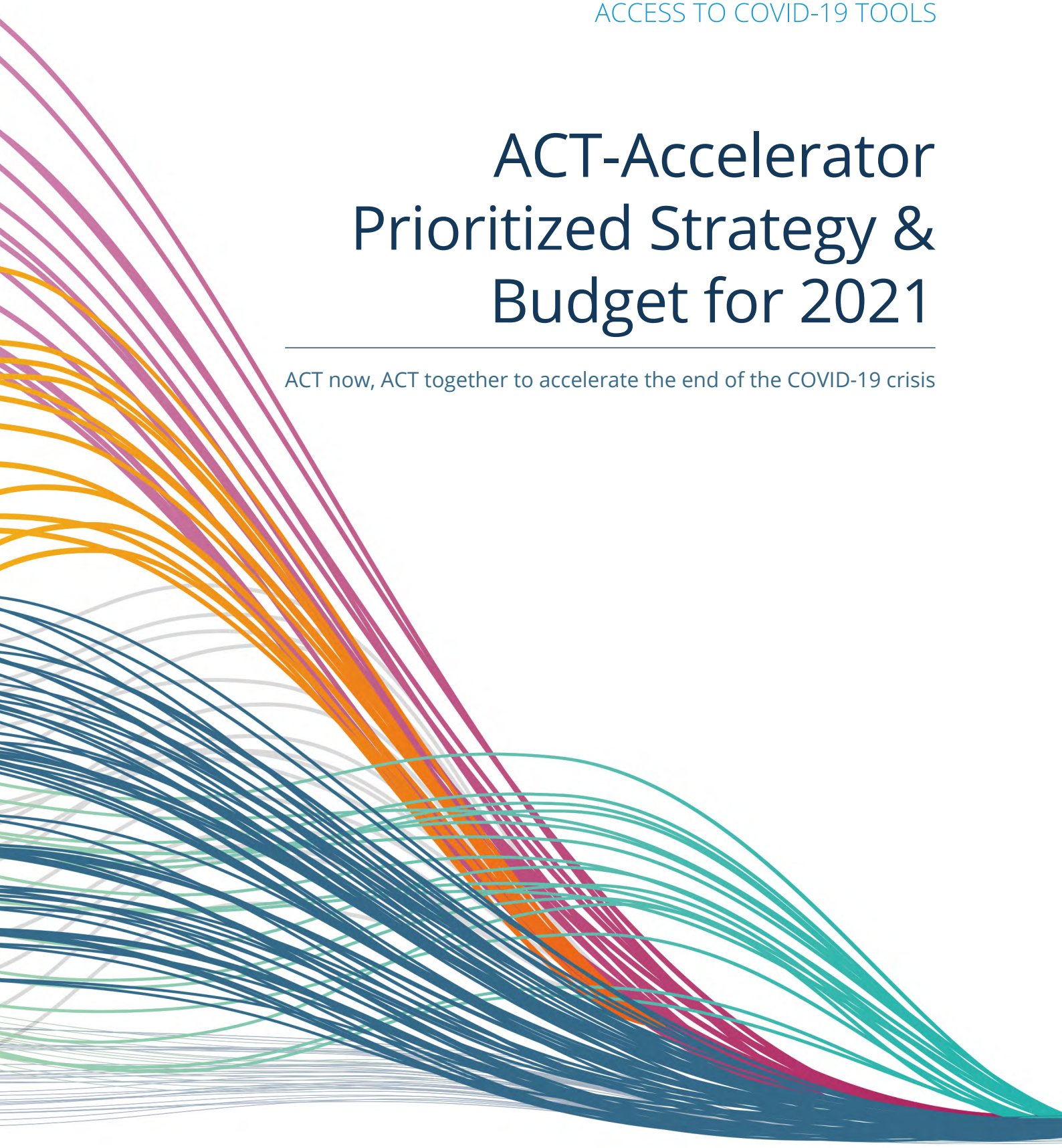
ACTaccelerator
ACCESS TO COVID-19 TOOLS

ACT-Accelerator Prioritized Strategy & Budget for 2021

ACT now, ACT together to accelerate the end of the COVID-19 crisis



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

Working with governments, civil society and industry

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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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ACRONYMS

Ag	antigen-detecting
ACT	Access to COVID-19 Tools
AMC	advance market committment
BMGF	Bill & Melinda Gates Foundation
CEPI	Coalition for Epidemic Preparedness Innovations
EUL	emergency use listing
FIND	The Foundation for Innovative New Diagnostics
GDP	gross domestic product
GFF	The Global Financing Facility for Women, Children and Adolescents
HCW	healthcare worker
HICs	high-income countries
HSC	Health Systems Connector
IP	intellectual property
IPC	infection prevention and control
IMF	international Monetary Fund
LICs	low-income countries
LMICs	low- and middle-income countries
NPIs	non-pharmaceutical interventions
mAbs	intellectual property
MPA	World Bank's Multiphase Programmatic Approach
NDVP	National Deployment Vaccination Plan
ODA	Official Development Assistance
PAHO	Pan American Health Organization
PCR	polymerase chain reaction
PHSM	public health and social measures
PPE	public health and social measures
SM NAV	small molecule novel antivirals
SPRP	Strategic Preparedness and Response Program
SRA	stringent regulatory authority
STAG-IH	Strategic Technical Advisory Group on Infectious Hazards
R&D	research & development
RDT	rapid diagnostic test
UMIC	upper-middle-income countries
UNICEF	United Nations International Children's Emergency Fund
VIRAT	Vaccine Introduction Readiness Assessment Tool
VRAF 2.0	Vaccine Readiness Assessment Framework
WHO	World Health Organization

01

EXECUTIVE SUMMARY

The world continues to face an unprecedented and rapidly evolving threat from COVID-19. By early March 2021, there had been over 117 million cases and more than 2.6 million deaths. Susceptibility to the virus remains high around the world. Many countries are experiencing a resurgence in cases, often more extreme than previous waves, putting immense strain on health systems. While roughly 319 million vaccinations have been given, billions of at-risk people have not received a shot. Vaccine supply remains constrained and is not, on its own, enough to end the acute phase of the crisis.

Over the past few months, three major shifts have characterized the COVID-19 pandemic and the operating environment for ACT-Accelerator. These shifts require a refresh of ACT-Accelerator priorities, financing requirements, and investment case. First, thanks to unprecedented scientific endeavor, we have entered the 'era of COVID-19 vaccines.' The world now has a reliable tool at hand to prevent COVID-19 and protect the most vulnerable populations. However, given the immense demand, supply constraints remain. Second, virus variants are emerging with increasingly concerning characteristics. As of early March 2021, three variants of concern had been detected, with others under active investigation. Third, despite valuable support from governments, regulators, manufacturers, and other stakeholders, there has been insufficient investment in global solutions to scale COVID-19 tools.

ACT-Accelerator is well positioned to respond to these challenges. In under one year, ACT-Accelerator has driven real progress, bringing together an unprecedented partnership of global health partners to accelerate the end of the COVID-19 pandemic.

Perhaps most significantly, it has enabled the first international deliveries of vaccines to low- and middle-income economies within 12 weeks of their introduction in high-income countries, and is on track to deliver at least 2 billion doses in 2021. ACT-Accelerator has also identified and validated quality rapid diagnostic tests and significantly reduced their cost for low income countries. In addition, ACT-Accelerator supported identification of the first life-saving therapy (dexamethasone), secured 2.9 million treatment courses and procured more than US$ 500 million worth of PPE.

In 2021 ACT-Accelerator will intensify its drive for equity and scale in the delivery of essential COVID-19 tools, while managing emerging viral risks. To address these major shifts and maintain momentum, ACT-Accelerator has defined **four strategic priorities for 2021**:

Rapidly scale up the **delivery of at least 2 billion doses of vaccines**

Bolster R&D, evaluations & regulatory pathways to **optimize products and address variants**

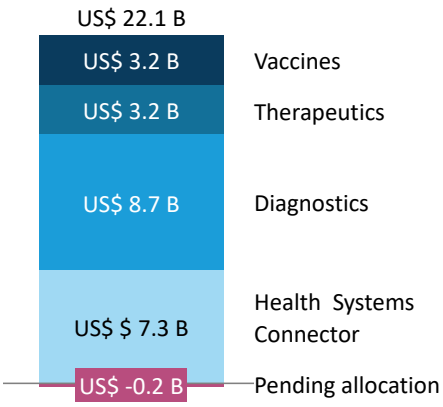
Stimulate rapid and effective uptake and use of **COVID-19 tests, treatments, and PPE**

Ensure a **robust pipeline** of essential tests, treatments, and PPE

To manage resource constraints, ACT-Accelerator has sequenced its activities in 2021 based on these strategic priorities. In 2020, a substantial focus of ACT-Accelerator was on developing and evaluating a sound product portfolio by investing in R&D, product assessment, and market shaping, while laying the groundwork for large-scale procurement and in-country delivery. Now that an initial set of effective and affordable COVID-19 tools is available, resources are increasingly focused on optimizing their public health impact. In 2021, ACT-Accelerator aims to fully leverage these existing tools and available volumes, then expand manufacturing, while continuing to invest in further R&D and product optimization.

The original ACT-Accelerator investment case published in September 2020 outlined a total requirement of US$ 38.1 billion to fully fund its work. Based on the refreshed strategic priorities outlined above, the Pillars have adjusted their resource needs. Despite generous donor contributions amounting to US$ 11.0 billion to date, ACT-Accelerator continues to require an additional US$ 22.1 billion in 2021 to deliver on its full promise. To ensure that all potential financial contributors to ACT-Accelerator contribute their fair share to these collective efforts, the ACT-Accelerator Facilitation Council, through its Financial Working Group, has developed a financing framework for ACT-Accelerator and proposed a burden-sharing model to help donors understand how to close the **funding gap**.

ACT-Accelerator funding gap for 2021



While the 2021 financial needs of ACT-Accelerator are substantial, they represent only a subset of the overall funding required to comprehensively and equitably respond to the magnitude of the COVID-19 crisis. Beyond the ambition of accelerating the development of COVID-19 tools and ensuring their equitable access, ACT-Accelerator aims to support the COVID-19 response while complementing the broader ongoing efforts to drive sustainable and long-term improvements to national health systems.

Tackling COVID-19 requires substantial financial investments, but the financial and economic ramifications of inaction are far greater. In January 2021, a study commissioned by the International Chamber of Commerce demonstrated that even with strong COVID-19 vaccine coverage in high-income countries, inequitable access to COVID-19 tools elsewhere would cost high-income economies an additional US$ 2.4 trillion in 2021 alone. Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments.
If COVID-19 transmission is uncontrolled anywhere in the world, it remains a threat to everyone everywhere in the world. We must ACT now, and ACT together, to end the acute phase of the pandemic.

02

CONTEXT: 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. **Virus variants are emerging with increasingly concerning characteristics**
3. **There is insufficient investment in global solutions, with increasing bilateral initiatives and deals**

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 to address the ramifications of COVID-19. As of early March, COVID-19 has tragically claimed more than 2.6 million lives and infected over 117 million people worldwide[1]. Many countries are experiencing a resurgence in cases, often more extreme than previous waves, putting immense strain on health systems. New and more transmissible variants of the virus are taking hold in many countries. Evidence is also growing of the long-term health effects of COVID-19 or 'Long COVID', amplifying the burden on health systems and economies, and increasing the importance of disease prevention. We must ACT now and ACT together to end the acute phase of the pandemic as quickly as possible. Only then can we save lives, stabilize health systems, and restore the global economy.

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. A collaboration of leading public health agencies (see **Appendix A**), it 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 rolling out worldwide, low-cost high-performing antigen rapid diagnostic tests (Ag-RDTs) can now detect transmission anywhere, affordable treatment (e.g. corticosteroids, medical oxygen) for severe disease can save lives in any setting, and health systems are supported in the roll-out of these tools. 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. Generous donor commitments of US$ 11.0 billion to date, and adjustment of costs for the current priorities, have reduced the funding gap for 2021 to US$ 22.1 billion.

[1] WHO Coronavirus Disease (COVID-19) Dashboard. Geneva: World Health Organization; 2020 (https://covid19.who.int/, accessed 11 March 2021).

Three major shifts have underpinned the need for a refresh of the ACT-Accelerator plan[1], financing requirements[2], and investment case[3]:

1. **We have entered the 'era of COVID-19 vaccines.'** We are moving from a phase where COVID-19 vaccines were an uncertain scientific endeavour to a phase where vaccines are a reality, in high demand, and with the race on to accelerate, scale, and facilitate 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 130 economies have started vaccination. More vaccine candidates are expected to follow soon and manufacturing is being scaled at unparalleled speed. The world now has a reliable tool at hand to prevent COVID-19 and protect the most vulnerable populations; however, given the immense demand, supply constraints remain. This high demand for vaccines also risks crowding out demand for other tools in some settings.

2. **Virus variants are emerging with increasingly concerning characteristics.** Speed and continued investment in Research & Development (R&D) matters. We need to continually assess our portfolio of tools, and the strategy for their use, to ensure that they remain fit-for-purpose. As of early March 2021, three variants of concern had been detected, with others under active 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 an even greater risk to health systems. Our best response to these risks is to decrease the global circulation of the virus as rapidly as possible and advance our R&D agenda, while considering the need to refine control strategies, such as introducing booster doses of vaccines and increasing vaccine coverage to reduce opportunities for mutation. It is vital for ACT-Accelerator and the world to monitor viral evolution very closely and invest further in scaling up diagnostic testing and sequencing to enhance global surveillance, especially in low- and middle-income countries (LMICs). Besides bolstering investments in R&D, it is also essential to address gaps in delivery systems and to continue providing rigorous product assessment, ensuring regulatory activities (e.g. harmonization of regulatory standards) allow for rapid global adoption.

3. **There is insufficient investment in global solutions to scale COVID-19 tools, with increasing bilateral initiatives and deals.** The ACT-Accelerator collaboration was founded on the principle of global solidarity and equity, with an exceptionally strong multilateral commitment from governments, manufacturers, regulators, and other stakeholders. However in spite of this valuable support, ACT-Accelerator faces a funding gap of US$ 22.1 billion for 2021. At the same time, escalation in the number and reach of bilateral deals for key products needed to control the pandemic – particularly vaccines – needs to be addressed through greater global collaboration with countries and manufacturers.

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[1] 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).
[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] 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).

While these shifts pose challenges, ACT-Accelerator is well-equipped to respond. At the time that ACT-Accelerator was launched in 2020 very few tools were available to countries in the fight against COVID-19. Since then, thanks to the hard work and ingenuity of scientists, academics and the pharmaceutical industry; remarkable collaboration across agencies and organizations; and the support of donors, the world has made significant progress in the development of an initial critical portfolio of tools and strategies to fundamentally change the course of the pandemic. These efforts will need to be strengthened and adapted as the pandemic evolves.

As we move forward, ACT-Accelerator is well positioned to further strengthen the **three lines of defense** (vaccines, tests, treatments) established against COVID-19, each of which is essential to an effective and integrated response to overcome this pandemic through an effective health system. One line of defense, vaccines, can now dramatically reduce the disease burden and protect the highest risk and most exposed populations. Another line of defense is testing. The development and scale-up of RDTs has reinforced our ability to identify and isolate cases, 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 effective therapeutic for severe disease (dexamethasone) and acceleration of the 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 (including genomic sequencing) and treatments, mechanisms for equitable allocation of vaccines [e.g. the COVAX Facility and the Gavi COVAX Advance Market Commitment (AMC) to secure doses for 92 low- and middle-income countries and economies].

03

KEY ACHIEVEMENTS: ACT-Accelerator is making a real difference

In less than one year, ACT-Accelerator has made real progress, bringing together an unprecedented partnership of global health partners to accelerate the end of the COVID-19 pandemic. **Table 1** outlines ACT-Accelerator achievements to date.

ACT-Accelerator activities and achievements span the value chain, from assessing a wide range of products and providing information to countries on what does and does not work, through strengthening country capacity to implement COVID-19 tools and integrate them into health systems.

Table 1 - *ACT-Accelerator's key achievements at end February 2021, by Pillar*

R&D and product assessment	Market shaping & manufacturing	Procurement	Demand generation & in-country delivery
Vaccines			
Established **portfolio of 11 vaccine candidates across 4 technology platforms** Invested **US$ 1.2 billion** in vaccine **development**	Established the **indemnification & liability** and **no-fault compensation programme** for AMC economies	Established the **COVAX Facility** for **procurement and equitable distribution of vaccines** to 191 countries **>2** billion doses secured through **6** deals	Supported the development of at least **>100 National Development and Vaccination Plans** First international delivery of COVAX doses to **AMC countries within 12 weeks** after first country started vaccinating, with a total of **28 million doses** shipped to **33 countries** as of 10 March 2021
Diagnostics			
Expedited development and regulatory approval of quality tests, supporting product selection of **3 Ag-RDTs** that received **WHO EUL**	Expedited the introduction of Ag-RDTs, **reducing the cost** of the test for LMICs to a price ceiling of US$ 5 a test by September 2020, and further to a ceiling price of US$ 2.50 in 2021 **Fast-tracked access at scale** through set of agreements, including **technology transfer, regionalized manufacturing** and **manufacturing scale-up**	**Procured 60+ million molecular and Ag-RDTs** for LMICs	Supported **70+ countries** in **expanding laboratory infrastructure** and **ramping up testing** Developed **policy and implementation guidance**, **training tools** and **technical assistance**
Therapeutics			
Tracked > 300 actionable trials across products (mAbs, novel antivirals and repurposed therapeutics) **Supported 2 large randomized controlled platform trials** and identification of the first **life-saving therapy** dexamethasone, and provided global guidance on its use	Identified **US$ 90 million immediate funding needs for medical oxygen** in up to 20 LMICs.	Catalyzed and supported the use of **dexamethasone,** securing **2.9 million treatment courses**	Formed **COVID-19 Oxygen Emergency Taskforce** to assess and address COVID-19 surges in oxygen demand and cut preventable deaths Immediate contribution of up to **US$ 20 million to kick off the emergency response**
Health Systems Connector			
Focus was to **support in-country delivery of COVID-19 tools** by building capacities and infrastructure, resolving bottlenecks, and strengthening health systems		Procured PPE for a total value of more than **US$ 500 million**	Mapped **system requirements** for the introduction of new COVID-19 tools in 4 out of 6 world regions Conducted **national pulse surveys in 129 countries** to assess bottlenecks Established a **common knowledge sharing platform** Developed **global guidelines and training** across multiple critical health system areas

Pillar-specific achievements to date

Vaccines

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 has positioned the world for equitable access to this vital product. COVAX, the Vaccines Pillar of ACT-Accelerator, accelerated the development of vaccines through investments totaling US$ 1.2 billion in a broad portfolio of vaccine candidates (currently 11 across 4 technology platforms). It set up the COVAX Facility, a global mechanism to procure and distribute doses in record time. There are now 99 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 AMC (AMC92).

Based on current projections, COVAX is on track to hit its target of supplying at least 2 billion vaccine doses in 2021, of which at least 1.3 billion will be for AMC countries. COVAX is also laying the groundwork for an additional 500 million doses to be secured through cost-sharing, supported by domestic and 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 and created a Joint Allocation Taskforce (WHO-Gavi taskforce) and an Independent Allocation of Vaccine Group to ensure transparent governance of the allocation process. Furthermore, a broad range of ACT-Accelerator partners are helping countries to prepare for the roll-out of vaccines and performed country readiness assessments in 142 countries as of early March, using the Vaccine Introduction Readiness Assessment Tool (VIRAT) and Vaccine Readiness Assessment Framework (VRAF 2.0).

COVAX partners have also made tremendous progress on other enablers critical for delivering vaccines, especially in regulatory activities and in issuing guidance, tools and trainings on topics such as cold chain requirements and community engagement. The former have been accelerated by bringing critical actors to the table (e.g. manufacturers and governments) to negotiate and agree on standard indemnification and liability language in order to facilitate access to vaccines and establish a no-fault compensation programme available to all AMC economies to address potential adverse events resulting from vaccine use. Over 100 countries have been supported in developing and submitting their National Deployment and Vaccination plans based on this guidance. Despite substantial challenges, COVAX made it possible for the first international vaccine deliveries in LMICs to take place within 12 weeks from introduction in the first few high-income countries (HICs). In comparison, the WHO H1N1 influenza vaccine deployment initiative delivered the first vaccine doses in Africa 145 days after the first countries started vaccinating[2].

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[1] ACT-Accelerator: Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility, September 2020. Geneva: World Health Organization; 2020. (https://www.gavi.org/sites/default/files/covid/covax/who-covid19-vaccine-allocation-final-working-version-9sept.pdf, accessed 18 January 2021).
[2] Report of the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative, Geneva: World Health Organization; 2012. (https://www.who.int/influenza_vaccines_plan/resources/h1n1_deployment_report.pdf, accessed 3 March 2021).

Diagnostics

ACT-Accelerator has enabled access to easier-to-use, accurate and more affordable diagnostic tests, such as well-performing Ag-RDTs, by fast-tracking R&D, independent assessment, EUL and manufacturing scale-up. Expediting the introduction of Ag-RDTs reduced the cost for LMICs down to a ceiling price of US$ 5 a test by September 2020, and down further to a ceiling price of US$ 2.50 in 2021[1,2]. ACT-Accelerator and its partners have procured more than 60 million molecular and Ag-RDTs for LMICs, providing better access and improved equity in those geographies. Three Ag-RDTs have WHO EUL, and through a new set of R&D agreements (e.g. technology transfer and manufacturing scale-up), ACT-Accelerator aims to make over 250 million Ag-RDTs available in 2021 to 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 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.

Therapeutics

ACT-Accelerator plays a vital role in identifying and integrating effective treatments with good clinical care to treat those affected. To date, ACT-Accelerator has tracked over 300 actionable trials across product categories and supported two large randomized controlled platform trials which led to the identification of the first life-saving therapy, dexamethasone. ACT-Accelerator continues to advance the research agenda for monoclonal antibodies (mAbs) adapted for LMICs, small molecule novel antivirals (SM NAV) and repurposed therapeutics. ACT-Accelerator has also provided global guidance on the clinical use of corticosteroids (including dexamethasone) and integrated its use with medical oxygen into 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 LMICs. The COVID-19 Oxygen Emergency Taskforce has been launched to assess and address COVID-19 surges in oxygen demand and to reduce preventable deaths.

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[1] Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries [website]. Geneva: World Health Organization; 2020 (https://www.who.int/news/item/28-09-2020-global-partnership-to-make-available-120-million-affordable-quality-covid-19-rapid-tests-for-low--and-middle-income-countries, accessed 3 March 2021).

[2] Cost of rapid COVID-19 tests halved as global investment ensures availability of high volumes for low- and middle-income countries [website]. Geneva: Unitaid; 2021 (https://unitaid.org/news-blog/cost-of-rapid-covid-19-tests-halved-as-global-investment-ensures-availability-of-high-volumes-for-low-and-middle-income-countries, accessed 3 March 2021).

Health Systems Connector

ACT-Accelerator protects and strengthens health systems to facilitate the rapid uptake of new tools. The Health Systems Connector (HSC) 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, ACT-Accelerator partners have procured more than US$ 500 million in PPE for LMICs. System requirements for the delivery of COVID-19 tools have been mapped in four out of six world regions. Evidence of priority areas for work was gathered through multiple mechanisms, including by conducting national pulse surveys on service disruptions and readiness in 129 countries, examining data on community engagement in COVID-19 responses, and developing more detailed facility studies and dashboards in pilot countries, among many other evidence-gathering exercises. Furthermore, global and regional guidance and training materials have been developed to support health financing and COVID-19 costing, strengthen community engagement in the COVID-19 response, bolster critical supply chain capabilities, enhance engagement with the private sector, and several other critical areas. As countries deploy new tools, these accompanying materials will be further developed, refined, and tailored to individual country needs.

HSC has also established common knowledge platforms for countries to share country-level knowhow and best practices for strengthening health systems responding to COVID-19. These insights are critical to enable and accelerate the roll-out and optimal use of ACT-Accelerator tools across the globe.

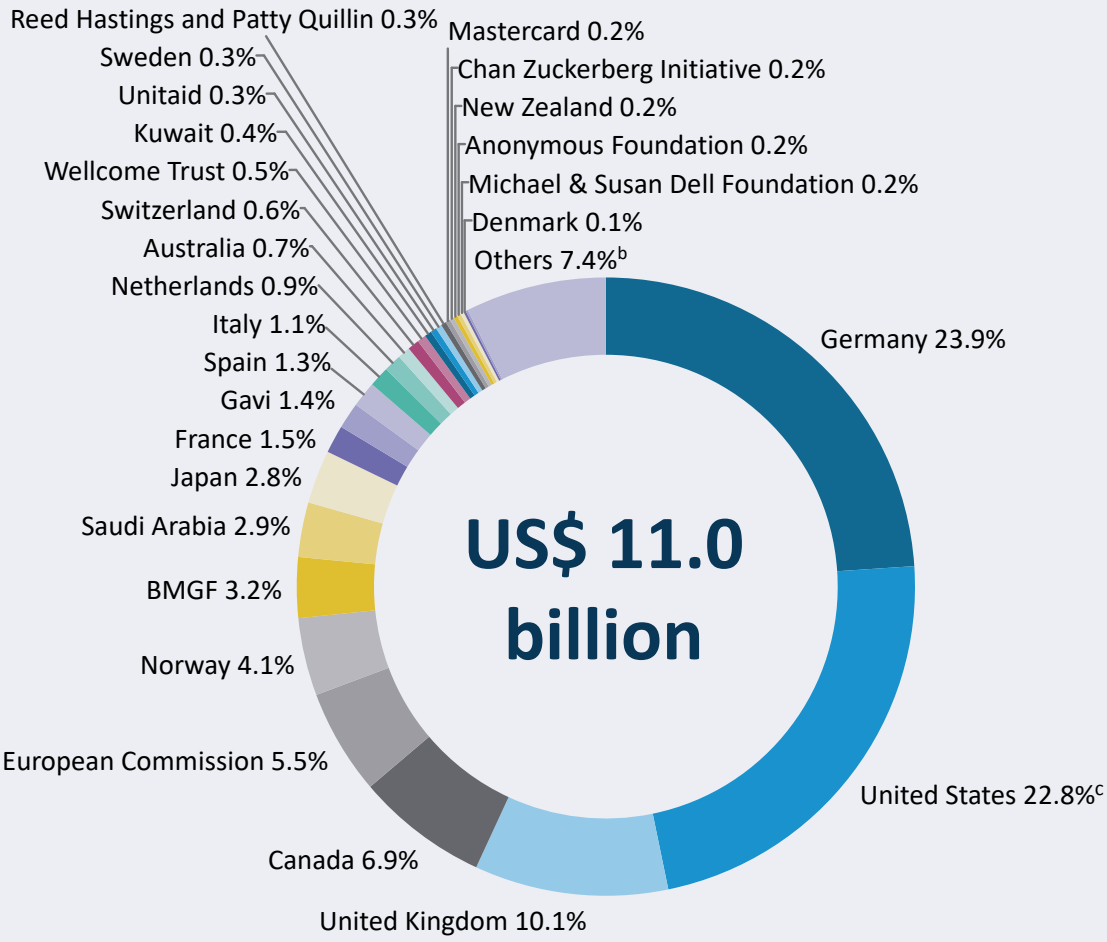
The crucial role of our financing partners

These achievements have been made possible through the generous support of donors. Thus far, US$ 11 billion has been committed to ACT-Accelerator from a broad coalition of public (87%), private (6%) and multilateral (7%) donors. In February, the United States of America announced US$ 2.5 billion, and will release an additional US$ 1.5 billion for vaccine procurement and delivery through 2021 and 2022. On 11 March, the US Government approved substantial additional contributions to the global response for health programmes to prevent, prepare for, and respond to COVID-19[1]. This funding is expected to begin to be operationalized in the coming months.

The detailed contributions supporting the work of ACT-Accelerator are made available online in the ACT-Accelerator Commitment Tracker, which is updated on a bi-weekly basis.[2] **Figure 1** provides an overview of the contributions received to date.

[1] This includes US$ 3.5 billion for the Global Fund.
[2] 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 11 March 2021).

Figure 1 – *ACT-Accelerator contributions in % of total commitments[a] – as of 11 March 2021*



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

[a] US$ 11 billion include US$ 470 million contributed by the Diagnostics Consortium to procure automated and manual molecular tests for LMICs.
[b] Contributions <US$ 12 million, and including US$ 470 million contributed by the Diagnostics Consortium to procure automated and manual molecular tests for LMICs.
[c] Does not reflect new financing announced by the US Government on 11 March 2021.

04

PRIORITIES IN 2021: ACT-Accelerator is driving for equity and scale in the delivery of essential tools while managing emerging virus risks

ACT-Accelerator's four Strategic Priorities for 2021:

1. **Rapidly scale up the delivery of at least 2 billion doses of vaccines**
2. **Bolster R&D, evaluations & regulatory pathways to optimize products and address variants**
3. **Stimulate rapid and effective uptake and use 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

IIn 2021, ACT-Accelerator and the global COVID-19 response have the opportunity to shift from being reactive to proactively controlling and ultimately overcoming the pandemic. ACT-Accelerator's critical path spans the whole value chain (see **Figure 2**) and aims to achieve four strategic priorities in 2021:

1. Rapidly scale up the delivery of at least 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 vaccines. This is critical for ensuring equity, achieving global health security, and getting our economies back on track. COVAX is making significant strides towards addressing vaccine inequities. COVAX enabled the first international vaccine deliveries in LMICs to take place within 12 weeks from introduction in the first few high-income countries (HICs), an unprecedented achievement despite the challenges presented. This is a significant improvement compared to the WHO H1N1 influenza vaccine deployment initiative, which delivered the first vaccine doses in Africa 145 days after the first countries started vaccinating[1].

[1] Report of the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative. Geneva: World Health Organization; 2012. (https://www.who.int/influenza_vaccines_plan/resources/h1n1_deployment_report.pdf, accessed 3 March 2021).

Further work will be needed, and COVAX aims to:

- Facilitate ending the acute phase of the pandemic by delivering vaccine doses to all of COVAX's 191 participating and eligible economies in 2021, targeting at least 20% of their population to protect those at highest risk, including health workers and older adults. 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 at least 2 billion doses of vaccines in 2021, including at least 1.3 billion doses for AMC economies. There is also a possibility of an additional 500 million doses in AMC economies, allowing countries to get closer to 30% population coverage. This would require an additional US$ 2.0 billion on top of the US$ 6.3 billion already contributed by donors. The self-financing countries will receive vaccines at competitive prices, while also benefiting from COVAX's R&D and marketing shaping activities.

- Continue to foster agreements with vaccine manufacturers and governments, through a joint negotiation process for COVAX countries, and by continuing to reduce process complexities for all stakeholders (e.g. indemnification and liability, compensation for adverse events, and procurement mechanisms).

- Facilitate rapid regulatory standards and processes for review of priority products while maintaining rigorous assessment (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.

- Enhance country readiness for the deployment of vaccines by providing support on norms, guidance and policies, supporting capacity 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.

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

The emergence of new virus variants requires that both ACT-Accelerator and the world prepare for a scenario where some existing or pipeline tools (e.g. mAbs) may no longer be fully adequate. As a result, tools may need to be modified or new ones may need to 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 through product optimization. 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 programmatic use and efficacy against new variants and will:

- Support the accelerated development of vaccines, and evidence on their implementation, that offer clear programmatic benefits (e.g. single dose vaccines, more thermostable options, optimum dosing and intervals).

- Continue to financially and technically support vaccine development in the wake of new variants, with a US$ 1 billion investment to adapt existing vaccines, support multiple vaccine candidates through late-stage clinical trials and scale-up manufacturing, build an approach that protects against a broader range of variants, and support development of a universal coronavirus vaccine.

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

- Enhance the global genomic surveillance system to monitor for the emergence, evolution and spread of virus variants in close coordination with global, regional, and country partners and linked to efforts to strengthen monitoring of respiratory pathogens. Strengthening global monitoring of the emergence, evolution and spread of new virus variants will support planning and decision-making to target effective responses to mitigate the threat from emerging COVID virus variants and other respiratory pathogens.

- 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 new variants or in regions with suboptimal roll out.

- Promote increased immunisation coverage rates to reduce the opportunities for variants of concern to emerge.

3. Stimulate rapid and effective uptake and use of COVID-19 tests, treatments, and PPE in LMICs

New innovations in technologies have not been fully translated into appropriate uptake. Availability of financing has been a significant limiting factor. Other factors include clarity around use cases and limited countries' readiness to implement 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, 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 the development of integrated country plans and enhance country readiness across the full spectrum of activities needed for the successful introduction of new tools including, where needed, regulatory authorizations and indemnification. This may also include targeted technical assistance and provision of readiness tools for vaccines, procurement, and training to ensure optimal and successful uptake of the most appropriate and effective COVID-19 tools for each country. Findings of the country readiness assessments are feeding into various partners' existing country projects and platforms, such as the World Bank's Multiphase Programmatic Approach (MPA).

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

ACT-Accelerator aims to:

- Raise the initial target of supplying 500 million diagnostic tests in 2021 by 400 million tests, leading to a total of 900 million tests over a period of 12 months (in addition to tests provided through domestic planning and procurement). The aim is to expand equitable access to quality lower-cost molecular tests, Ag-RDTs, self tests and sequencing solutions, reducing the gap in testing rates between LMICs and HICs by one third. Molecular tests and Ag-RDTs will remain instrumental to address clinical needs and identify and contain hotspots, while genomic sequencing solutions are critical to monitor and rapidly detect novel variants across regions.

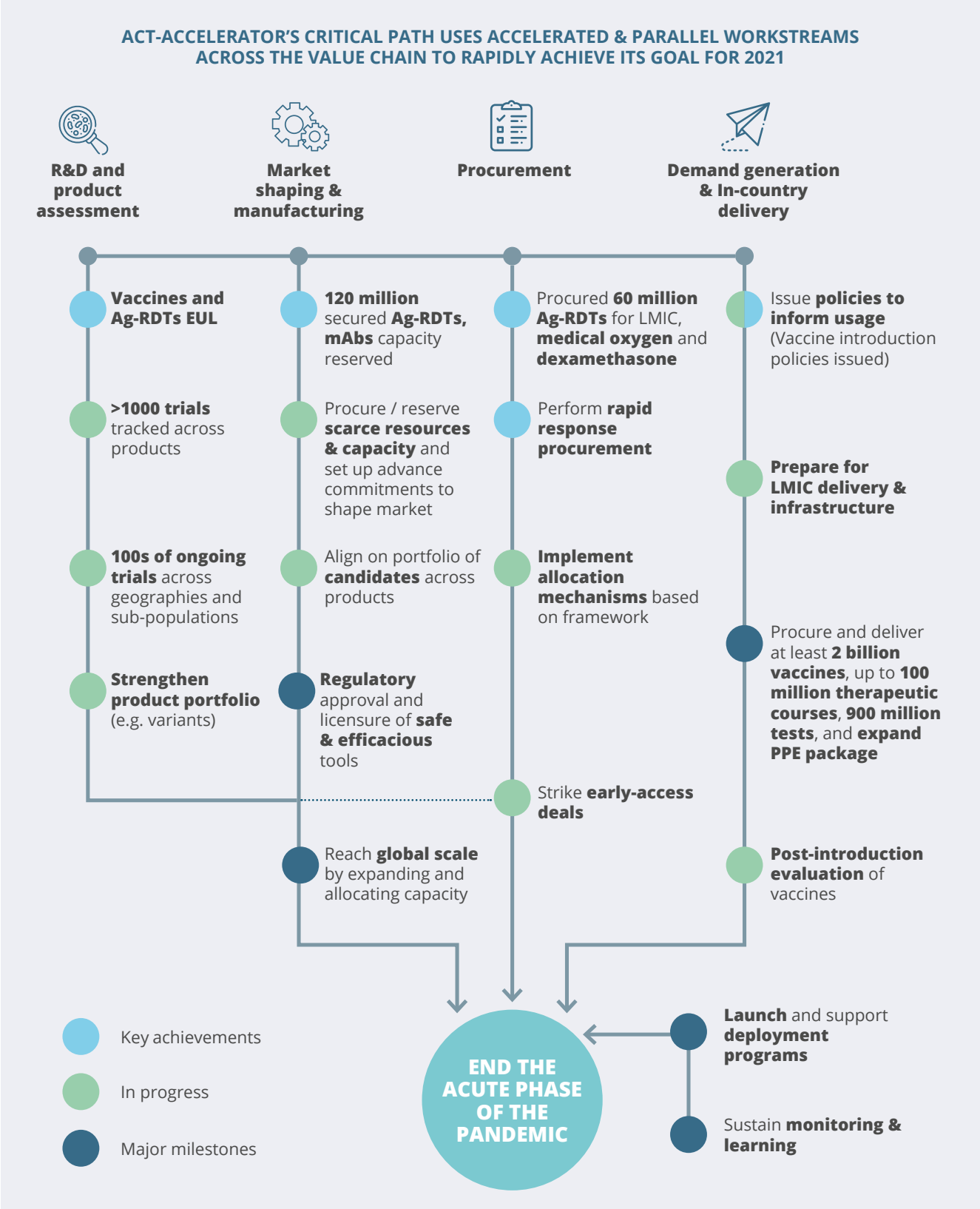
- Ensure access to quality clinical management, including medical oxygen, corticosteroids such as dexamethasone, and other therapeutics if proven efficacious (i.e. prophylactic, treatment for early and mild cases, and treatment for severe and critical cases). The target is to promote successful uptake of medical oxygen and corticosteroids for up to 12 million severe and critical patients and introduce new COVID-19 therapies for up to 100 million treatment courses across all use cases.

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

- Fully integrate the work of ACT-Accelerator and the WHO Strategic Preparedness and Response Plan (SPRP)[1], to facilitate seamless end-to-end solutions for the delivery of tests, treatments (particularly medical oxygen) and PPE at scale, including through the use of systems such as the United Nations COVID-19 Supply Chain System.

[1] COVID-19 Strategic Preparedness and Response Plan. Operational planning guideline. 1 February 2021 to 31 January 2022. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/covid-19-strategic-preparedness-and-response-plan-(sprp-2021), accessed 3 March 2021).

Figure 2 - *ACT-Accelerator's critical path across the value chain 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. In this situation, COVAX plays a key role in securing access to safe and effective vaccines and closing the vaccination divide between the wealthiest countries and the rest of the world.

While there is a growing number of vaccines that have received approval from SRAs and WHO EUL, demand continues to exceed supply and competition for doses is intense. Additionally, virus variants of concern are emerging, calling for ACT-Accelerator and the world to prepare for a scenario where some developed vaccines may no longer provide adequate protection against new virus strains. COVAX needs to be forward-looking, securing doses early and adapting its portfolio.

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

The key priorities for COVAX for 2021 are:

1. Ensure timely delivery of at least 2 billion doses of COVID-19 vaccines through the COVAX Facility in 2021, of which at least 1.3 billion will be for AMC countries, to cover initial high-risk target groups:

    - provide norms, guidance, policies and tools for all countries worldwide, including policies for optimum vaccine use, and an approach towards readiness assessment and national planning using the VIRAT/VRAF2.0[1], and National Deployment Vaccination Plans (NDVPs[2]), supply chain and logistics, demand and community engagement, data monitoring and vaccine-specific trainings and tools;

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

    - provide catalytic support for in-country delivery, alongside domestic funding and support from development banks and other partners; and

    - support capacity building (e.g. cold chain, training, planning, pharmacovigilance).

[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).

2. Support countries' needs and ambitions to end the pandemic through, for example, expanded coverage, optimized products and schedules, increased manufacturing capacity, and procurement of at least 500 million additional vaccine doses in 2021:

    - establish an updated COVAX strategy based on the latest available insights, supply forecasts, and epidemiological scenarios;
    - confirm COVAX's aspirations to help countries access the vaccines they need to end the pandemic (likely including expanded vaccine coverage and roll-out of boosters as needed);
    - explore whether and how COVAX can help address the challenges regarding manufacturing scale up, technology transfers and input supply security; and
    - materialize the initial additional commitment to procure and plan for the use of an additional 500 million doses for AMC countries in 2021.

3. Ensure equitable access and fair allocation of COVID-19 vaccines:

    - reduce the complexity of vaccine access and delivery, through a joint negotiation process for COVAX countries, and by reducing process complexities for all stakeholders. These process complexities include regulatory processes, indemnification and liability, compensation for adverse events, labelling and procurement mechanisms;
    - raise and provide funds to cover procurement of vaccines for AMC countries and implement a fair allocation mechanism[1] to enable equitable access, both in terms of quantities and timely access;
    - organise the equitable and efficient distribution of shared doses in line with the dose-sharing principles.

4. Accelerate and expand the COVAX R&D agenda for programmatically-optimized vaccines that also address new and emerging risks due to SARS-CoV-2 variants:

    - invest 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 virus variants, as well as have better fit-for-purpose operational profiles, e.g. single dose, more thermostable, easier administration. Additionally, initiate development of vaccines protecting against multiple coronaviruses;
    - coordinate trials (e.g. Solidarity trials) to advance the knowledge base on the efficacy and safety of different vaccine candidates used in different combinations;
    - develop a smart vaccination (digital) certificate and other digital solutions to support vaccine roll-out on microplanning, track and trace vaccines, vaccine monitoring and safety monitoring; and
    - perform post-introduction evaluation of vaccines.

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[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 on 18 January 2021).

All participating economies are expected to have access to doses in the first half of 2021, with the first COVAX deliveries having started in February 2021, contingent upon regulatory approvals and each country's readiness for delivery. This will allow all COVAX's 191 participating and eligible economies to access doses to protect vulnerable groups in the first half of 2021, targeting at least 20% population coverage by the end of the year.

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 robust regulatory process. It is critical for populations to have confidence in vaccines against COVID-19 as well as other infectious diseases.

Diagnostics

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

Diagnostic testing is essential to address clinical needs and manage outbreaks to bring the COVID-19 pandemic under control. 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, isolate, trace and treat' strategies in some countries, particularly in lower-resourced settings. Testing is also critical for managing outbreaks through 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 and increased testing is essential for early detection and containment of such variants.

A portfolio of well-performing regulatory-approved diagnostic tests already exists on the market. However, significant funding is urgently needed to meet the increasing demand from countries, particularly for LMICs that cannot afford these tests. Additionally, ACT-Accelerator aims to further drive down the price of diagnostic tests while ensuring continued availability of effective diagnostics despite the emergence of variants.

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 LMICs to put in place effective 'test, isolate, and trace' 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 prepare for scale-up.

The key priorities for the Diagnostics Pillar for 2021 are:

1. Ensure equitable access to new and existing tests, including the procurement and distribution of at least 900 million molecular and Ag-RDTs

   Diagnostic testing in LMICs[1] is occurring at <15% of the rate in HICs[2]. To reduce this gap, ACT-Accelerator aims to procure 900 million tests (including molecular tests and Ag-RDTs), instrumental for effective 'test, isolate, trace, and treat' measures, and expand

[1] Excluding China.
[2] Rolling 7-day averages per 100,000 population. Source: FIND test tracker (as of 10 March 2021).

sequencing capabilities to support a global system for genomic surveillance linked to epidemiological and clinical data to improve early detection and monitoring of variants of concern.

2. Stimulate rapid and effective uptake of appropriate and quality-assured diagnostics 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. by repurposing existing testing infrastructure and scaling up country laboratory networks). This would be complemented by an effort to build capabilities and support countries with testing roll-out (e.g. training laboratory technicians and healthcare workers, creating technical assistance networks to help countries understand how tests differ and how to best deploy them, exploring 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 LMICs[1] may contract COVID-19 in 2021, 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 to 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 the successful uptake of existing effective products, including medical oxygen and corticosteroids (e.g. dexamethasone), the introduction of new COVID-19 therapies once benefit is established, and the acceleration and intensification of research efforts to expand the therapeutic clinical pipeline.

Emerging 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

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

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, especially with corticosteroids and medical oxygen.

The key priorities for the Therapeutics Pillar for 2021 are:

1. Ensure the successful uptake of existing products, including medical oxygen and corticosteroids (e.g. dexamethasone), for up to 12 million severe and critical patients:
    - provide visibility on country demand and mobilize resources to support adequate and timely supply of therapeutics;
    - bridge gaps in use of existing products (i.e. dexamethasone and oxygen) and apply key learnings to roll-out efforts for future therapeutics; and
    - support dissemination of clear policy and regulatory guidance to accelerate the availability of safe and efficacious products.
2. Introduce new COVID-19 therapies for up to 100 million treatment courses across all use cases, subject to evidence supporting the use case and product availability:
    - support market interventions such as voluntary licensing, technology transfers, regulatory and policy processes, as relevant;
    - initiate operational research to support optimized clinical care, including oxygen and 'test-treat-isolate' approaches, jointly with the Diagnostics Pillar; and
    - support procurement and country allocation for at-scale deployment of proven products as available, utilizing tools such as advanced purchase agreements to secure supply. Maintaining flexibility on procurement budgets across asset classes will be important to anticipate changes in clinical development.
3. Accelerate and intensify research efforts to expand the therapeutics clinical pipeline, broadening the portfolio of effective tools, including combinations of therapeutics:
    - support existing candidates in ongoing phase 2/3 trials;
    - optimize promising products for use in low-resource settings;
    - proactively accelerate introduction of repurposed therapeutics, including antivirals, with meta-analyses of promising therapies and targeted support on evidence generation in existing platform trials (e.g. ANTICOV); and
    - 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.

Health Systems Connector

Health systems enable the uptake and delivery of COVID-19 tools in countries while providing lasting benefits.

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 aspects 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 tests, treatments and vaccines; 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 LMICs to protect frontline health care workers and to enhance the ability of health systems to save lives.

The primary role of HSC is not to provide a direct source of financing for health systems strengthening beyond the procurement and deployment of PPE and catalytic investment for effective roll out of COVID-19 tools. The role of HSC is rather to identify critical needs and serve as a common link with existing technical and financial country partners and platforms, such as multilateral agencies, bilateral donors, multilateral development banks including the World Bank's MPA, UHC2030, etc. The adequate resourcing of these health system enablers – from domestic and external sources – is critical and will require significant additional investments that are complementary to, but currently outside the scope of ACT-Accelerator (see also **Section 08**). The wide impacts of the COVID-19 pandemic, including on access to essential services, call for these complementary efforts to dramatically scale up investment in health systems as well as to rethink service delivery to respond to the pandemic and ensure continuity of health services, while preparing countries to roll out the new COVID-19 tests, treatments and vaccines as part of an essential health package.

For 2021, HSC will support the integrated delivery of COVID-19 tools, rapidly identifying and addressing health systems bottlenecks where and when most needed, while managing linkages and synergies with complementary activities for the delivery of essential health services and strengthening of health systems.

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

Individual countries face individual issues. HSC responds to country needs, taking a country-context approach of translating global knowledge for local problems.

The key priorities for HSC for 2021 are:

1. Fully integrate the work and products of the Pillars with a strengthened, ongoing COVID-19 response:

    - strengthen core components of the response including overall coordination, operational support and logistics, integrated data management and clinical care; and

    - strengthen linkages with key elements of the WHO SPRP, particularly surveillance, public health and social measures (PHSM), risk communications and community engagement, laboratories and diagnostics, case management and infection, prevention and control (IPC).

2. Rapidly identify and address country-specific health systems bottlenecks to ensure readiness and enable rapid scale up and delivery of COVID-19 tools:

    - address areas of health work force, health financing, private sector engagement and supply chain strengthening;

    - identify health systems bottlenecks and weaknesses through country assessments and monitoring tools (e.g. assessments of health facilities, essential services, community demand, health capacity and frontline readiness) to inform country plans;

    - address bottlenecks by providing guidance, tools, technical and catalytic support tailored to specific country contexts. This includes support related to equitable community systems and responses, training materials, coaching, costing mechanisms, dashboards, and policy documents. HSC also facilitates rapid sharing of knowledge and best practices through knowledge platforms.

3. Accelerate availability and use of PPE as a crucial tool for protecting health workers and ensuring the resilience of the health system:

    - procure and enhance access to PPE for health care workers to protect those on the frontline, focusing on quality control and standards, security of supply and access, improvement to supply chain monitoring and traceability, environmental impact and disposal, and local production and procurement; and

    - address issues related to product innovation, IPC training, safety standards and rational use for health workers, and private sector engagement.

4. Manage linkages and synergies with complementary activities for the delivery of essential health services and strengthening of health systems:

    - ensure coordination of the work of HSC with the ongoing efforts by countries, global organizations, donors, civil society organizations and affected communities to build sustainable and resilient integrated people-centered health systems to support a comprehensive response to COVID-19 and address the secondary health crisis arising from focus on the pandemic at the expense of other regular health services;

    - coordinate with the broader complementary health systems work, including the UHC2030 and the UHC partnership; and

    - support countries in delivering COVID-19 tools by increasing capacity of existing health systems and preventing the disruption, draining or redirecting of limited resources to the pandemic response. Achieving this goal will enable countries to benefit from longstanding and sustainable strengthened systems and new technical abilities, supporting not only an improved epidemic response now and in the future, but also improved capacity to manage health systems as a whole.

05

MAXIMIZING IMPACT: Sequencing ACT-Accelerator's interventions in 2021

In striving to end the acute phase of the COVID-19 pandemic, ACT-Accelerator continuously evaluates and reprioritizes areas promising the highest impact. When ACT-Accelerator was launched in April 2020, there were insufficient tools to facilitate ending the acute phase of the pandemic. Consequently, ACT-Accelerator was initially set up to accelerate the development of COVID-19 tools, running four key workstreams across the value chain in parallel: R&D and product assessment; market shaping and manufacturing; procurement; and demand generation and in-country delivery (see **Figure 2**). However, under resource constraints, ACT-Accelerator has been and will continue to sequence its interventions to achieve maximal impact.

In the first year after the launch of ACT-Accelerator, the focus was on developing and evaluating a sound product portfolio by investing most substantially in R&D and product assessment, and market shaping (e.g. AMC countries), while laying the groundwork for large-scale procurement and delivery by securing volumes, establishing policies for usage, and supporting countries in their preparations for roll-out and delivery. Now that an initial set of effective and affordable tools has been established, investment is increasingly focused on optimizing the public health impact of these tools. In 2021, ACT-Accelerator aims to fully leverage existing tools and volumes, then expand manufacturing, and continue to invest in further R&D and optimization (**Figure 3**).

The detailed activities for each of the areas can be found under the Pillar-specific priorities (see **Section 04**), and include the following for 2021:

1. **Fully leverage existing tools**

   As COVID-19 tools are being rolled out, ACT-Accelerator aims to optimize full use of these existing tools by focusing on procurement and delivery. This encompasses: fast-tracking the roll-out of vaccines; accelerating the scale-up of Ag-RDTs, molecular tests and sequencing; boosting access to and scaling up of corticosteroids and medical oxygen; and scaling up PPE.

   In order to deliver on these objectives, basic health systems will need to be in place. The cross-cutting HSC will play a critical role in supporting countries to identify and address bottlenecks for uptake.

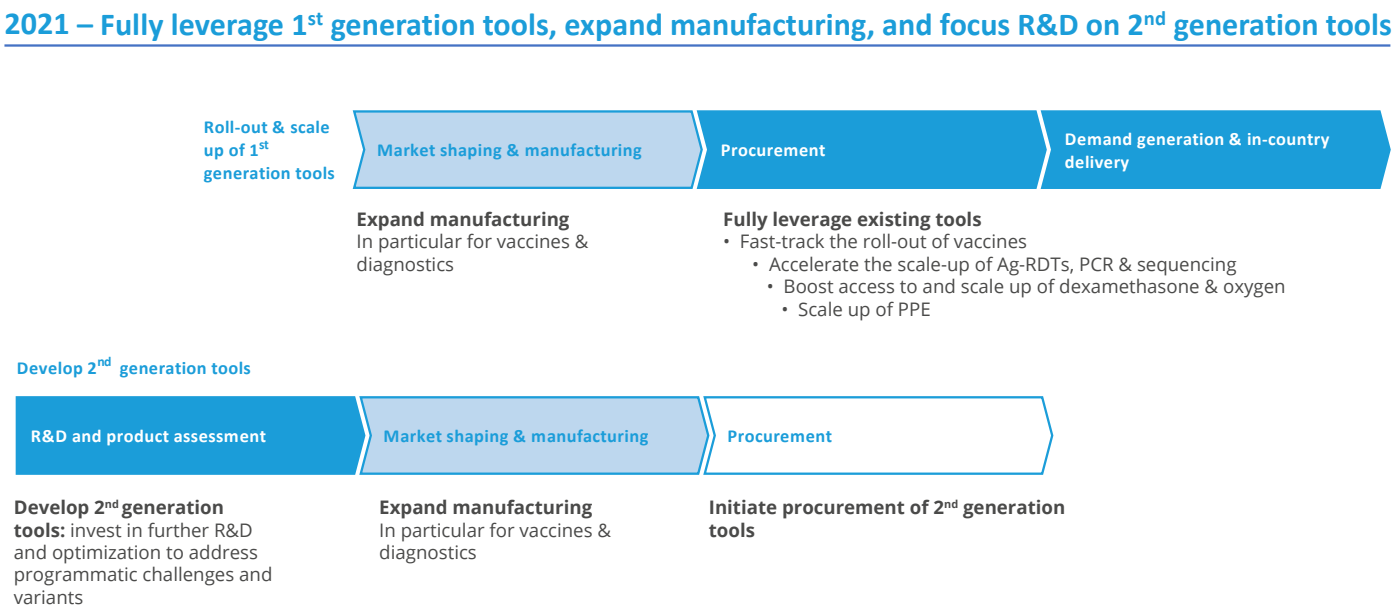
2. **Expand manufacturing**

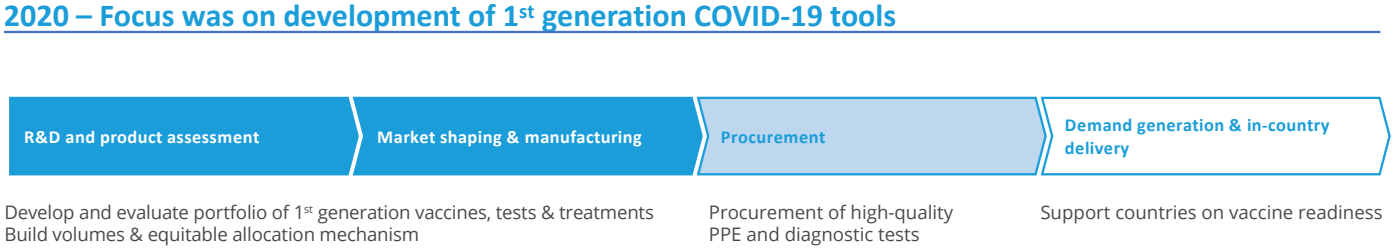
   Scaling up production, in particular for vaccines and diagnostics, is one of the key bottlenecks to address. By improving regionalized manufacturing and technology transfers, and reducing complexities (e.g. harmonized regulatory standards, indemnification and liability, compensation for adverse events, labelling and procurement mechanisms), ACT-Accelerator aims to expand manufacturing for increased coverage of tests, treatments and vaccines.

3. **Invest in further R&D to optimize products**

   With the emergence of new virus variants, existing or pipeline tools (e.g. mAbs) may no longer be fully adequate. Therefore, further R&D to modify or develop new tools will remain of high importance. Additionally, optimization to establish programmatic advantages (e.g. vaccines without need for ultra-cold chain, single dose vaccines) could facilitate and enhance the delivery of COVID-19 tools.

Figure 3 – *Sequencing of ACT-Accelerator interventions in 2021 to maximize public health impact*





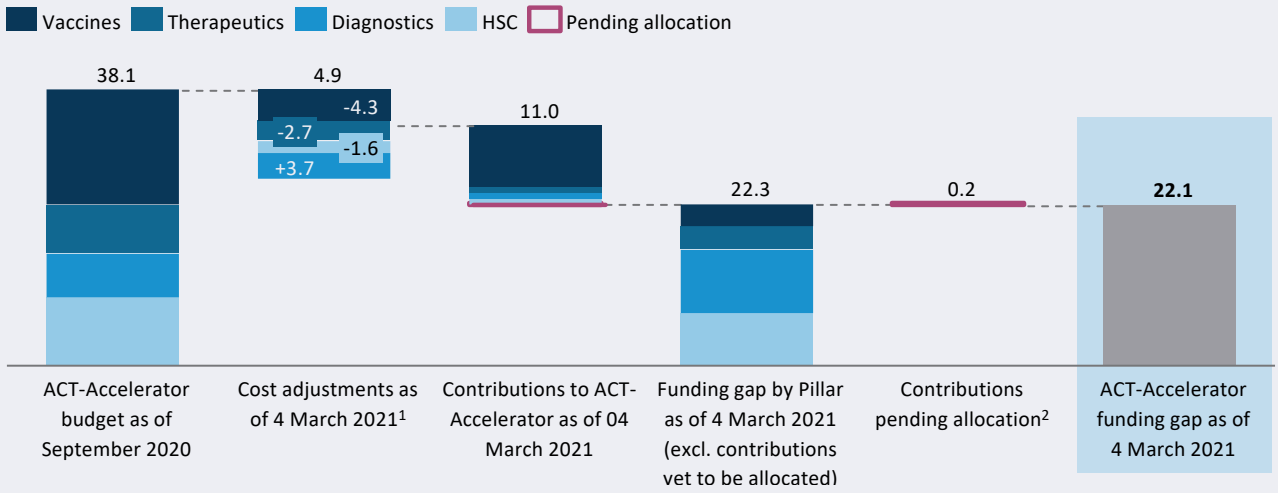
06

FUNDING GAP: Delivering on ACT-Accelerator's promise requires an additional US$ 22.1 billion in 2021

ACT-Accelerator funding gap across Pillars

The initial ACT-Accelerator investment case that was published in September 2020 outlined a total requirement of US$ 38.1 billion to fully fund ACT-Accelerator to deliver on its promise. Reflecting on the refreshed strategic priorities outlined in previous sections and taking into account generous contributions made so far, ACT-Accelerator Pillars have recalculated their funding gaps for 2021. US$ 22.1 billion is required by the end of 2021 for ACT-Accelerator to deliver on its full promise. **Figure 4** shows the evolution of ACT-Accelerator budget and gaps from September 2020 through March 2021. A detailed walkthrough is provided in **Appendix C**.

Figure 4 – *ACT-Accelerator budget and funding gap: bridge between September 2020 budget and March 2021 funding gap - in US$ billion (See **Appendix C** for details)*



[1] Of which US$ 1,650 million of need for oxygen activities moved from the Health Systems Connector to the Therapeutics Pillar.
[2] Includes US$ 199 million from Canada pending allocation to ACT-Accelerator agencies and Pillars.

The funding gaps for 2021 can be broken down by Pillar, as shown in **Table 2**, and by strategic priority, as shown in **Table 3**.

Table 2 provides an overview of the funding gap by Pillar, broken down by semester in 2021. An additional contribution of US$ 0.2 billion is yet to be allocated by donors and further decreases the overall ACT-Accelerator funding gap.

Table 2 – *ACT-Accelerator funding gap for 2021, by Pillar, as of March 2021 – in US$ billion*

Pillar	Q1/Q2 2021	Q3/Q4 2021	Total 2021
Diagnostics	$ 1.7 B	$ 7.0 B	**$ 8.7 B**
Therapeutics	$ 1.4 B	$ 1.8 B	**$ 3.2 B**
Vaccines	$ 3.2 B		**$ 3.2 B**
Health Systems Connector	$ 3.4 B	$ 3.9 B	**$ 7.3 B**
Contributions yet to be allocated to Pillars	*- $ 0.2 B*		***- $ 0.2 B***
TOTAL	**$ 9.2 B**	**$ 13.0 B**	**$ 22.1 B**

In the case of Vaccines, most of the funding gap will need to be frontloaded in 2021 to secure doses, although there is US$ 0.2 billion funding gap in Q3/Q4 for R&D.

ACT-Accelerator funding gap across strategic priorities

Table 3 provides a view of the 2021 financing gap by each of the strategic priorities outlined above, in 'Key strategic priorities for ACT-Accelerator in 2021' of **Section 04** of this document.

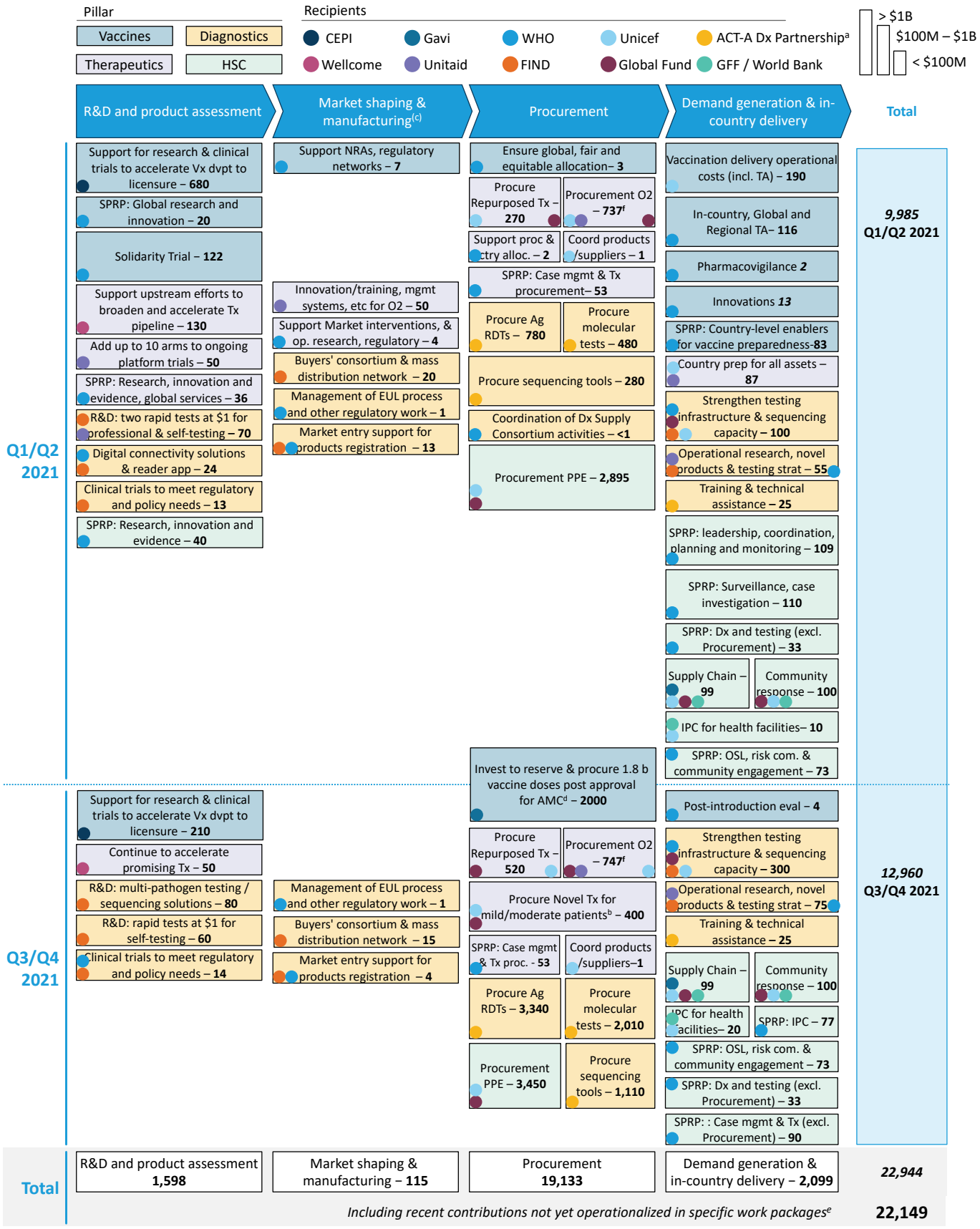
Table 3 – *ACT-Accelerator funding gap by strategic priority, as of March 2021 – in US$ billion*

Strategic priorities	Q1/Q2 2021	Q3/Q4 2021	Total 2021
1. Rapidly scale up the delivery of at least 2 billion doses of vaccines through COVAX to the most high risk and highly exposed populations globally	$ 2.4 B		**$ 2.4 B**
2. Bolster the R&D agenda, product evaluation, and regulatory pathways for new and modified tests, treatments, and vaccines to respond to emerging variants and programmatic needs	$ 1.2 B	$ 0.4 B	**$ 1.6 B**
3. Stimulate rapid and effective uptake and use of COVID-19 tests, treatments and PPE in LMICs	$ 0.9 B	$ 5.3 B	**$ 6.2 B**
4. Ensure a robust supply pipeline of essential tests, treatments, and PPE to support broader access in LMICs and protect vital health infrastructure	$ 5.5 B	$ 7.2 B	**$ 12.7 B**
Contributions not yet operationalized into specific work activities	*- $ 0.8 B*		*- $ 0.8 B*
TOTAL	**$ 9.2 B**	**$ 13.0 B**	**$ 22.1 B**

The ACT-Accelerator funding gap is detailed in **Figure 5**, which provides a consolidated view across deliverable packages, time (Q1/Q2 2021 and Q3/Q4 2021), Pillars, and recipient agencies, with the associated funding gap for each. Packages for the same Pillar are represented with the same color. The height of the box is an indication of 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 08**, the ACT-Accelerator work packages on *Procurement* and *Demand generation & in-country delivery* are catalytic investments as they do not cover the total cost of the COVID-19 response implementation.

Figure 5 – *ACT-Accelerator funding gap by period and deliverable packages – in US$ million*



[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 actdiagnostics@who.int. Funding gap for Procurement of Ag RDTs, molecular tests and sequencing tools include US$ 184 million as budgeted in the WHO Strategic Preparedness and Response Plan. [b] Canada has pledged a contribution of Can$ 230 million to procure COVID-19 treatments for developing countries (recipient: UNICEF). To be evaluated in light of evolving clinical information. [c] Market-shaping activities may leverage funding embedded in country preparedness or procurement line items for Therapeutics (e.g. for advanced purchase arrangements or other price-volume agreements, reserved volumes for operational research and/or early adopter countries). [d] Those funds, while needed across 2021, need to be frontloaded to allow for rapid reservation of doses. [e] US$ 795 million yet to be operationalized: includes EUR 250 million from Germany to WHO, EUR 140 million from Germany to the Global Fund, EUR 50m from Germany to FIND, US$ 60 million from Canada to Gavi, and US$ 199 million from Canada yet to be allocated. [f] Funding requirements for medical oxygen are subject to review as the scope of the COVID-19 Oxygen Emergency Taskforce is developed, and a better understanding of country-specific needs is available.

07

FINANCING ACT-ACCELERATOR

Financing Framework

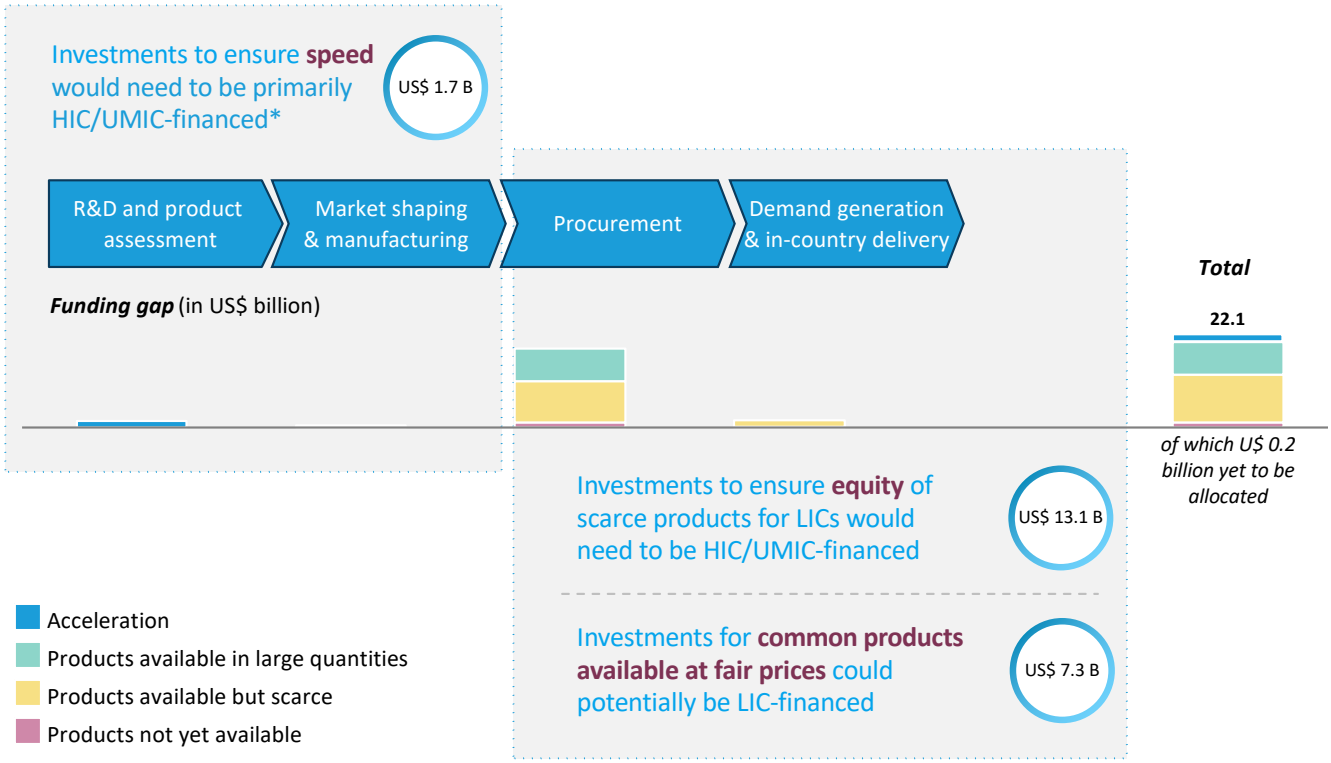
The Facilitation Council's Financial Working Group was formed after the first Facilitation Council meeting in September 2020. It is chaired by Norway, and includes representatives from South Africa, Germany, the United Kingdom, the European Commission, Italy, Canada, Mexico, Indonesia, and was recently joined by representatives from the United States of America and France. The Financial Working Group has been leading discussions with Treasuries of Facilitation Council members, and collected feedback from G7 and multilateral partners as well as internationally recognized economists. These discussions have led to the development of the Financial Framework, which assesses potential financial sources and financing mechanisms, as well as the development of a fair burden-sharing model.

Different funding sources to close the ACT-Accelerator funding gap were evaluated: sovereign contributors, private sector, and Multilateral Development Banks. For each avenue, the Facilitation Council estimated the potential contributions and evaluated a landscape of financing mechanisms to disburse funds, going beyond traditional Official Development Assistance (ODA). The resulting Financing Framework clearly demonstrates that fully funding ACT-Accelerator would require sovereign contributors to go beyond existing ODA, and to significantly invest in ACT-Accelerator through direct grants.

To ensure that all potential financial donors to ACT-Accelerator contribute their fair share to these collective efforts, the Facilitation Council's Financial Working Group proposed a burden-sharing model. It is built on a 5-step approach to determine a rational range of contribution by country, modelled after the IMF quota formula, adjusted for GDP/capita and finalized with qualitative analysis. This approach paves the way for a 'fair contribution' by country, and will serve as a basis for bilateral discussions led by the Facilitation Council co-chairs, Norway and South Africa, on behalf of the Facilitation Council, with each sovereign contributor to determine their 'fair contribution' to fully fund ACT-Accelerator.

The Financial Framework distributes ACT-Accelerator funding needs across the value chain of COVID-19 tools: R&D and product assessment, Market shaping & manufacturing, Procurement, and Demand generation & in-country delivery. It also distinguishes funds: (i) that aim for acceleration and speed of product development, (ii) that aim for equitable access to scarce products that are yet to be rolled out, and (iii) that aim for making available products accessible to those who cannot afford (see **Figure 6**).

Figure 6 – *Breakdown of ACT-Accelerator 2021 funding gap across the value chain, and by type of cost*



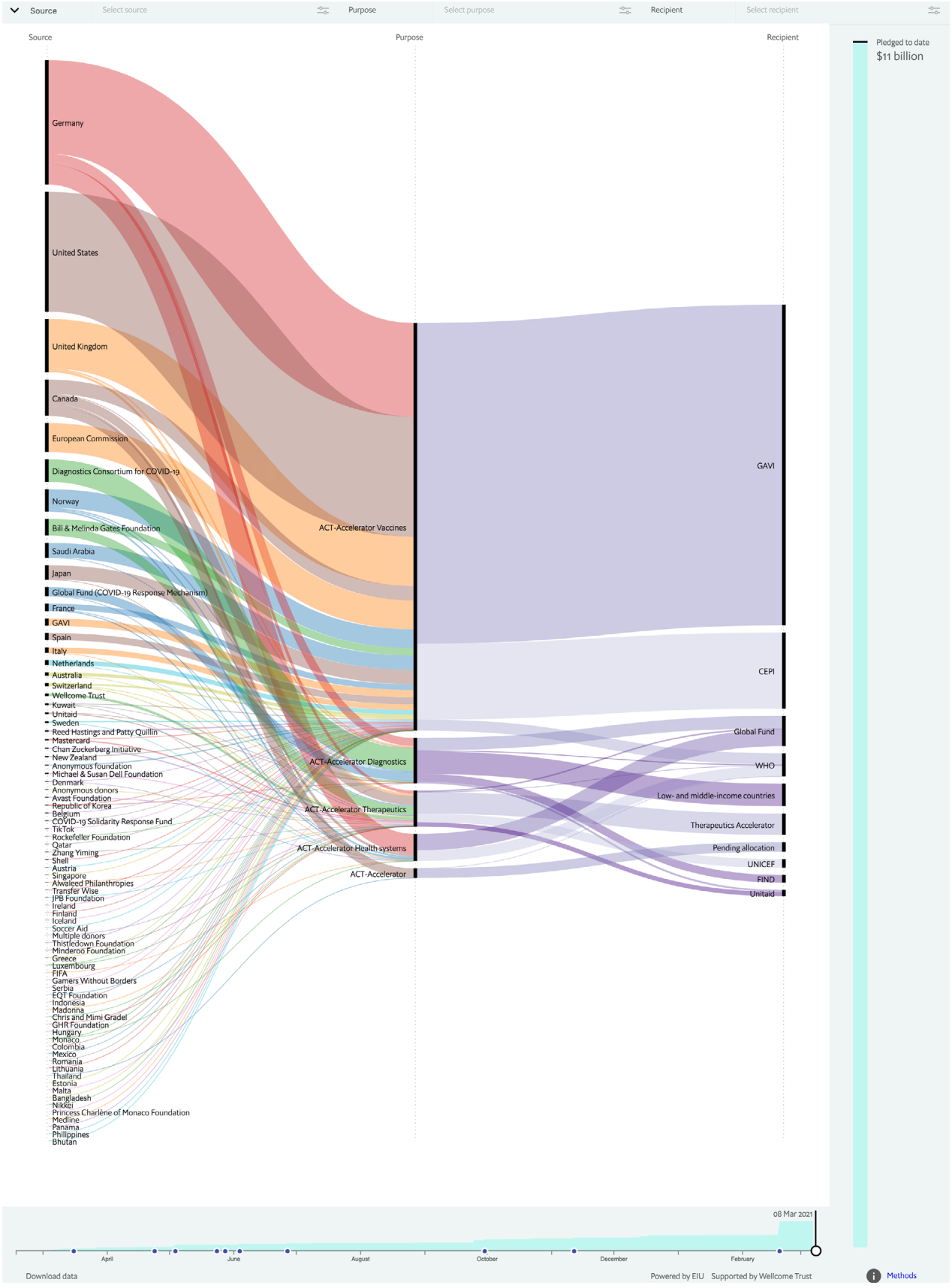
* these activities generate global public goods, primarily through multilateral and private sector investments

Accountability

Ending the pandemic requires a strong and coordinated response from institutions across and beyond the public health sphere. ACT-Accelerator is not a new legal organization or decision-making entity. Formal governance of the work of each agency within each Pillar (including transparency of administration and accountability of resources raised and used) is provided by the existing systems, frameworks, Boards and governing bodies of each of the co-convening and lead organizations. The co-conveners of each Pillar are fully accountable for the development and oversight of the workplans and investment case for that area of work. Grant management and financial reporting to donors is managed by the receiving entity.

The ACT-Accelerator Commitment Tracker provides transparent reporting of funding commitments made against ACT-Accelerator Pillar budgets. The interactive funding tracker visualizes commitments made against the ACT-Accelerator Pillars, showing both the source and the recipient organization for each pledge (see **Figure 7**).

Figure 7 – *The ACT-Accelerator Commitment Tracker provides reporting on funding commitments made against Pillar budgets (accessed in March 2021)*



08

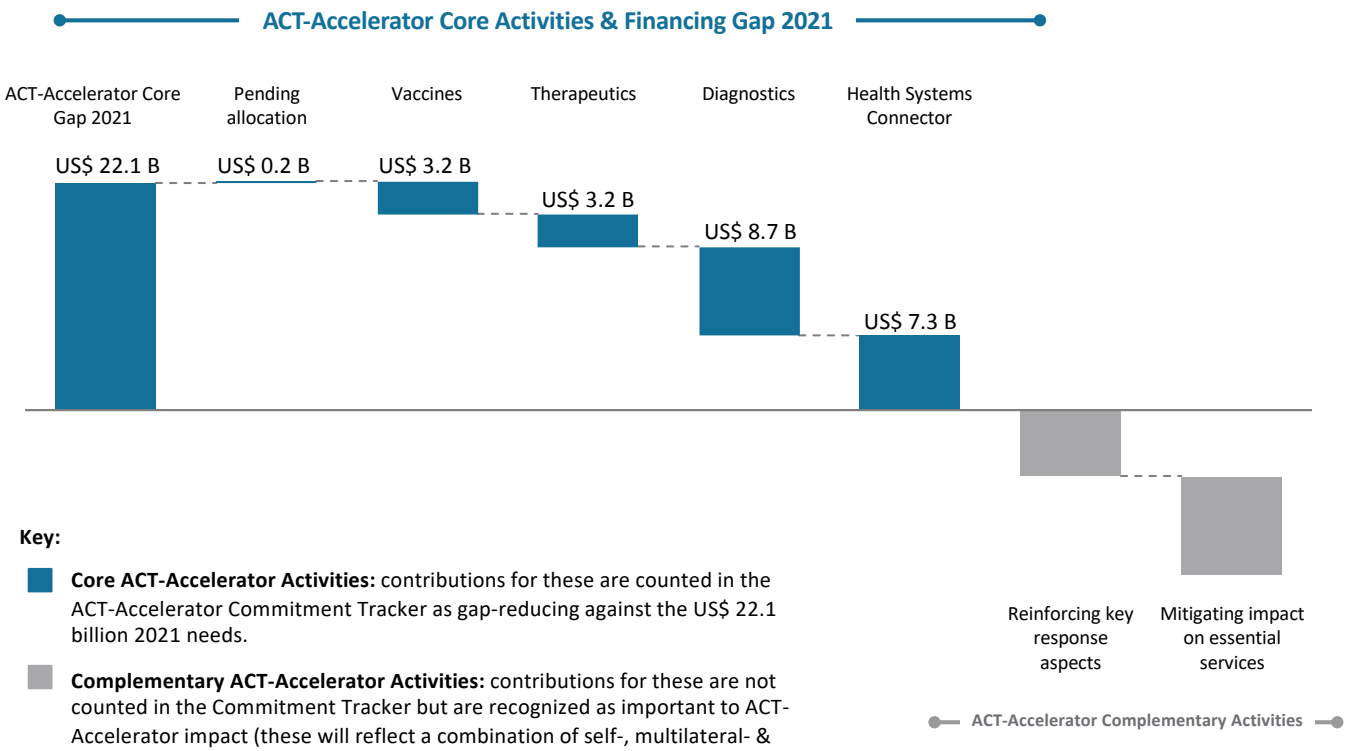
COMPLEMENTARY ACTIVITIES AND INVESTMENTS: Complementary investment in the COVID-19 response and health systems will ensure the full impact of ACT-Accelerator is delivered

Alongside ACT-Accelerator's ambition of accelerating the development of and equitable access to COVID-19 tools, ACT-Accelerator aims to complement the broader COVID-19 response and drive sustainable and long-term improvements to national health systems. For instance, ACT-Accelerator accelerates the availability of essential COVID-19 tools and makes sure they are scaled everywhere as rapidly as possible. The broader COVID-19 response is outlined in WHO's COVID-19 SPRP that sets out the strategic objectives to guide the public health response, at national and subnational levels, and helps achieve them. Part of ACT-Accelerator is integrated within SPRP. Initiatives supporting universal health coverage, such as UHC2030 and the UHC Partnership, aim to ensure affordable access to essential health services through the strengthening of health systems, including improving the health workforce in-country infrastructure – all of which will help mitigate the impact of COVID-19 on other public health issues.

Therefore, while the 2021 financial needs of ACT-Accelerator are substantial, they represent only a subset of the overall funding required to comprehensively and equitably respond to the magnitude of the COVID-19 crisis, as shown in **Figure 8**.

For example, substantial additional investments are needed to achieve the vaccination coverage rates of 60-80% that most 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 LMICs would need to be significantly higher to approximate those of HICs and to come in line with levels that are increasingly considered best practice. More generally, deploying ACT-Accelerator tools at national level will require significant investments in the workforce that are beyond the scope of ACT-Accelerator. Though these adjacent costs are beyond the scope of ACT-Accelerator, they support ACT-Accelerator activities, without duplicating efforts, and are necessary for ACT-Accelerator to reach its full impact. Therefore, funds allocated to these activities will be considered as complementary to ACT-Accelerator.

Figure 8 – *Articulation between ACT-Accelerator core activities and complementary investments*



Key:

- **Core ACT-Accelerator Activities:** contributions for these are counted in the ACT-Accelerator Commitment Tracker as gap-reducing against the US$ 22.1 billion 2021 needs.
- **Complementary ACT-Accelerator Activities:** contributions for these are not counted in the Commitment Tracker but are recognized as important to ACT-Accelerator impact (these will reflect a combination of self-, multilateral- & MDB-financing)

09

ECONOMIC CASE FOR INVESTING IN ACT-ACCELERATOR: 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), have 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 HICs, inequitable access to COVID-19 tools elsewhere would cost HIC economies an additional US$ 2.4 trillion in 2021 alone[2]. As shown in **Figure 9**, the impact in GDP's estimated losses could range from US$ 4.4 trillion to US$ 9.2 trillion in 2021.

Figure 9 – *Should countries continue to pursue an uncoordinated approach in access to COVID-19 tools, the world risks up to $9.2 trillion of GDP loss in 2021*[2]

	Assumptions on vaccine coverage	Global GDP estimated losses in 2021
Scenario 1	• **HIC:** immediate vaccination • **LIC:** no vaccination and no lockdown	**US$ 4.8 trillion**
Scenario 2	• **HIC:** immediate vaccination • **LIC:** no vaccination with lockdowns	**US$ 9.2 trillion**
Scenario 3	• **HIC:** fast vaccination • **LIC:** slow vaccinations with lockdowns	**US$ 4.4 trillion**

[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).

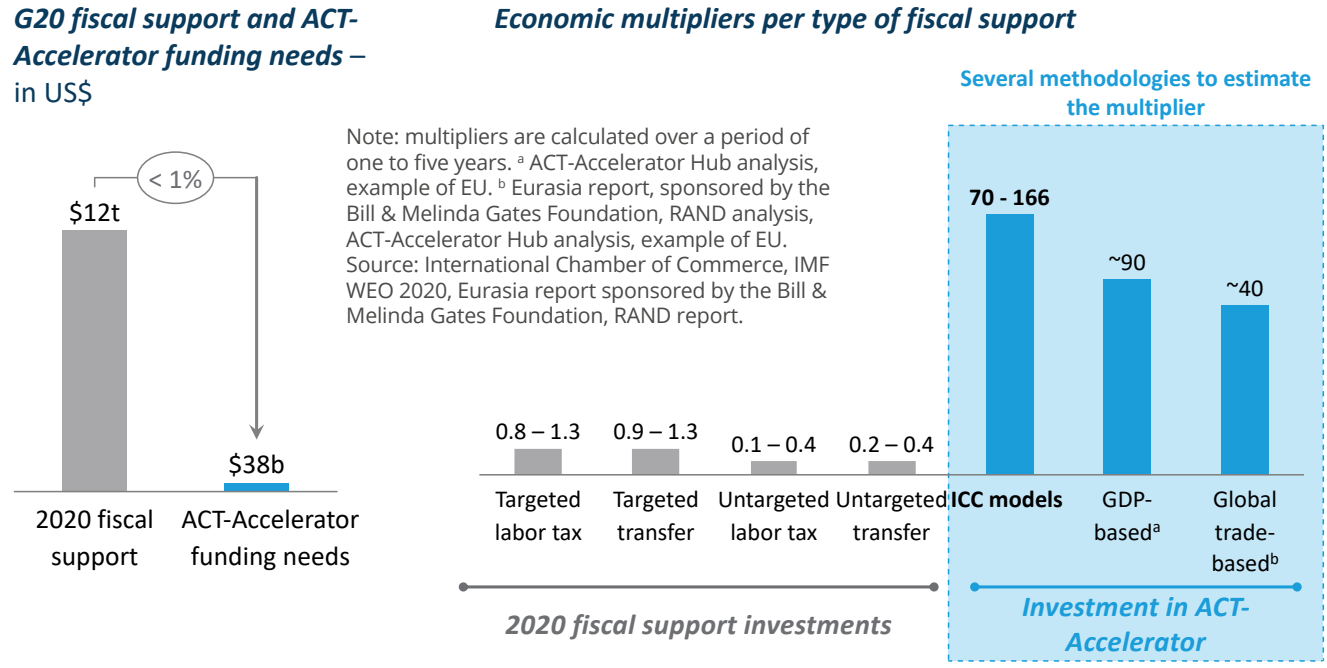
An earlier Eurasia Group study showed that for just 10 HICs, investing the US$ 22.1 billion needed by ACT-Accelerator in 2021 would produce over US$ 466 billion in economic benefits over five years[1], with a higher return than investing in the domestic economy.

> ***"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

A study from the International Chamber of Commerce[2] found that 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 (see **Figure 10**).

Another study found that in the United States America, for example, the multiplier (expressing the 'return on investment') for general domestic investments is estimated to be between 0.36x and 0.88x[3], while an investment of US$ 6 billion in equitable access to COVID-19 tools would deliver a multiplier estimated at 0.9-7.8x[4].

Figure 10 – *Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments*



[1] 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. Geneva: World Health Organization; 2020 (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).
[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] 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).
[4] 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).

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, and due to the potential significant long-term health effects of COVID-19. 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[1]. There are also growing reports of persistent symptoms in some patients with COVID-19. ACT-Accelerator tools act as primary prevention to reduce both the acute and chronic burden of COVID-19 on health systems and economies.

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[2].

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

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 need to maximize the use of existing tools now, globally and equitably, to rapidly bring an end to the pandemic.

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[1] COVID-19 significantly impacts health services for noncommunicable diseases. 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).

[2] 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.

[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).

10

APPENDICES

APPENDIX A – ACT-ACCELERATOR STRUCTURE AND RESPONSIBILITIES

ACT-Accelerator is a time-limited global collaboration designed to rapidly leverage existing global public health infrastructure and expertise to expedite the end of the COVID-19 pandemic by accelerating the 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. Civil Society and community engagement is integrated across all Pillars.

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), with UNICEF as a key delivery partner.

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, and country access and support, while supporting R&D efforts.

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, with support from The Global Financing Facility for Women, Children and Adolescents (GFF).

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

Gavi, the Vaccine Alliance, is focused on procurement and delivery for COVAX: coordinating the design, implementation and administration of the COVAX Facility and the COVAX AMC and working with its Alliance partners, along with governments, on country readiness and delivery. The COVAX Facility is the global pooled procurement mechanism for COVID-19 vaccines through which COVAX will ensure fair and equitable access to vaccines for all 191 participating economies by pooling buying power from participating economies and providing volume guarantees across a range of promising vaccine candidates. The Gavi COVAX AMC is the financing mechanism that will support the participation of 92 low- and middle-income economies in the Facility, enabling access to donor-funded doses of safe and effective vaccines.

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. **GFF** supports HSC and provides catalytic grants and technical assistance in GFF's 36 partner countries.

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.

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.

Figure A.1 – *ACT-Accelerator structure, with Pillar co-conveners and leads*

Inter-agency coordination and workstreams

Each Pillar is fully empowered to make decisions regarding the coordination and management mechanisms required to support its work. Each has established (a) coordination mechanisms to facilitate the joint work across the co-convening organizations of that Pillar and the relevant WHO lead; and (b) a technical workstream structure and schedule of regular meetings for collaboration both within and across workstreams, including regular meetings of the relevant agency Principals.

Within the Vaccines Pillar (COVAX) specific new mechanisms and coordination bodies have been created for the day-to-day work of the Pillar, and – separately – for the governance of the COVAX Facility given its unique role in securing vaccine deals, navigating a complex regulatory environment, developing policy, and determining allocation, some of which could not be carried out through existing mechanisms. A detailed description of these structures and mechanisms (both new and previously existing) can be found in COVAX: the Vaccines Pillar of the Access to COVID-19 Tools (ACT) Accelerator – structure and principles.

Coordinating committees

The Platform for ACT-A Civil Society and Community Representatives supports the coordination of civil society and community representation across all the ACT-A Pillars and within Pillar workstreams.

Pillar-level Coordinating Committees

Each Pillar has a Coordinating Committee composed of representatives of the co-convening organizations, WHO and the workstream leads. The Coordinating Committee defines the strategy, principles, policies, key targets and resource mobilization priorities across the Pillar, monitors progress, and coordinates actions and decisions on the day-to-to-day work amongst partners. Meeting frequency and participation is defined by the co-convening and lead agencies of each Pillar.

Workstream-level technical coordination

The work of each Pillar is divided into workstreams, with each workstream being led or co-led by 1-2 organizations who are responsible for convening and coordinating the relevant work of the stream through interagency working groups. Organizational participation in these working groups extends beyond ACT-Accelerator co-convening and lead organizations to optimize expertise, efficiency and impact. Each workstream is responsible for drafting its own workplan and budget. The workstream working groups meet on a regular basis (usually weekly or biweekly, as defined by the individual workstream). **Figure A.1** provides an overview of the workstreams and lead agencies within each Pillar.

Cross-pillar strategic alignment

Coordination and strategic and operational alignment across Pillars are managed through several mechanisms.

The Principals Group is comprised of the Principals of the co-convening agencies as well as lead agencies, such as UNICEF and the Bill & Melinda Gates Foundation, and industry associations. The Principals of ACT-Accelerator agencies meet weekly, coordinated by the ACT-Accelerator Executive Hub and co-chaired by the WHO Special Envoys. The Principals Group discusses key developments and challenges, the overall strategic direction of ACT-Accelerator and pillar-specific priorities, and addresses and aligns on cross-cutting issues and key bottlenecks. Representatives of key industry groups, such as the International Federation of Pharmaceutical Manufacturers & Associations (IPFMA), International Generic and Biosimilar Medicines Association (IGBA), and Developing Countries Vaccine Manufacturers Network (DCVMN), participate as relevant.

Sir Andrew Witty and Dr Ngozi Okonjo-Iweala served as **WHO Special Envoys for ACT-Accelerator**. Both have been instrumental in advocating for ACT-Accelerator and amplifying the global call for solidarity in accelerating the development of and equitable access to new COVID-19 tools. The Special Envoys co-chair the weekly Principals Group calls, provide the Pillars with guidance on key strategic issues, and facilitate high-level advocacy and political engagement, both directly and through the Facilitation Council.

A small **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 partnerships [e.g. with civil society organizations (CSOs), International Chamber of Commerce, Group of 7 (G7) and Group of 20 (G20)], and tracking and reporting on the overall ACT-Accelerator status of financing. The Hub also hosts weekly resource mobilization and communications calls with ACT-Accelerator partners to coordinate efforts, providing lift to individual Pillar/agency outreach. 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.

ACT-Accelerator Facilitation Council

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. As of February 2021, the United States of America joined the Facilitation Council as a full member. The Facilitation Council is comprised of ACT-Accelerator founding donor countries, major market shaper countries and current chairs of regional cooperation groups, with non-governmental partners [the 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 Pillars, Principals and partners, 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.

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 **B.2**.

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

Metrics[a]	2021 Assumptions	Source	Utility
1. Infected & symptomatic rate[b] of individual presenting for care in LMICs (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) • IHME Global Burden of Disease tool[f] (high risk) • Physician interviews	Basis for estimating priority vaccine coverage
3. Symptom severity	40% mild 40% moderate 15% severe 5% critical	• September ACT-Accelerator workstream 4 model • Age stratification based on estimates from Imperial College[g] • 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 15% asymptomatic	• Meta-analysis (15% asymptomatic)[i] • 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
Diagnostic testing 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 Coverage in LMICs	Based on product availability and use cases (2.9 million doses of dexamethasone)	Severe: lower need due to vaccines Moderate: increased medical oxygen Mild: novel antivirals and repurposed, depending on supply
Vaccines[a] Vaccines coverage in LMIC	N/A	At least 20% of the total population, including 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. The bridge between the US $38.1 billion budget reported in September 2020 and the updated US$ 22.1 billion ACT-Accelerator funding gap for 2021 is illustrated in **Table C.1**.

Table C.1 – *ACT-Accelerator budget and funding gap, bridge between September 2020 budget and March 2021 funding gap*

Pillar	2020-21 budget	Cost adjustments	Contributions	2021 funding gap
Diagnostics	$ 6.0 B	+ $ 3.7 B	$ 1.0 B	**$ 8.7 B**
Therapeutics	$ 6.6 B	- $ 2.7 B	$ 0.8 B	**$ 3.2 B**
Vaccines	$ 16.0 B	- $ 4.3 B	$ 8.5 B	**$ 3.2 B**
Health Systems Connector	$ 9.5 B	- $ 1.6 B	$ 0.6 B	**$ 7.3 B**
Sub-Total	**$ 38.1 B**	**- $ 4.9 B**	**$ 10.8 B**	**$ 22.3 B**
ACT-A pending allocation			**$ 0.2 B**	**- $ 0.2 B**
TOTAL	**$ 38.1 B**	**- $ 4.9 B**	**$ 11.0 B**	**$ 22.1 B**

[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).

Diagnostics Pillar – Increase of US$ 3.7 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 virus transmission and reported a new variant of the virus to WHO in December 2020. Further testing revealed that this virus strain had been circulating since September 2020.

ACT-Accelerator aims to scale-up testing in 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$ 2.7 billion

With early availability of vaccines and expected 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[1]. Additionally, in the light of recent epidemiological observations, the rate of infected and symptomatic individuals has been estimated at 2.31%,[2] reducing the funding requirement for procuring treatments. Nevertheless, it is essential that fit-for-purpose treatments are available for the broad population,[3] 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 Connector, where these costs had previously been budgeted.

Funding requirements for medical oxygen are subject to review as the scope of the COVID-19 Oxygen Emergency Taskforce is developed, and a better understanding of country-specific needs is available.

Vaccines Pillar - Decrease of US$ 4.3 billion

Since an initial reduction of funding need of US$ 4.9 billion laid out in the ACT-Accelerator Urgent Priorities & Financing Requirements at 10 November 2020, and 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 from emerging variants of concern, the funding need for vaccines is revised upwards by US$ 0.6 billion. To secure these doses and up to an additional 500 million doses by the end of 2021, the funding gap for procurement in 2021 is brought to US$ 2 billion. This is offset by shifting COVAX in-country delivery costs to ACT-Accelerator complementary investments. The US$ 1.3 billion corresponding costs will need to be covered through domestic, bilateral and/or multilateral funding complementary to ACT-Accelerator.

Additional health workforce to deliver doses for 2021 are estimated at 120,000 - 470,000 in AMC countries at a cost ranging from US$425 million to US$1.5 billion depending on the efficiency of vaccination. These costs are not included in the financing estimates because of the range of uncertainty and with the expectation they will be included by national government health planning.

New contributions of US$ 6.3 billion between November 2020 and March 2021 bringing total contributions to US$ 11.0 billion

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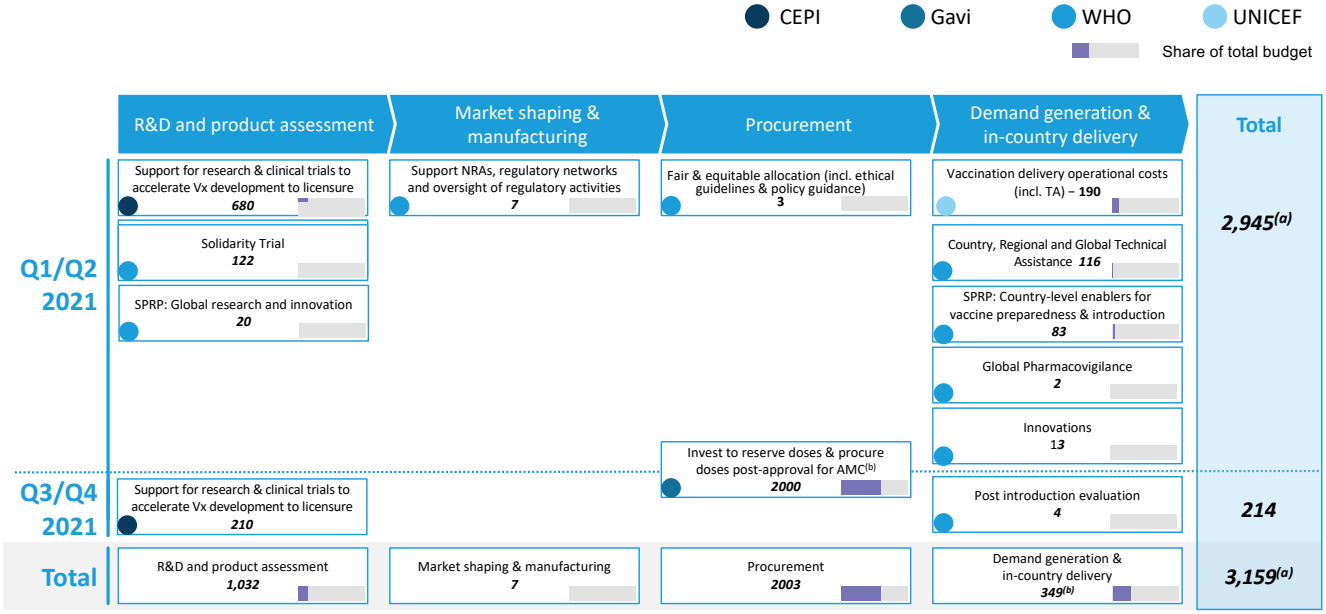
[1] With a vaccine efficacy of 80%.
[2] On average. Rates are differentiated by income category.
[3] 80% of cases expected to be in broad population, not in the population covered with the first vaccination waves.

APPENDIX D – DETAILED FUNDING GAPS

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

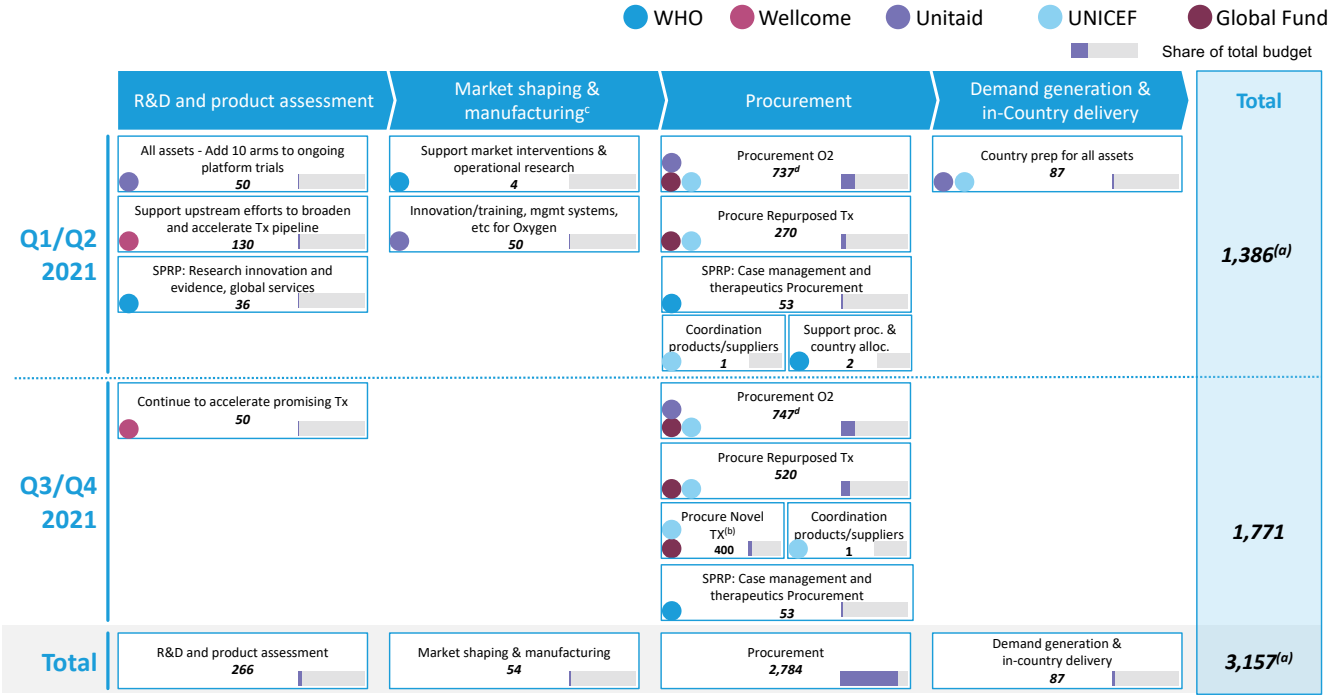


NOTE: SPRP is Strategic Preparedness and Response Plan (https://www.who.int/publications/m/item/covid-19-strategic-preparedness-and-response-plan).

[a] Additional contributions of US$ 292 million reduce Vaccines funding gap to US$ 3,159 million for 2021 (US$ 232 million from Germany to WHO, yet to be allocated to specific activities; and US$ 60 million from Canada to GAVI for delivery). These contributions are in the process of being operationalized into specific work packages by the recipient agencies at the date of publication of this document.

[b] Additional contribution of US$ 60 million from Canada to Gavi for delivery reduce the funding gap.

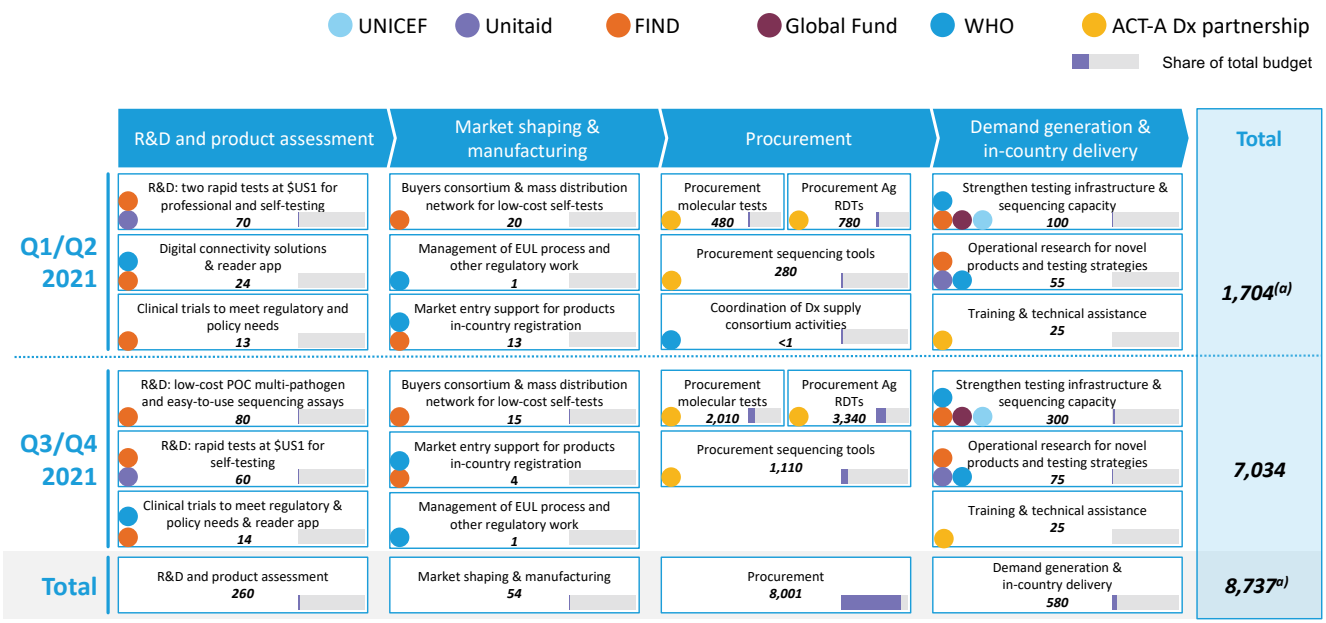
Figure D.2 – *Therapeutics Pillar funding gap by period and deliverable packages – in US$ million*



NOTE: SPRP is Strategic Preparedness and Response Plan (https://www.who.int/publications/m/item/covid-19-strategic-preparedness-and-response-plan).

[a] Additional contributions of US$ 33 million reduce Therapeutics funding gap: Including an additional recent contribution of USD 6 million allocated to WHO that is decreasing the funding gap, and US$ 27 million allocated to Global Fund yet to be approved through the Global Fund COVID-19 Response Mechanism. While they are not yet operationalized in specific work packages, they will reduce the funding gap of WHO and Global Fund work packages.
[b] Canada has pledged a contribution of Can$ 230 million to procure COVID-19 treatments for developing countries (recipient: UNICEF). To be evaluated in light of evolving clinical information.
[c] Market-shaping activities may leverage funding embedded in country preparedness or procurement line items for Therapeutics (e.g. for advanced purchase arrangements or other price-volume agreements, reserved volumes for operational research and/or early adopter countries).
[d] Funding requirements for medical oxygen are subject to review as the scope of the COVID-19 Oxygen Emergency Taskforce is developed, and a better understanding of country-specific needs is available.

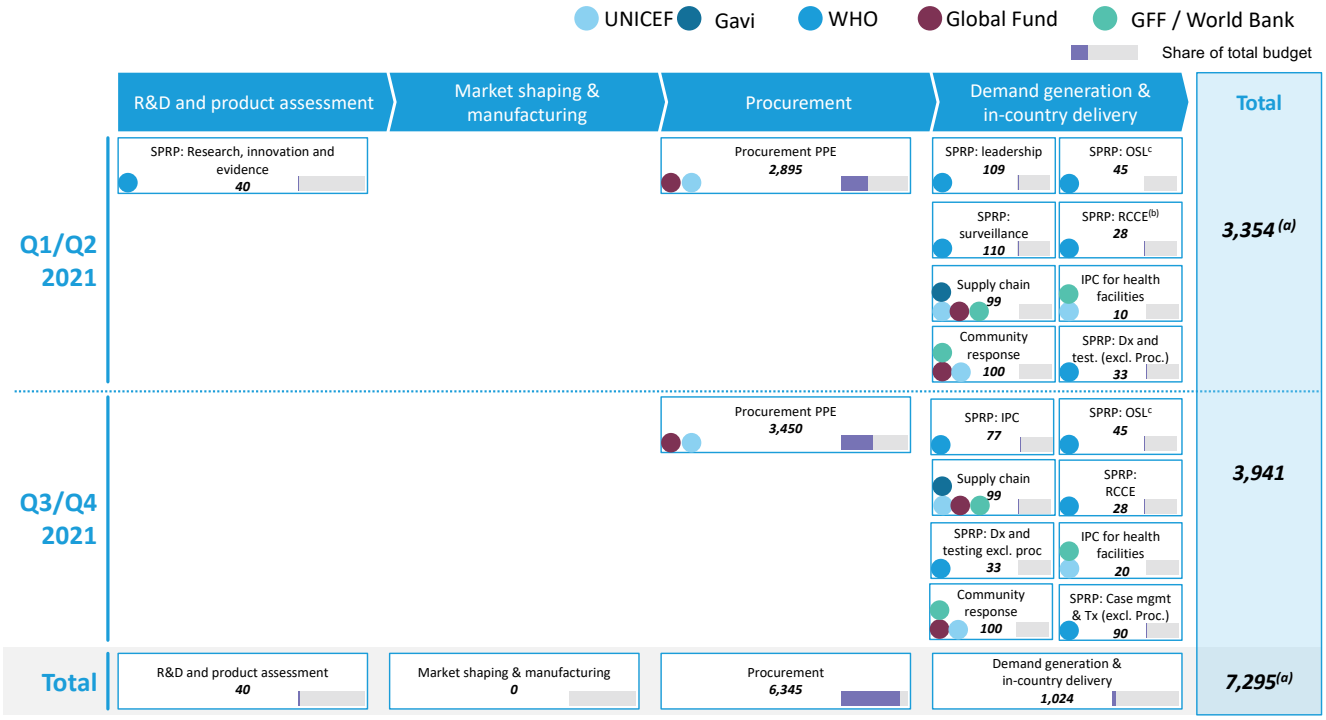
Figure D.3 – *Diagnostics Pillar funding gap by period and deliverable packages – in US$ million*



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 actdiagnostics@who.int.

[a] Additional contributions of US$ 158 million reduce Diagnostics funding gap: Including an additional recent contribution of US$ 18 million allocated to WHO, USD 61 million allocated to FIND and US$ 79 million allocated to Global Fund, yet to be approved through the Global Fund COVID-19 Response Mechanism. While they are not yet operationalized in specific work packages, they will reduce the funding gap of WHO, FIND and Global Fund work packages.

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



NOTE: SPRP is Strategic Preparedness and Response Plan (https://www.who.int/publications/m/item/covid-19-strategic-preparedness-and-response-plan).

[a] Additional contributions of US$ 114 million reduce HSC funding gap: Including an additional recent contribution of USD 49 million allocated to WHO, and US$ 65 million allocated to Global Fund that is decreasing the funding gap, yet to be approved through the Global Fund COVID-19 Response Mechanism. While they are not yet operationalized in specific work packages, they will reduce the funding gap of Global Fund and WHO work packages.
[b] Risk Communication and Community Engagement.
[c] Operational Support and Logistics.

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

Vaccines Pillar

			Funding gap			
Deliverable	**Area of work**	**Strategic priority**	**Q1 / Q2 2021**	**Q3 / Q4 2021**	**Total 2021**	**Designated recipient and/or lead agency**
Total			**9,190**	**12,960**	**22,149**	
Sub-total Vaccines			**2945**	**214**	**3159**	
Ensure global, fair and equitable allocation, incl. creation of global ethical guidelines, and provide policy guidance	Procurement	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	3	-	3	WHO
Vaccination delivery operational costs (incl. TA)	Demand generation & in-country delivery	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	190	-	190	UNICEF
Country, regional and global technical assistance	Demand generation & in-country delivery	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	116	-	116	WHO
Global Pharmacovigilance	Demand generation & in-country delivery	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	2	-	2	WHO
Innovations	Demand generation & in-country delivery	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	13	-	13	WHO
Invest upfront in manufacturers to reserve doses now and procure doses post-approval for the 92 AMC eligible economies	Procurement	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	2000		2000	GAVI
Post introduction evaluation	Demand generation & in-country delivery	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	-	4	4	WHO
SPRP: Country-level enablers for vaccine preparedness	Demand generation & in-country delivery	1. Rapidly scale-up delivery of 1.8+ billion doses of vaccine through COVAX	83	-	83	WHO
SPRP: Global research and innovation	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	20	-	20	WHO
Solidarity trial	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	122	-	122	WHO
Support for research and clinical trials to accelerate vaccine development to licensure	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	680	210	890	CEPI
Support NRAs, regulatory networks and oversight of regulatory activities	Market shaping & manufacturing	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	7	-	7	WHO
Additional funds to be operationalized into specific work packages			*-291*	-	*-291*	

Therapeutics Pillar

Deliverable	Area of work	Strategic priority	Funding gap			Designated recipient and/or lead agency
			Q1 / Q2 2021	Q3 / Q4 2021	Total 2021	
Sub-total Therapeutics			**1386**	**1771**	**3157**	
Add up to 10 arms to ongoing platform trials	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	50	-	50	Unitaid
Continue to accelerate promising Tx	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	-	50	50	Wellcome
Coordination of products and suppliers workstream	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	1	1	2	UNICEF
Country preparedness for all assets	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	87	-	87	Unitaid / UNICEF
Innovation/training, mgmt systems, etc for oxygen	Market shaping & manufacturing	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	50	-	50	Unitaid
Oxygen procurement (ex HSC)	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	737	747	1484	UNICEF / Global Fund / Unitaid
Procure 35M Repurposed Tx	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	270	-	270	UNICEF / Global Fund
Procure 60M novel Tx for mild/ mod patients	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	-	400	400	UNICEF / Global Fund
Procure 70M repurposed Tx	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	-	520	520	UNICEF / Global Fund
SPRP: Case management and therapeutics procurement	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	53	53	106	WHO
SPRP: Research innovation and evidence, global services	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	36	-	36	WHO
Support market interventions: voluntary licensing, technology transfers, regulatory and policy processes	Market shaping & manufacturing	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	4	-	4	WHO
Support procurement & country allocation	Procurement	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	2	-	2	WHO
Support upstream efforts to broaden & accelerate TX pipeline	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	130	-	130	Wellcome
Additional funds to be operationalized into specific work packages			*-33*	-	*-33*	

Diagnostics Pillar

Deliverable	Area of work	Strategic priority	Funding gap			Designated recipient and/or lead agency
			Q1 / Q2 2021	Q3 / Q4 2021	Total 2021	
Sub-total Diagnostics			**1704**	**7034**	**8737**	
Buyers consortium and mass distribution network for LMIC access to low-cost self-tests	R&D and product assesment / Market shaping & manufacturing	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	20	15	35	FIND
Clinical trials to meet regulatory and policy needs	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	13	13	26	FIND / WHO
Coordination of Dx Supply Consortium activities	Procurement	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	1	-	1	WHO
Digital connectivity & data sharing solutions	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	9	-	9	FIND
Digital connectivity solutions & reader app	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	15	1	16	FIND / WHO
Management of EUL process and other regulatory work	Market shaping & manufacturing	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	1	1	2	WHO
Market entry support for products in-country registration	Market shaping & manufacturing	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	13	4	17	FIND / WHO
Operational research for novel products and testing strategies	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	55	75	130	FIND / Unitaid / WHO
Procure Ag RDTs	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	780	3340	4120	ACT-A Dx partnership
Procure molecular tests	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	480	2010	2490	ACT-A Dx partnership
Procure sequencing solutions	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	280	1110	1390	ACT-A Dx partnership
R&D: low-cost POC multi-pathogen and easy-to-use sequencing assays	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	-	80	80	FIND
R&D: two rapid tests at US$ 1 for professional and self-testing; tech transfer for regional production	R&D and product assesment	2. Bolster R&D, product evaluation & regulatory pathways, to also address variant risks	70	60	130	FIND/ Unitaid
Strengthen/expand country testing infrastructure & sequencing capacity	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	100	300	400	FIND/ Global Fund / UNICEF / WHO
Train healthcare workers & laboratorians and provide technical assistance	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	25	25	50	ACT-A Dx partnership
Additional funds to be operationalized into specific work packages			*-158*	-	*-158*	

Health Systems Connector

Deliverable	Area of work	Strategic priority	Funding gap			Designated recipient and/or lead agency
			Q1 / Q2 2021	Q3 / Q4 2021	Total 2021	
Sub-total Health Systems Connector			**3354**	**3941**	**7295**	
Community Response	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	100	100	200	Global Fund / UNICEF / GFF World Bank
IPC for health facilities	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	10	20	30	UNICEF / GFF / World Bank
Procurement PPE	Procurement	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	2895	3450	6345	Global Fund / UNICEF / GFF World Bank
SPRP: Case management and therapeutics (excl. procurement)	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	-	90	90	WHO
SPRP: Diagnostics and testing (excl. procurement)	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	33	33	65	WHO
SPRP: Infection, prevention and control	Demand generation & in-country delivery	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	-	77	77	WHO
SPRP: Leadership, coordination, planning and monitoring	Demand generation & in-country delivery	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	109	-	109	WHO
SPRP: Operational support and logistics	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	45	45	89	WHO
SPRP: Research, innovation and evidence	R&D and product assesment	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	40	-	40	WHO
SPRP: Risk communication & community engagement	Demand generation & in-country delivery	3. Stimulate rapid & effective uptake and use of tests, treatments and PPE	28	28	56	WHO
SPRP: Surveillance, case investigation and contact tracing	Demand generation & in-country delivery	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	110	-	110	WHO
Supply chain	Demand generation & in-country delivery	4. Ensure robust supply pipeline of essential tests, treatments & PPE in LMICs	99	99	198	GAVI / Global Fund / UNICEF / GFF World Bank
Additional funds to be operationalized into specific work packages			*-114*	-	*-114*	
Additional funds to be allocated by donors to specific pillars			*-199*	-	*-199*	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The Vaccine Alliance

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BILL & MELINDA
GATES foundation

FIND
Because diagnosis matters

unicef

The Global Fund

Unitaid