R&D agenda, product evaluation, and regulatory pathways for new and modified tests, treatments and vaccines | $ 1.6 B | $ 0.2 B | **$ 1.8 B** |
| 3. Enhance and catalyze the utilization of COVID-19 tests, treatments and PPE in LICs and LMICs | $ 2.0 B | $ 3.8 B | **$ 5.8 B** |
| 4. Ensure a robust pipeline of essential tests, treatments and PPE to support broader access in LICs and LMICs and protect vital health infrastructure | $ 4.2 B | $ 9.0 B | **$ 13.2 B** |
| **TOTAL** | **$ 14.2 B** | **$ 13.1 B** | **$ 27.2 B** |

2. **Respond to emerging variants and programmatic needs by driving the R&D agenda, product evaluation and regulatory pathways for new and modified tests, treatments and vaccines: US$ 1.8 billion.**

   All Pillars will expand R&D efforts to optimize their products for programme use and efficacy against variants. ACT-Accelerator will: i) support the accelerated development of vaccines; ii) support and monitor R&D efforts on novel antivirals and repurposed theapeutics; and iii) accelerate evaluation studies to assess potential impact on the performance of existing diagnostic tests and catalyze the availability of RDTs, low-cost point-of-care multi-pathogen testing platforms and digitally connected sequencing solutions.

3. **Enhance and catalyze the utilization of COVID-19 tests, treatments and PPE in LICs and LMICs: US$ 5.8 billion.**

   These efforts include, for example, coordination among all stakeholders to operationalize roll-outs and prepare scale-up, and the rapid development of integrated technical and clinical guidance and policy support for new product, technical assistance but also procurement of catalytic amounts of tests to implement test, treat, and isolate strategies.

3. **Ensure a robust pipeline of essential tests, treatments and PPE to support broader access in LICs and LMICs and protect vital health infrastructure: US$ 13.2 billion.**

   ACT-Accelerator aims to raise the initial target of the supply of diagnostic tests for 2021 with 400 million tests on top of the 500 million initially planned over a period of 12 months; ensure access to quality clinical management, including medical oxygen, corticosteroids such as dexamethasone, and other therapeutics if proven efficacious (165 million therapeutic courses); and roll out the delivery of the full package of quality PPE for health workers in LICs and LMICs that are projected to be in direct contact with persons with COVID-19, to enhance safe clinical management.

These funding needs are detailed in **Figure 3**, which provides a consolidated view across deliverable packages, time (Q1/Q2 2021 and Q3/Q4 2021), Pillars, and recipient agencies[1], with the associated funding gap for each. Packages for the same Pillar are represented with the same colour. The height of the box indicates the cost of the package. Each package is positioned either on the first or second semester of 2021, but also within the value chain from *R&D and product assessment* to *Demand generation & in-country delivery*. A view per Pillar is available in Appendix D.

As described in Section 06, the ACT-Accelerator work packages on *Procurement* and *Demand generation & in-country delivery* are catalytic investments as they do not cover the overall cost of the COVID-19 response implementation.

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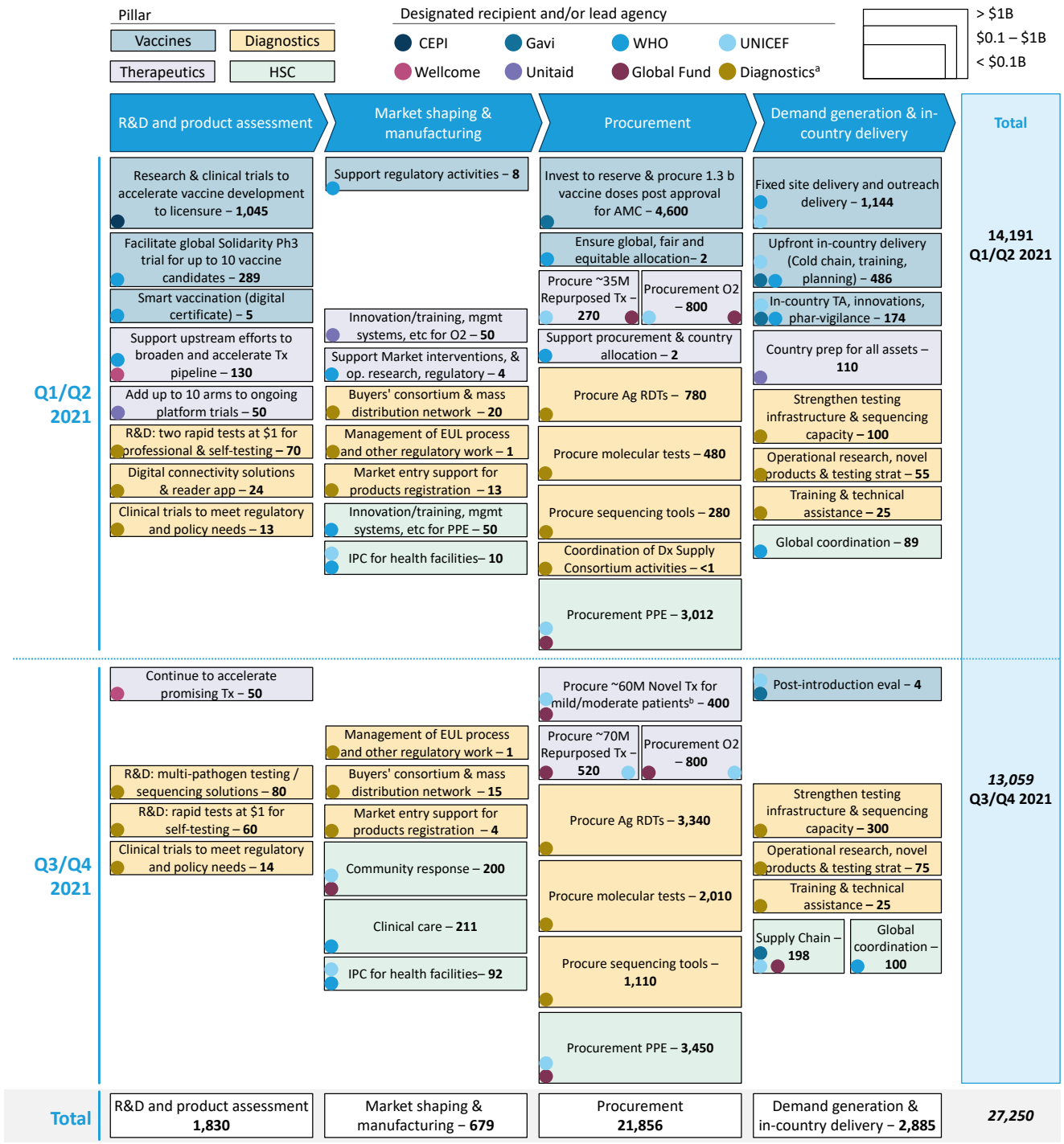
[1] Including UNICEF, who is a recognized recipient for work packages in the Therapeutics and Vaccines Pillars.

***Figure 3 –*** *ACT-Accelerator funding gap by period and deliverable packages – in US$ million*




Note: The United States has committed $4 billion for COVID-19 vaccine procurement and delivery, which will reduce the funding gap. However, the allocation of these funds and timing of disbursements has yet to be determine. [a] Diagnostics Pillar convenes many stakeholders who play multiple roles across the workstreams due to the evolution of the pandemic, changing needs of countries and the dynamic multifaceted collaboration. Workstreams are coordinated by FIND, Global Fund and WHO and funding flows directly to multiple partners depending on their role and country needs. For further details, please reach out to ACTADiagnostics@finddx.org , gf_acta@theglobalfund.org or ACTADiagnostics@who.int. [b] Canada has pledged US$ 163 million to ACT-Accelerator for the procurement of 2-4 million mAbs through the Fuji capacity reservation (recipient: UNICEF). To be evaluated in light of evolving clinical information.

# 05

# INVESTING IN ACT-ACCELERATOR IS, MORE THAN EVER, THE 'RIGHT' AND 'SMART' THING TO DO

Since mid-2020, economic expert groups, including the International Monetary Fund (IMF), called for investment in global solutions to deliver COVID-19 tools. *ACT-Accelerator's Urgent priorities & financing requirements at 10 November 2020*[1] covered these arguments in detail.

In January 2021, even more compelling evidence was published supporting the economic imperative for investing in ACT-Accelerator. This study, commissioned by the International Chamber of Commerce, is the most extensive study to date and demonstrates that **even with strong vaccine coverage in high-income countries (HICs), inequitable access to COVID-19 tools elsewhere would cost HIC economies an additional US$ 2.4 trillion in 2021 alone**[2].

An earlier Eurasia Group study had shown that for just 10 HICs, investing the US$ 27.2 billion needed by ACT-Accelerator in 2021 would produce over US$ 466 billion in economic benefits over five years[3], with a higher return than investing in the domestic economy.

***"Investing in ACT-Accelerator delivers a higher multiplier than any domestic fiscal measure."***

**Lord Jim O'Neill**
High level ACT-Accelerator Finance Ministries meeting, 29 January 2021

Yet another study investigated whether the ACT-Accelerator was a better economic choice than domestic investments, such as those financed through the US$ 12 trillion that G20 countries have invested to date to stimulate domestic demand or protect businesses from immediate bankruptcy. This study found, for example, that in the United States of America, the multiplier (expressing the 'return on investment') for general domestic investments is estimated to be between 0.36x and 0.88x[4], while an

[1] ACT-Accelerator: Urgent priorities & financing requirements at 10 November 2020. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/urgent-priorities-financing-requirements-at-10-november-2020, accessed 20 January 2021).
[2] Çakmakli C, Demiralp S, Kalemli-Özcan S, Yeşiltaş, Yildirim MA. The economic case for global vaccinations: an epidemiological model with international production networks. Paris: International Chamber of Commerce; 2021 (https://iccwbo.org/publication/the-economic-case-for-global-vaccinations/, accessed 01 February 2021).
[3] Global equitable access to COVID-19 vaccines estimated to generate economic benefits of at least US$ 153 billion in 2020-21, and US$ 466 billion by 2025, in 10 major economies, according to new report by the Eurasia Group [website]. Geneva: World Health Organization; 2020 Replace with (https://www.who.int/news/item/03-12-2020-global-access-to-covid-19-vaccines-estimated-to-generate-economic-benefits-of-at-least-153-billion-in-2020-21, accessed 26 January 2021).
[4] These multipliers are lower than the historical range of 1.1x-1.4x in Global Financial Crisis, because of social distancing. Source: Comparing Fiscal Multipliers [website]. Washington DC: Committee for a Responsible Federal Budget; 2020 (http://www.crfb.org/papers/comparing-fiscal-multipliers, accessed 26 January 2021).

investment of US$6 billion in equitable access to COVID-19 tools would deliver a multiplier estimated at 0.9-7.8x[1].

**The world needs to invest in ending the pandemic now in order to avert the much greater future costs to health systems.**

Beyond direct economic costs, this pandemic has unleashed a secondary crisis by disrupting essential health services. A WHO survey on the effects of COVID-19 showed that essential health services have been disrupted in more than half of the countries surveyed, particularly for the prevention and treatment of hypertension, diabetes, cancer, and cardiovascular emergencies.[2]

**Investing in a global solution to end the pandemic is a sound investment in global health security.**

As long as COVID-19 transmission is uncontrolled anywhere in the world, we will continue to see the emergence of new virus variants that may render our existing COVID-19 tests, treatments and vaccines obsolete.[3] This reinforces the vital need to maximize the use of existing tools now, globally and equitably, to rapidly bring an end to the pandemic.

**Public health budgets are already squeezed: 10% of the annual budget of ACT-Accelerator's global health partners has already been repurposed to ACT-Accelerator.[4]**

ACT-Accelerator is already increasing the availability of COVID-19 tools in LICs and LMICs. In 2020 alone, ACT-Accelerator global health partners have contributed US$ 1 billion to ACT-Accelerator's activities. This has been made possible as a result of flexibilities afforded by their respective governance mechanisms which allowed them to utilize budgets and savings from other programmes that were funded through Official Development Assistance (ODA). This accounts for at least 10% of their cumulated annual budget.

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[1] The recurrent yearly cost of the LIC/LMIC not getting vaccines could be between $US 6 and $US 30 billion in GDP. Source: Hafner M, Yerushalmi E, Fays C, Dufresne E, Van Stolk C, COVID-19 and the cost of vaccine nationalism. Santa Monica, CA: RAND Corporation; 2020 (https://www.rand.org/pubs/research_reports/RRA769-1.html, accessed 26 January 2021).

[2] COVID-19 significantly impacts health services for noncommunicable diseases [website]. Geneva: World Health Organization; 2020 (https://www.who.int/news/item/01-06-2020-covid-19-significantly-impacts-health-services-for-noncommunicable-diseases, accessed 26 January 2021).

[3] Emerging evidence that some mAbs developed so far are already proven ineffective against the 501Y. V2 variant, identified in South Africa Sources: Greaney AJ, Loes AN, Crawford KHD, Starr TN, Malone KD, Chu HY et al. Comprehensive mapping of mutations to the SARS-CoV-2 receptor-binding domain that affect recognition by polyclonal human serum antibodies. bioRxiv 2020.12.31.425021 (doi: https://doi.org/10.1101/2020.12.31.425021, accessed 20 January 2021). Baum A, Fulton BO, Wloga E, Copin R, Pascal KE, Russo V et al. Antibody cocktail to SARS-CoV-2 spike protein prevents rapid mutational escape seen with individual antibodies. Science. 2020;369:1014-1018. doi: 10.1126/science.abd0831 (https://science.sciencemag.org/content/369/6506/1014, accessed 20 January 2021). Thomson E, Rosen LE, Shepherd JG, Spreafico R, da Silva Filipe A, Wojcechowskyj JA et al. The circulating SARS-CoV-2 spike variant N439K maintains fitness while evading antibody-mediated immunity. bioRxiv, 20200.11.04.355842 (doi: https://doi.org/10.1101/2020.11.04.355842, accessed 26 January 2021).

[4] In 2019, Unitaid, Finddx, Wellcome Trust, Gavi, CEPI, WHO and Global Fund reported a cumulated annual expenditure of US$ 8.2 billion. Source: public Financial report, 2019 or latest available.

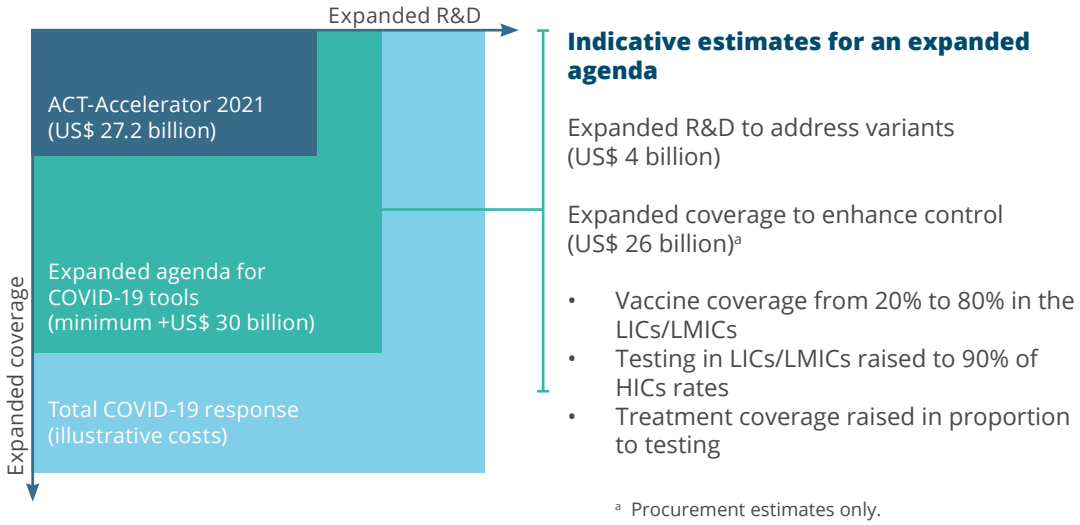
# 06

# SUBSTANTIAL ADDITIONAL INVESTMENT IN 2021 MUST COMPLEMENT THE FINANCING OF ACT-ACCELERATOR TO DELIVER A COMPREHENSIVE RESPONSE

While the 2021 financial needs of ACT-Accelerator are substantial, they represent only a fraction of the overall funding required to comprehensively and equitably respond to the unprecedented magnitude of the COVID-19 crisis. For example, substantial additional investments are needed to achieve the vaccination coverage rates of 60-80% that most LICs and LMICs are now aiming for and that may be required to reduce the risk of emergence of new virus variants. Similarly, current testing rate targets in LICs and LMICs would need to be significantly higher to approximate those of HICs and UMICs and to come in line with levels that are increasingly considered best practice.

**Figure 4** provides an illustrative example of the financial impact of such increases in the coverage rates for tests, treatments and vaccines in LICs and LMICs.

***Figure 4 –*** *ACT-Accelerator within a broader need for COVID-19 tools– in US$ billion*




Even these illustrative additional costs for an expanding agenda for COVID-19 tools would not cover the full costs of handling the pandemic in these settings: additional investments in health systems are needed to optimize the use of these tools at this scale (e.g. in the areas of human resources, local supply chains). Further costs will be associated with the uncertainties that are inherent in the complex evolution of this pandemic, as new virus variants and operational challenges will emerge with the roll out of new tools and the further scale up of the global response.

# 07

# APPENDICES

## Appendix A – ACT-Accelerator Structure

ACT-Accelerator is a time-limited collaboration designed to rapidly leverage existing global public health infrastructure and expertise to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Each contributing organization brings key components to the global COVID-19 response. As shown in Figure A.1, the work of these organizations is driven in three product Pillars (Vaccines, Therapeutics, Diagnostics), supported by the cross-cutting Health Systems Connector (HSC) and guided by the Access & Allocation workstream, all of which are fully empowered to develop and implement workplans through their own structures and processes. The Civil Society engagement workstream ensures civil society and community input across the Accelerator.

The **Vaccines Pillar**, also known as **COVAX**, is co-convened by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO).

The **Diagnostics Pillar** is co-convened by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund, with WHO leading on regulatory, policy, product procurement and allocation, as well as country access.

The **Therapeutics Pillar** is co-convened by Unitaid, and the Wellcome Trust, with WHO leading on policy and regulatory work, and the Global Fund leading work on procurement and deployment.

The **Health Systems Connector** is co-convened by the Global Fund, the World Bank and WHO.

The **Access & Allocation** workstream is led by WHO and directs ACT-Accelerator's work on global access and allocation.

**CEPI** was launched after the Ebola crisis in West Africa, as the result of consensus that a coordinated, international, and intergovernmental plan was needed to develop and deploy new vaccines to prevent future epidemics. Its mission is to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks. The unique innovation ecosystem (public, private, philanthropic, civil society organization partnerships) that CEPI can leverage makes it the right leader for vaccine development. CEPI was able to react very quickly to respond to the COVID-19 outbreak at the end of January 2020. Within two weeks of the publication of the SARS-CoV-2 sequence, CEPI was able to leverage and support several of its research partners to pivot and start developing vaccines against the virus.

**FIND**, the international alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. FIND connects countries, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems.

In the last 20 years, **Gavi, the Vaccine Alliance**, has helped vaccinate 820 million people through routine immunization and one billion through campaigns to deal with outbreaks and boost immunization rates, rolled out 496 new vaccines in the poorest 73 countries and established global vaccine stockpiles against major health threats, such as Ebola. On vaccine delivery, Gavi will use the strength of the full Alliance and their collective experience to help Gavi-supported countries (and others if so needed) prepare for vaccine introduction and provide support for the operational costs of vaccine introduction.

**The Global Fund** mobilizes and invests more than US$ 4 billion a year to support programs to fight HIV/AIDS, tuberculosis and malaria, and to strengthen systems for health while promoting human rights and gender equality. The Global Fund partnership operates across more than 100 countries and has invested over US$ 45 billion over the past 19 years, saving some 38 million lives. It has a proven record in strengthening procurement and delivery systems. Since March 2020, the Global Fund has awarded nearly US$1 billion to 106 countries and 14 multi-country programs to support their responses to COVID-19. Along with other partners, the Global Fund is actively involved in the WHO Diagnostics Consortium to monitor the supply and demand of tests for COVID-19 and implement the WHO allocation for scarcely available COVID-19 products.

**Unitaid**, a partnership hosted by WHO, invests in innovations to prevent, diagnose and treat diseases – including HIV and coinfections and comorbidities, tuberculosis, and malaria – more quickly, affordably and effectively. Unitaid's work ensures access to critical health products, making it a world-class downstream convener for Therapeutics.

**Wellcome Trust** is an independent foundation that exists to improve health by helping great ideas to thrive. Wellcome supports researchers, takes on big health challenges, campaigns for better science, and helps everyone get involved with science and health research. In March 2020, Wellcome co-founded the COVID-19 Therapeutics Accelerator with the Bill & Melinda Gates Foundation and Mastercard. The Therapeutics Accelerator is an initiative to coordinate research, remove barriers to drug development and scale up treatments to address the pandemic.

**The World Bank** works to help countries build healthier, more equitable societies as well as improve their fiscal performance and economic competitiveness. Through the International Development Association (IDA), which provides financing to the poorest countries, the World Bank has provided US 13.5 billion over the past decade to fund essential health interventions for 770 million people, and immunizations for 330 million children. The World Bank closely works with donors, development partners, governments, and the private sector, and can provide unique expertise in strengthening health systems. The World Bank has mounted the largest, broadest and fastest financing platform to support countries' emergency health response to COVID-19. This includes its Global Health Multi-Phase Approach program, which has approved US$ 7.6 billion for 111 countries within 3 months, as part of the World Bank Group's broad commitment to provide up to US$160 billion to help address the pandemic through June 2021.

As the United Nations agency specializing in global health, the **World Health Organization** provides global leadership in the monitoring and reporting on health security threats including the COVID-19 pandemic, sets norms and standards, and issues technical guidance on all areas of public health. WHO collaborates with scientists and policy makers on a global scale to drive the R&D agenda for COVID-19 tools and develops standards on the manufacturing, testing and regulatory oversight of products developed. WHO's 150 country offices and close working partnerships (with Ministries of Health, other UN agencies including UNICEF and development partners such as the World Bank) enables the provision of technical assistance 'on the ground' to support country readiness and build capacities.

***Figure A.1 –*** *ACT-Accelerator structure and co-conveners*

**UNICEF** is the leading cross-cutting partner, providing programmatic support and procurement of supplies for countries across all Pillars. UNICEF is a member of the ACT-Accelerator Principals group and participates in the Facilitation Council. Additional agencies contribute to Pillar workstreams. The Global Financing Facility for Women, Children and Adolescents (GFF) is one such agency, supporting HSC and providing grants and technical assistance in GFF's 36 partner countries.

The **ACT-Accelerator Facilitation Council** is co-chaired by the Governments of Norway and South Africa, and co-hosted by WHO and the European Commission. It is comprised of ACT-Accelerator founding donor countries, major market shaper countries and current chairs of regional cooperation groups, with non-governmental partners [Bill & Melinda Gates Foundation, Wellcome Trust, World Economic Forum, and World Bank (observer)] and standing invitees from civil society and industry. The Council provides high-level advice and guidance to ACT-Accelerator, along with global leadership and advocacy with particular emphasis on ensuring the full financing of the work of ACT-Accelerator and addressing barriers to the equitable allocation of COVID-19 tools. For more information, see *ACT-Accelerator Facilitation Council Terms of Reference*.

An **ACT-Accelerator Executive Hub**, hosted by WHO, supports and enables the work of the co-convening and lead organizations in each Pillar and the ACT-Accelerator Facilitation Council. The Hub serves as a central coordination function and aims to facilitate synergies across the partnership by hosting cross-Pillar coordination meetings, developing key strategic joint publications, and tracking and reporting on the overall ACT-Accelerator status of financing. In its role as Secretariat for the Facilitation Council it supports the regular and intersessional work of the Council Co-Chairs and the convening of the Council itself.

## Appendix B – Assumptions underpinning the 2021 Strategy & Budget

Developing the ACT-Accelerator budget in its first year required making specific assumptions concerning the epidemiology of COVID-19, and setting specific targets for coverage with key response interventions. One year into the pandemic, our understanding of the evolving epidemiology, virus and response is improving. Working with the WHO Emergencies Programme and WHO's Strategic Technical Advisory Group on Infectious Hazards (STAG-IH), ACT-Accelerator has developed and updated a common set of assumptions to underpin the prioritized Strategy and Budget for 2021. These assumptions are summarized in **Tables B.1** and **B2.**

***Table B.1** – Underlying epidemiological assumptions*

| Metrics[a] | 2021 Assumptions | Source | Utility |
|---|---|---|---|
| 1. Infected & symptomatic rate[b] of individual presenting for care in LICs, LMICs & UMICs (excluding China) | 2.31% (70 million presenting for care) | • Extrapolation of John Hopkins database[c] on reported cases to a 12-month period, assuming a constant level of government interventions as per the Oxford Stringency Index[d] | Basis for estimation rate of test & treat |
| 2. Percent population at high risk & healthcare workers (HCW) | 25% | • WHO Global Health Observatory[e] (# HCW)<br>• IHME Global Burden of Disease tool[f] (high risk)<br>• Physician interviews | Basis for estimating priority vaccine coverage |
| 3. Symptom severity | 40% mild<br>40% moderate<br>15% severe<br>5% critical | • September ACT-Accelerator workstream 4 model<br>• Age stratification based on estimates from Imperial College[g]<br>• Summary of 70,000+ cases analysed by China CDC (81% classified as mild/moderate; about half mild, half moderate), 14% severe (require oxygen) and 5% critical (i.e. respiratory failure)[h] | Basis for estimating number of patients needed therapeutic per use case |
| 4. Symptomatic & asymptomatic rates | 85% symptomatic<br>15% asymptomatic | • Meta-analysis (15% asymptomatic)[i]<br>• CDC study from USS Theodore Roosevelt[b,j] (18.5% asymptomatic) | As seroprevalence data improves, can be basis for determining rates of susceptibility |

[a] Global averages unless otherwise stated. [b] Infected and symptomatic rate = infection rate x symptomatic rate (85%). [c] COVID-19 Dashboard [online database]. In: Coronavirus Resource Center. Baltimore: Johns Hopkins University & Medicine; 2021 (source, accessed 30 January 2021). [d] Hale T, Webster S, Petherick A, Phillips T, Kira B. Oxford COVID-19 Government Response Tracker [online database]. Oxford: Blavatnik School of Government; 2020 (source, accessed 30 January 2021). [e] Health Workforce. In: The Global Health Observatory [online database]. Geneva: World Health Organization; 2021 (source, accessed 30 January 2021). [f] IHME Global Burden of Disease Results Tool [online database[. Seattle: Institute for Health Metrics and Evaluation; 2020 (source, accessed 30 January 2021). [g] Ferguson NM, Laydon D, Nedjati-Gilani G, Imai N, Ainslie K, Baguelin M et al. Report 9: Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand. London: Imperial College; 2020 (source, accessed 31 January 2021). [h] Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA. 2020;323:1239–42. doi:10.1001/jama.2020.2648 (source, accessed 31 January 2021). [i] He J, Guo Y, Mao R, Zhang J. Proportion of asymptomatic coronavirus disease 2019: A systematic review and meta-analysis. J Med Virol. 2021;93:820-30. doi: 10.1002/jmv.26326 (source, accessed 30 January 2021). [j] Payne DC, Smith-Jeffcoat SE, Nowak G, Chukwuma U, Geibe JR, Hawkins RJ et al. SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members — USS Theodore Roosevelt, April 2020. MMWR Morb Mortal Wkly Rep 2020;69:714–21 (source, accessed 30 January 2021).

***Table B.2 –*** *ACT-Accelerator coverage targets*

| Metrics[a] | 2020 | 2021 |
|---|---|---|
| **Testing**<br>Coverage in LMICs | Based on availability, prioritizing symptomatic and contacts (120 million Ag-RDTs) | Increase to 50% of median HICs testing rate (900 million tests) for containment |
| **Therapeutics**<br>Coverage in LMICs | Based on product availability and use cases (2.9 million doses of dexamethasone) | Severe: lower need due to vaccines<br><br>Moderate: increased medical oxygen<br><br>Mild: novel antivirals and repurposed, depending on supply |
| **Vaccines**[a]<br>Vaccines coverage in LMIC | N/A | 20% of total population<br>80% healthcare worker (HCW) and high-risk (HR) populations |
| Vaccines efficacy | N/A | 80% |

[a] Source: Boston Consulting Group. Therapeutics Needs Model. Updated 14 December 2020.

## Appendix C – Explanation of key budget adjustments since November 2020 ACT-Accelerator budget

In September 2020, the *ACT-Accelerator: An economic investment case & financing requirements*[1] presented a 2020–2021 budget estimate of US$ 38.1 billion. Cost adjustments of US$ 4.9 billion and financing commitments of US$ 4.7 billion had by November 2020 reduced the funding gap to US$ 28.4 billion, as presented in the *ACT-Accelerator Urgent Priorities & Financing Requirements at 10 November 2020*[2]. The following paragraphs summarize the evolution of costs, pledges and funding gaps since then. The bridge between the US $38.1 billion budget reported in September 2020 and the updated US$ 27.2 billion ACT-Accelerator funding gap for 2021 is illustrated in Figure C.1 and the ACT-Accelerator 2020-2021 funding commitments, as of 1 February 2021 are presented in Appendix E.

**Diagnostics Pillar – Increase of US$ 3.6 billion**

All countries need large-scale testing for COVID-19 domestically, through public, private and academic laboratories, in order to know where transmission of the virus is occurring and to monitor any variants to the virus circulating. This requires scaling up testing strategies with molecular and Ag-RDTs, and regular monitoring of the circulating virus using genome sequencing. As an example, the United Kingdom experienced increased viral transmission and reported a new variant of the virus to WHO in December 2020. Further testing revealed that this viral strain had been circulating since September 2020.

ACT-Accelerator aims to scale-up testing in LICs and LMICs, so that by the end 2021, they are testing a rate of 50% of that occurring in HICs (median in January 2021).

**Therapeutics Pillar – Decrease of US$ 4.6 billion**

With early availability of vaccines and excepted scale-up, the demand for therapeutics has decreased and further reductions are expected.

The Therapeutics Pillar assumes that the coverage rate of vaccines will reach about 20% by end of 2021[3] and grow by 10% every quarter to reach 60% by the end of 2022. Additionally, in the light of recent epidemiological observations, the rate of infected and symptomatic individuals has been estimated at 2.31%,[4] reducing the funding requirement for procuring treatments. Nevertheless, it is essential that fit-for-purpose treatments are available for the broad population,[5] and a strong push on R&D for therapeutics is required throughout 2021 to broaden the portfolio in the midterm.

This January 2021 budget refresh moves costs related to oxygen to the Therapeutics Pillar, from the Health Systems Connecter, where these costs had previously been budgeted.

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[1] ACT-Accelerator: An economic investment case & financing requirements, September 2020 – December 2021. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/an-economic-investment-case-financing-requirements, accessed 13 January 2021).
[2] ACT-Accelerator: Urgent priorities & financing requirements at 10 November 2020. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/urgent-priorities-financing-requirements-at-10-november-2020, accessed 20 January 2021).
[3] With a vaccine efficiency of 80%.
[4] On average. Rates are differentiated by income category
[5] 80% of cases expected to be in broad population, not in the population covered with the first vaccination waves.

**Vaccines Pillar - Increase of US $ 0.8 billion**

Following intensive efforts by COVAX to assess country readiness and preparedness in receiving vaccines, as well as a strong push on R&D to accelerate developments of new candidates and address emerging new risks, the funding need for vaccines is revised upwards by US$ 0.8 billion.

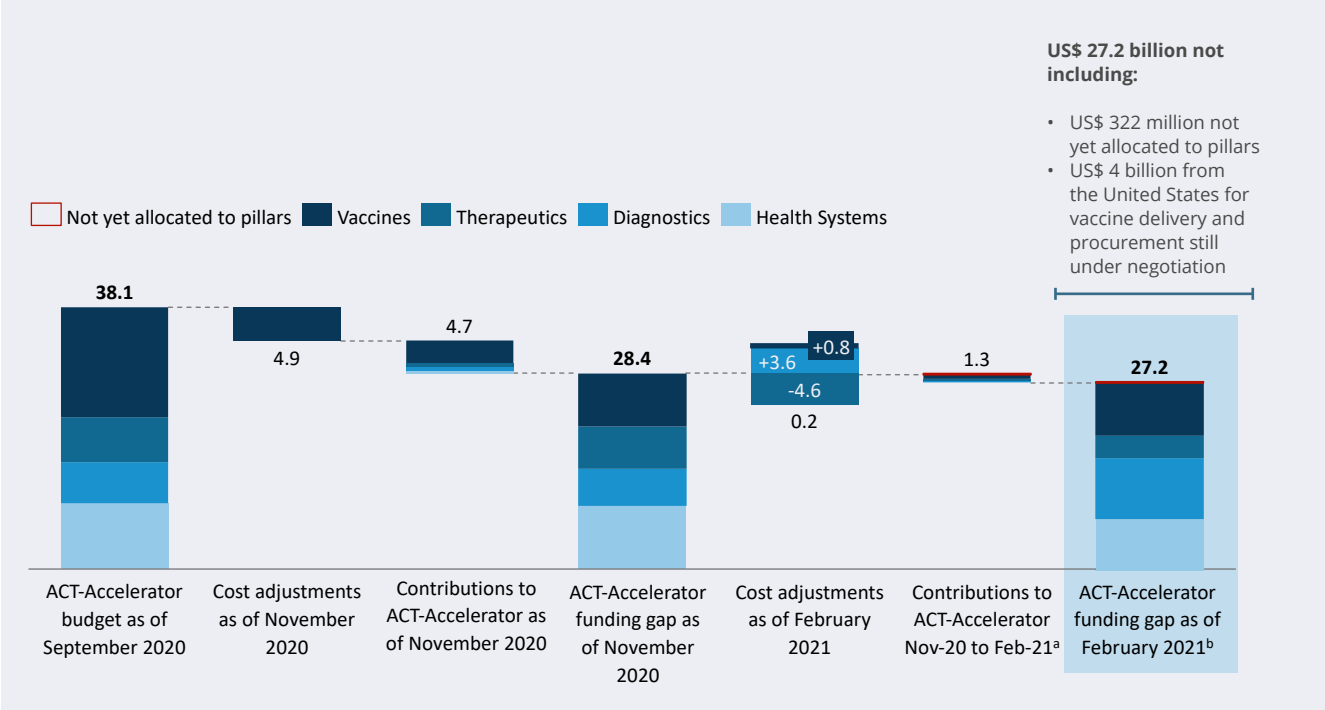
**New contributions of US$ 1.3 billion between November 2020 and February 2021 reduce Pillar 2021 funding gaps by US$ 0.9 billion**

Since November 2020, ACT-Accelerator received US$ 1.3 billion in new pledges, of which US$ 0.1 billion was for 2020 costs. An additional US$ 0.3 billion in commitments are pending allocation to Pillar/agencies, leaving US $ 0.9 billion in commitments that reduce Pillar funding gaps for 2021. As funds become allocated become to Pillars/agencies, they will in turn reduce ACT-Accelerator funding gaps.

Of note, a contribution from the United States of US$ 4 billion for vaccine delivery and procurement is being operationalized and will reduce ACT-Accelerator funding gaps once details are finalized.

Figure C.1 illustrates the bridge between the US$ 38.1 billion budget estimate of September 2020 and the current US$ 27.2 billion ACT-Accelerator funding gap for 2021.

***Figure C.1 –*** *ACT-Accelerator budget and funding gap, bridge between September 2020 budget and January 2021 funding gap - in US$ billion*




[a] Includes US$ 322 million not yet allocated to Pillars and US$ 100 million applied against 2020 costs.
[b] US$ 0.8 billion of procurement need for oxygen moved from the Health Systems Connector to the Therapeutics Pillar.

## Appendix D – Detailed funding gaps - in US$ million

***Figure D.1 –*** *Vaccines Pillar funding gap by period and deliverable packages – in US$ million*

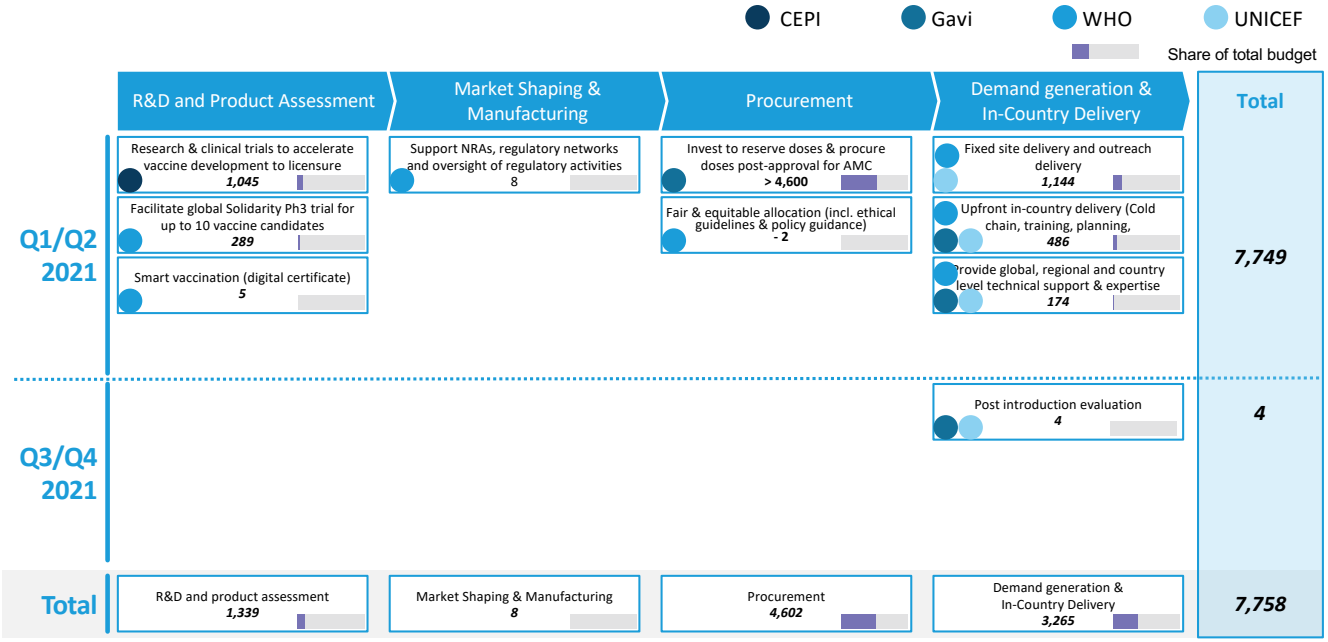
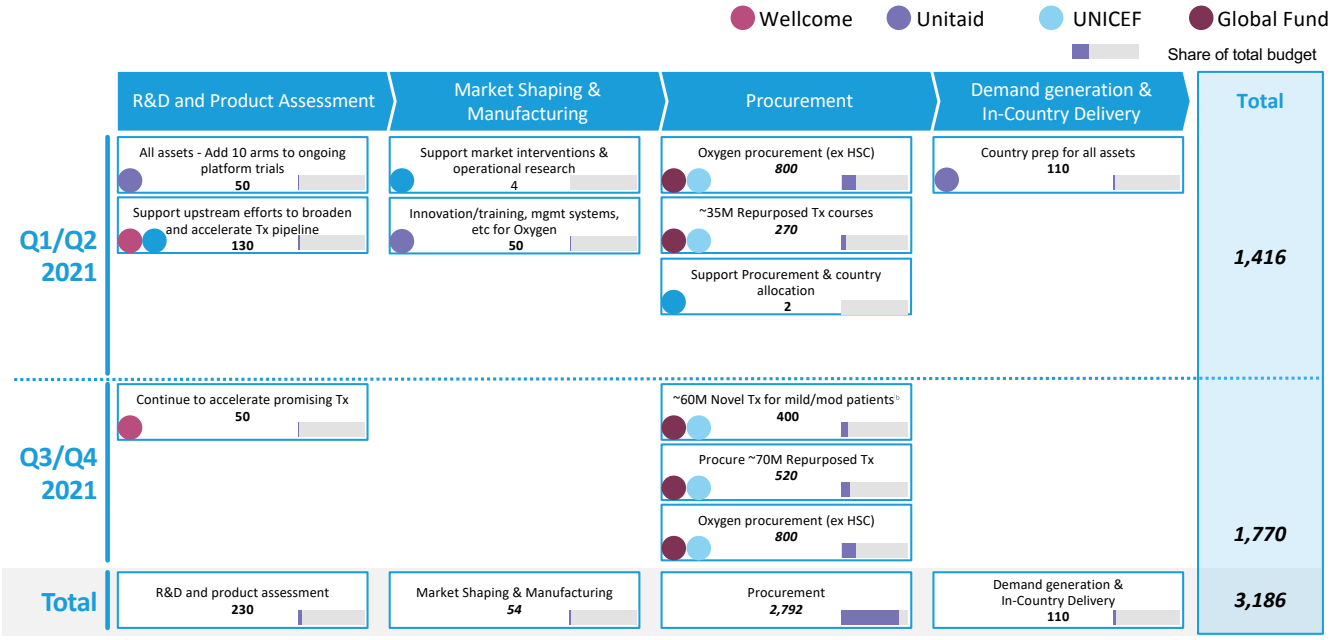
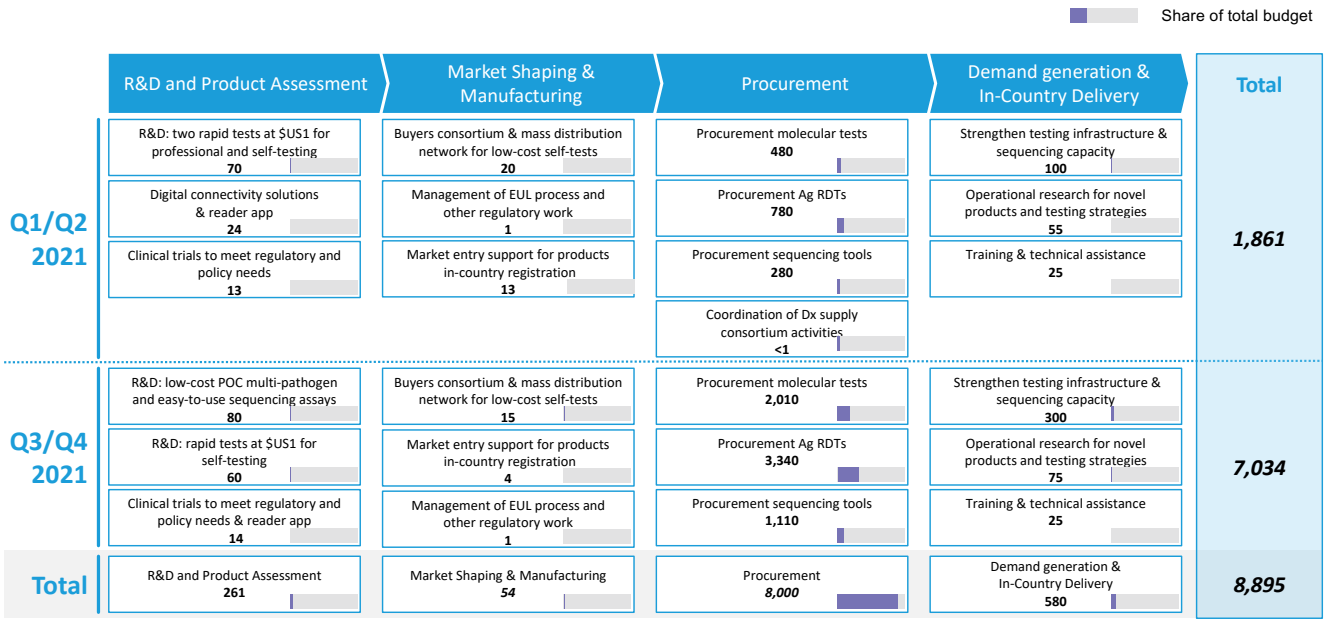



***Figure D.2 –*** *Therapeutics Pillar funding gap by period and deliverable packages – in US$ million*




[b] Canada has pledged US$ 163 million to ACT-Accelerator for the procurement of 2-4 million mAbs through the Fuji capacity reservation (recipient: UNICEF). To be evaluated in light of evolving clinical information.

***Figure D.3 –*** *Diagnostics Pillar funding gap by period and deliverable packages – in US$ million*




The Diagnostics Pillar convenes many stakeholders who play multiple roles across the workstreams due to the evolution of the pandemic, changing needs of countries and the dynamic multifaceted collaboration. Workstreams are coordinated by FIND, Global Fund and WHO and funding flows directly to multiple partners depending on their role and country needs. For further details, please reach out to ACTADiagnostics@finddx.org, gf_acta@theglobalfund.org or ACTADiagnostics@who.int.

***Figure D.4 –*** *Health Systems Connector funding gap by period and deliverable packages – in US$ million*

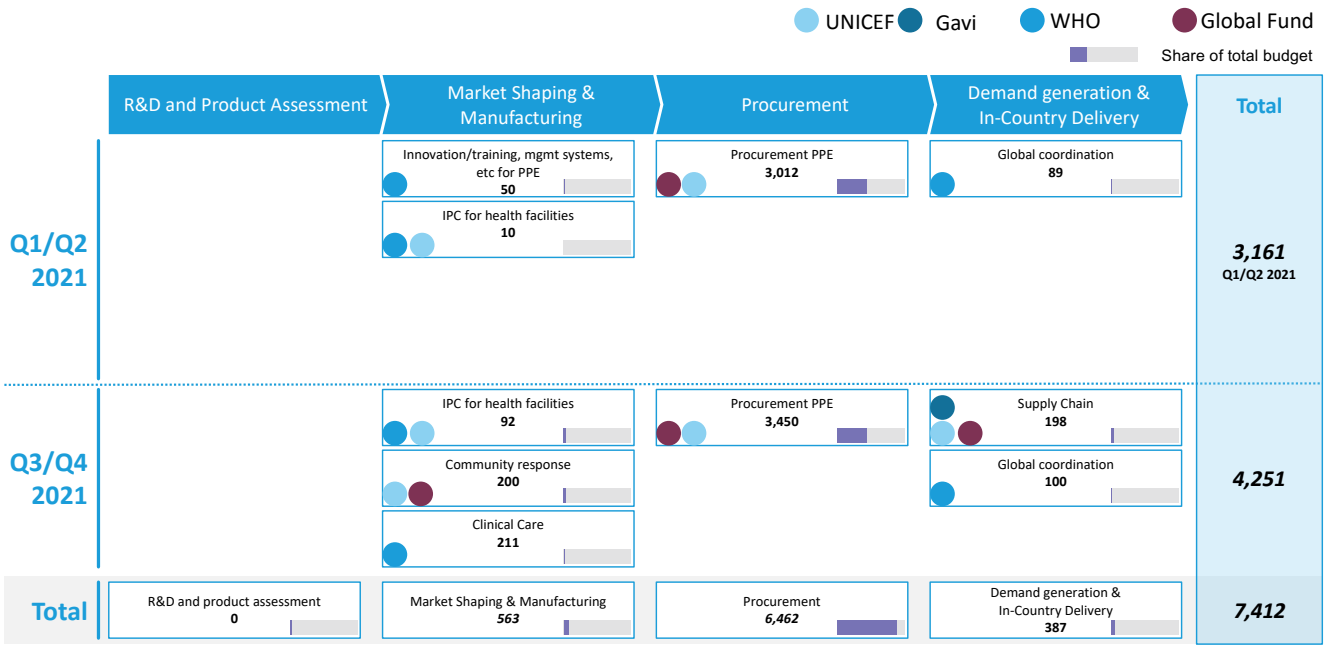


***Table D.5 –*** *ACT-Accelerator detailed funding gaps per deliverable packages, per pillar, per strategic priority, and by period – in US$ million*

| | | | | Funding gap | | | |
|---|---|---|---|---|---|---|---|
| **Deliverable** | **Pillar** | **Area of work** | **Strategic priority** | **Q1 / Q2 2021** | **Q3 / Q4 2021** | **Total 2021** | **Designated recipient and/ or lead agency** |
| **Total** | | | | **14,191** | **13,059** | **27,250** | |
| **Sub-total Vaccines** | **Vaccines** | | | **7.753** | **4** | **7.757** | |
| Support and funding for research and clinical trials to accelerate vaccine development to licensure | Vaccines | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 1045 | - | 1045 | CEPI |
| Facilitate global Solidarity Ph3 trial for up to 10 vaccine candidates | Vaccines | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 289 | - | 289 | WHO |
| Invest upfront in manufacturers to reserve doses now and procure doses post-approval for the 92 AMC eligible economies | Vaccines | Procurement | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 4600 | - | 4600 | GAVI |
| Ensure global, fair and equitable allocation, incl. creation of global ethical guidelines, and provide policy guidance | Vaccines | Procurement | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 2 | - | 2 | WHO |
| Support NRAs, regulatory networks and oversight of regulatory activities | Vaccines | Market Shaping & Manufacturing | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 8 | - | 8 | WHO |
| Fixed site delivery and outreach delivery | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 1144 | - | 1144 | GAVI, UNICEF |
| Cold chain, training, planning, pharmacovigilance | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 486 | - | 486 | GAVI, UNICEF |
| Global and regional TA | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 138 | - | 138 | GAVI, UNICEF |
| Innovations | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 34 | - | 34 | GAVI, UNICEF |
| Global pharmacovigilance | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 2 | - | 2 | GAVI, UNICEF |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Post introduction evaluation | Vaccines | Demand Generation & In country Delivery | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | - | 4 | 4 | GAVI, UNICEF |
| Smart vaccination (digital certificate) | Vaccines | R&D and Product Assesment | 1. Rapidly scale-up delivery of 2+ billion doses of vaccine through COVAX | 5 | - | 5 | WHO |
| | | | | **Funding gap** | | | |
| **Deliverable** | **Pillar** | **Area of work** | **Strategic priority** | **Q1 / Q2 2021** | **Q3 / Q4 2021** | **Total 2021** | **Designated recipient and/ or lead agency** |
| **Sub-total Therapeutics** | **Therapeutics** | | | **1416** | **1770** | **3186** | |
| Country preparedness for all assets | Therapeutics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 110 | - | 110 | Unitaid |
| Preliminary review & immediate action on market readiness for Novel & Repurposes Tx | Therapeutics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 0.2 | - | 0.2 | Unitaid |
| Innovation/training, mgmt. systems, etc. for oxygen | Therapeutics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 50 | - | 50 | Unitaid |
| Support market interventions: voluntary licensing, technology transfers, regulatory and policy processes | Therapeutics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 4.1 | - | 4.1 | WHO |
| Procure 35M Repurposed Tx | Therapeutics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | 270 | - | 270 | UNICEF/Global Fund |
| Oxygen procurement (ex HSC) | Therapeutics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | 800 | 800 | 1600 | UNICEF/Global Fund |
| Support Procurement & country allocation | Therapeutics | Procurement | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 2 | - | 2 | WHO |
| Procure 60M Novel Tx for mild/mod patients | Therapeutics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 400 | 400 | UNICEF/Global Fund |
| Procure 70M Repurposed Tx | Therapeutics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 520 | 520 | UNICEF/Global Fund |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Add up to 10 arms to ongoing platform trials | Therapeutics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 50 | - | 50 | Unitaid |
| Support upstream efforts to broaden & accelerate TX pipeline | Therapeutics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 130 | - | 130 | Wellcome / WHO |
| Continue to accelerate promising Tx | Therapeutics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | - | 50 | 50 | Wellcome |
| | | | | **Funding gap** | | | |
| **Deliverable** | **Pillar** | **Area of work** | **Strategic priority** | **Q1 / Q2 2021** | **Q3 / Q4 2021** | **Total 2021** | **Designated recipient and/ or lead agency** |
| **Sub-total Diagnostics** | **Diagnostics** | | | **1861** | **7034** | **8896** | |
| R&D: two rapid tests at $US1 for professional and self-testing; tech transfer for regional production | Diagnostics | R&D and Product Assesment / Market Shaping & Manufacturing | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 70 | 60 | 130 | FIND/ Unitaid |
| Digital connectivity solutions & reader app | Diagnostics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 14 | - | 14 | FIND |
| Digital connectivity & data sharing solutions | Diagnostics | R&D and Product Assesment / Market Shaping & Manufacturing | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 9 | - | 9 | FIND |
| Digital connectivity solutions & reader app | Diagnostics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 1 | 1 | 2 | WHO |
| Clinical trials to meet regulatory and policy needs | Diagnostics | R&D and Product Assesment / Market Shaping & Manufacturing | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | 13 | 13 | 26 | FIND |
| R&D: low-cost POC multi-pathogen and easy-to-use sequencing assays | Diagnostics | R&D and Product Assesment | 2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks | - | 80 | 80 | FIND |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Procure molecular tests | Diagnostics | Procurement | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 480 | - | 480 | Dx Consortium partners |
| Procure Ag RDTs | Diagnostics | Procurement | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 780 | - | 780 | Dx Consortium partners |
| Procure sequencing solutions | Diagnostics | Procurement | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 280 | - | 280 | Dx Consortium partners |
| Procure molecular tests | Diagnostics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 2010 | 2010 | Dx Consortium partners |
| Procure Ag RDTs | Diagnostics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 3340 | 3340 | Dx Consortium partners |
| Procure sequencing solutions | Diagnostics | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 1110 | 1110 | Dx Consortium partners |
| Coordination of Dx Supply Consortium activities | Diagnostics | Procurement | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 0.3 | 0.3 | 1 | WHO |
| Market entry support for products in-country registration | Diagnostics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 13 | 4 | 17 | FIND |
| Buyers consortium and mass distribution network for LMIC access to low-cost self-tests | Diagnostics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 20 | 15 | 35 | FIND |
| Management of EUL process and other regulatory work | Diagnostics | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 1 | 1 | 2 | WHO |
| Operational research for novel products and testing strategies | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 53 | 73 | 126 | FIND/ Unitaid |
| Operational research for novel products and testing strategies | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 2 | 2 | 4 | WHO |
| Strengthen/ expand country testing infrastructure & sequencing capacity | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 91 | 291 | 382 | FIND/ GF/ WHO |

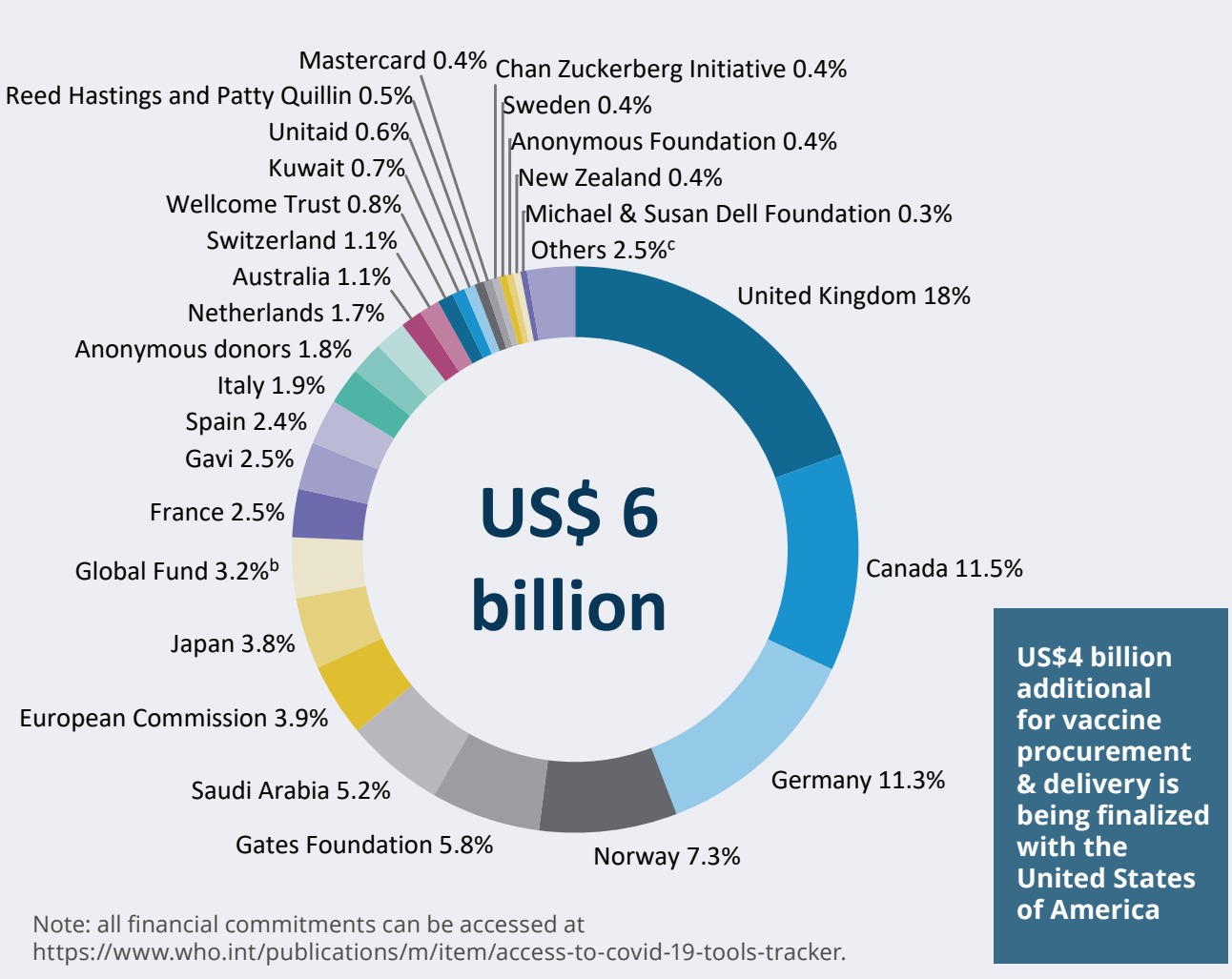
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Strengthen/ expand country testing infrastructure & sequencing capacity | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 9 | 9 | 18 | WHO |
| Train healthcare workers & laboratorians and provide technical assistance | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 24 | 24 | 48 | FIND with relevant country partners |
| Train healthcare workers & laboratorians and provide technical assistance | Diagnostics | Demand Generation & In country Delivery | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 1 | 1 | 2 | WHO |
| | | | | **Funding gap** | | | |
| **Deliverable** | **Pillar** | **Area of work** | **Strategic priority** | **Q1 / Q2 2021** | **Q3 / Q4 2021** | **Total 2021** | **Designated recipient and/ or lead agency** |
| **Sub-total Health Systems Connector** | **HSC** | | | **3161** | **4251** | **7412** | |
| Innovation/training, mgmt systems, etc for PPE | HSC | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 50 | - | 50 | WHO |
| IPC for health facilities | HSC | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | 10 | 92 | 102 | WHO / Unicef |
| Supply Chain | HSC | Demand Generation & In country Delivery | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | - | 198 | 198 | UNICEF / GAVI / Global Fund |
| Global coordination costs | HSC | Demand Generation & In country Delivery | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | 89 | 100 | 189 | WHO |
| Community response | HSC | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | - | 200 | 200 | Global Fund / UNICEF |
| Clinical Care | HSC | Market Shaping & Manufacturing | 3. Enhance utilization of diagnostics, therapeutics & PPE in LIC/LMICs | - | 211 | 211 | WHO |
| Procure PPE | HSC | Procurement | 4. Ensure robust pipeline of essential diagnostics, therapeutics & PPE in LICs/LMICs | 3012 | 3450 | 6462 | Global Fund / UNICEF |

## Appendix E – Overview of previous financial support to ACT-Accelerator

Since its inception in April 2020, a total of US$ 6 billion has been committed to ACT-Accelerator, from a broad coalition of public (70%), private (12%) and multilateral (18%) donors. The exact amount provided by donors to recipients is made available online every other week with the ACT-Accelerator Commitment Tracker.[1] **Figure E.1** gives an overview of the contributions.

[1] Access to COVID-19 tools funding commitment tracker. Geneva: World Health Organization; 2021 (https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker, accessed 01 February 2021).

***Figure E.1 –*** *ACT-Accelerator contributions in % of total commitments[a] – as of 01 February 2021*




Note: all financial commitments can be accessed at https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker.

[a] US$6 billion include US$470 million contributed by the Diagnostics Consortium to procure automated and manual molecular tests for LMICs. [b] Excluding US$ 267 million by donors to the Global Fund COVID-19 Response Mechanism and redistributed to ACT-Accelerator pillars. [c] Contributions <US$ 20 million.


Gavi
The Vaccine Alliance

CEPI

World Health
Organization

wellcome

BILL & MELINDA
GATES foundation

FIND
Because diagnosis matters

WORLD BANK GROUP

The Global Fund

Unitaid