ACTaccelerator
ACCESS TO COVID-19 TOOLS

Urgent Priorities & Financing Requirements at 10 November 2020

Averting the deepening human & economic crisis due to COVID-19

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

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Suggested citation: ACT-Accelerator Urgent Priorities & Financing Requirements at 10 November 2020.

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Design and layout: Studio FFFOG

Printed in Switzerland

Version uploaded on 23 November 2020

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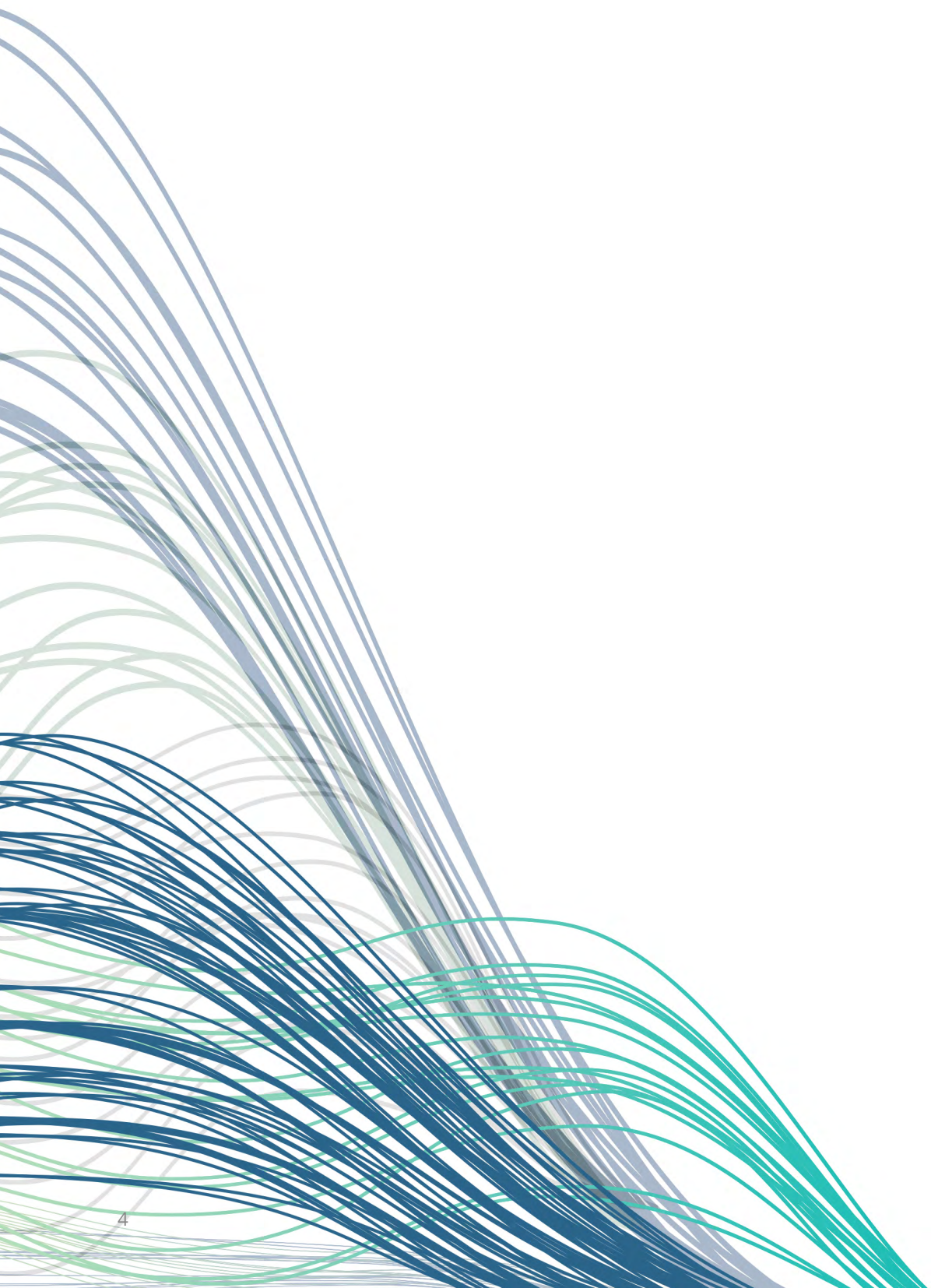


Acronyms used in this document

Ag	Antigen-detecting
AMC	Advance Market Commitment
APA	Advance Purchase Agreement
CEPI	Coalition for Epidemic Preparedness Innovations
FIND	The Foundation for Innovative New Diagnostics
G20	Group of Twenty
GDP	Gross Domestic Product
HICs	High-income Countries
HSC	Health Systems Connector
IMF	International Monetary Fund
IPC	Infection Prevention and Control
LICs	Low-income Countries
LMICs	Low- and middle-income Countries
mAbs	Monoclonal Antibodies
MPA	Multiphase Programmatic Approach
NPI	Non-pharmaceutical Interventions
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
SFP	Self-Financing Participants in the COVAX Facility
R&D	Research & Development
RDT	Rapid Diagnostic Test
WHO	World Health Organization

Foreword

Six months after its launch on 24 April, the Access to COVID-19 Tools (ACT) Accelerator has already delivered concrete results in speeding up the development of new therapeutics, diagnostics, and vaccines.

Now mid-way through the scale-up phase, the tools we need to fundamentally change the course of this pandemic are within reach. But to deliver the full impact of the ACT-Accelerator – and ultimately an exit to this global crisis – these tools need to be available everywhere.

On behalf of the ACT-Accelerator Pillar lead agencies – **CEPI**, **Gavi**, the **Global Fund**, **FIND**, **Unitaid**, **Wellcome Trust**, the **World Bank**, and the **World Health Organization**, as well as the **Bill & Melinda Gates Foundation** – I am pleased to share this document setting out the near-term priorities, deliverables and financing requirements of the ACT-Accelerator Pillars and Health Systems Connector.

Urgent action to address these financing requirements will boost the impact of the ACT-Accelerator achievements to date, fast-track the development and deployment of additional game-changing tools, and mitigate the risk of a widening gap in access to COVID-19 tools between low- and high-income countries.

Delivering on this promise requires strong political leadership, financial investment, and in-country capacity building.

COVID-19 cannot be beaten by any one country acting alone.

We must ACT now, and ACT together to end the COVID-19 crisis.

Tedros Adhanom Ghebreyesus
Director-General
World Health Organization

A rapidly evolving global landscape requires an early review of the ACT-Accelerator's scale-up priorities and financing

Launched in April 2020 with the vision of creating a global solution to expedite the end of the COVID-19 pandemic, the Access to COVID-19 Tools (ACT) Accelerator has since made **substantial strides** towards its goals of **accelerating the development of and equitable access** to COVID-19 diagnostics, therapeutics, and vaccines, along with the necessary health system enhancements. As described in its September 2020 *Status Report & Plan*, the ACT-Accelerator start-up phase made steady progress across all of its Pillars, and the momentum continues.

On 10 September 2020, the **ACT-Accelerator Facilitation Council kicked off the scale-up phase** which coincided with the release of the first *ACT-Accelerator Investment Case and Financing Requirements*. This laid out strong economic arguments for investing in the ACT-Accelerator as the most viable global solution for enabling countries to transition out of the current crisis and thereby restart the domestic and international economic engines driving our global economy.

Two months into this scale-up phase, **critical developments in the global landscape require a stock-taking and sharpening of our near-term priorities to refine our urgent financing requirements.** These developments include three important trends:

- increasing clarity on the pipeline for COVID-19 tools, driven by unprecedented speed of innovation in tests, treatments, and vaccines;
- growing evidence that a solution to the health and economic crises caused by the pandemic is rooted in fast and equitable access to COVID-19 tools by everyone, everywhere;
- escalating threats to equitable access to new tools, including concerning epidemiological trends in the northern hemisphere that could aggravate an already challenging access environment.

This document sets out the latest progress in our work to accelerate the discovery and development of COVID-19 tools and highlights emerging threats to equitable access. It then provides an **update on the sharpened priorities of the ACT-Accelerator Pillars and Health Systems Connector, and the urgent financing requirements for each.**

The ACT-Accelerator is already saving lives and accelerating the development of additional game-changing tools that could be available in the coming months

When the ACT-Accelerator was established less than seven months ago, few COVID-19 tools existed to fight the pandemic. The world had to rely almost entirely on non-pharmaceutical interventions (NPIs) such as physical distancing, lockdowns, and mobility restrictions that have proven both unsustainable as well as catastrophic to our social and economic lives. Testing kits were expensive and scarce, reserved only for those with severe symptoms. Personal protective equipment (PPE) was often in short supply. No treatments were yet proven to be effective, and only the most severe cases were supported with high-flow oxygen or mechanical ventilation (where available).

To date, COVID-19 has claimed more than 1.2 million lives and infected more than 48 million people all over the world. With entire continents now experiencing a resurgence in cases, living with and managing the impact and consequences of COVID-19 is the new global reality.

However, as the result of unprecedented international collaboration, much-needed investments, and world-class scientific efforts in research and development (R&D), significant progress has been made in developing new tools and strategies in the fight against this virus.

The ACT-Accelerator's integrated approach to catalyze research and development and the scale up of access capacities and activities is already benefiting people everywhere

Scale up and deployment of existing tools

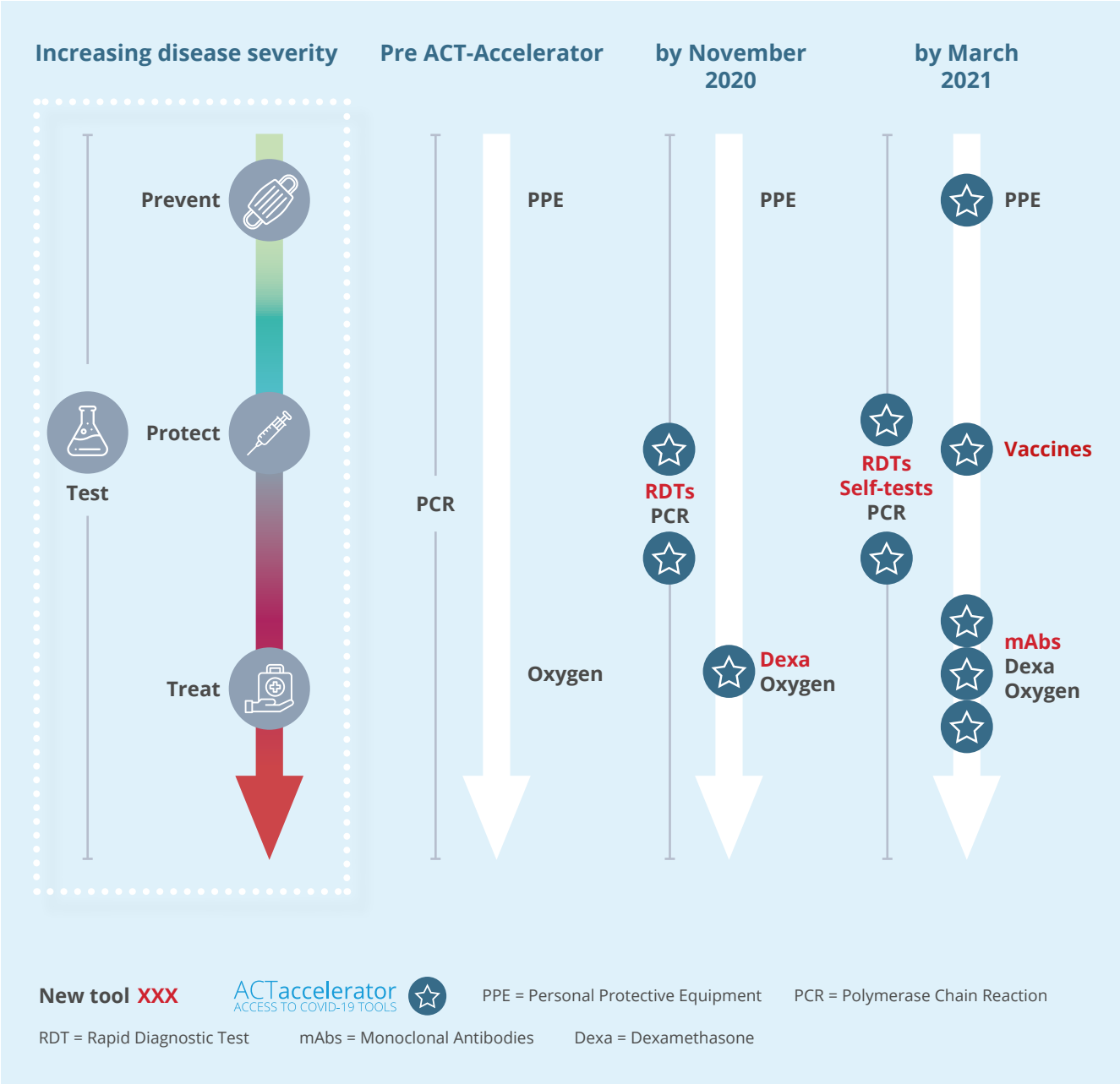
- **50 million PCR** tests have been made available to enhance testing in low- and middle-income (LMICs).
- **Access to Dexamethasone** to treat severe COVID-19 cases has been expedited through an Emergency Use Listing (EUL) procedure, publication of **treatment guidelines**, and establishment of a **stockpile for emergency use**.
- **US$ 200 million worth of personal protective equipment** (PPE) has been procured for LMICs.

Discovery and production of new tools

- **New rapid diagnostic tests (RDTs)** have been developed and affordable price guarantees secured for **120 million tests for LMICs**.
- **186 countries and economies have signed up** to the COVAX Facility to benefit from pooled procurement of vaccines from a broad portfolio. **Manufacturing capacities for 1 billion vaccine doses** are secured.
- **Manufacturing capacities** are reserved for scale-up of **monoclonal antibodies.**

If urgent funding gaps are filled by March 2021, vital R&D, operational research, production capacity scale-up and procurement efforts will deliver existing tools and ensure new[1] and improved tools can be taken to scale (see boxes above and Figure 1 below). Fully funded, the ACT-Accelerator can ensure these new and improved tools are fully leveraged to bring the pandemic to an end.

Figure 1: Impact of the accelerated development of new COVID-19 tools from April 2020 through March 2021



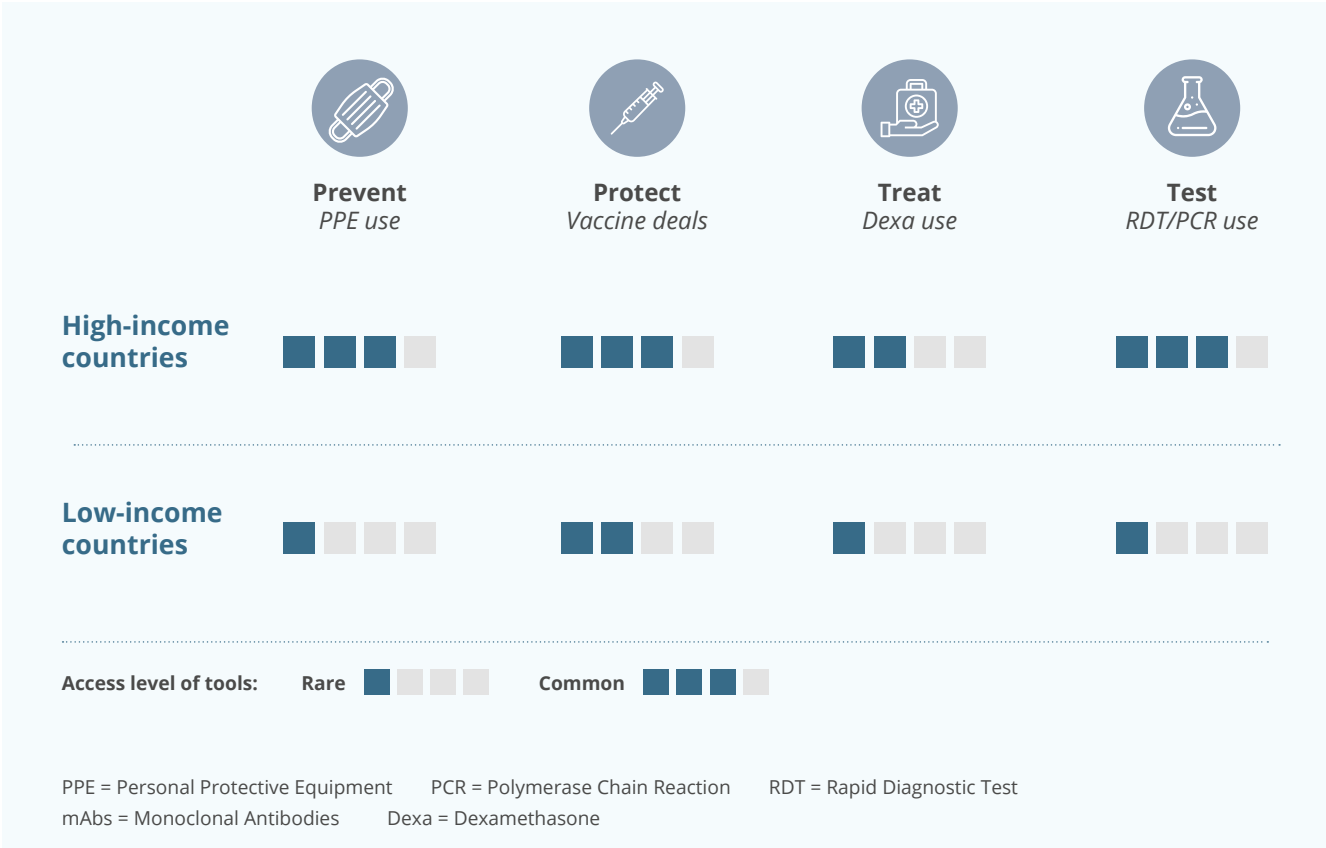
[1] In addition to vaccines, monoclonal antibodies are among the most promising interventions in the pipeline for 2021; the ACT-Accelerator Therapeutics Pillar aims to maximize their impact by supporting development and ensuring their availability in LICs and LMICs.

Midway into the ACT-Accelerator's scale-up phase, urgent financial challenges and overwhelmed or weak health systems are threatening equitable access

The ACT-Accelerator was founded on the concept of global solidarity and the twin goals of accelerating development and ensuring fair and equitable allocation to COVID-19 tools. Now at a critical point in taking the promise of the ACT-Accelerator to scale, we are faced with a real gap and increasing divergence in progress towards these two key objectives. While the development and rollout of new tools has been rapidly accelerated, with real progress in the areas of testing and treatment, the broad and equitable access needed to these tools – and ultimately to exit this global crisis – is still severely lacking.

Access to and uptake of existing tools remains extremely limited, especially in low- and low-middle-income countries (see Figure 2 below). If not urgently addressed, this growing equity gap will only worsen as new tools become available and supply remains scarce.

Figure 2: Level of access to COVID-19 tools as of November 2020 in high-income compared to low-income countries



Several challenges are contributing to this risk, calling for urgent mitigation in three key areas:

1. **Immediate financing.** Up-front financial commitments are urgently required to enable the ACT-Accelerator Pillars to negotiate and secure required global production capacity for pipeline tools (especially vaccines, monoclonal antibodies, additional rapid diagnostic tests), and to procure, deploy, and facilitate the uptake of new and existing tools and basic health systems commodities (e.g. new rapid diagnostic tests, dexamethasone, PPE, oxygen).

2. **Improved country demand and delivery capacities**. Bottlenecks in key areas of health systems, such as financing, data, workforce, clinical care, and supply chain, as well as access to key commodities such as PPE and oxygen, remain limiting factors to effective deployment and use of COVID-19 tools in many countries. Support is urgently needed for countries with weak health systems to develop integrated country response plans and ensure the use of available financing mechanisms to include new tools into national health systems, an increasingly critical role of the Health Systems Connector (HSC).

3. **Stronger global solidarity and commitment to equitable access and allocation.** As high-income countries in the northern hemisphere experience a resurgence in COVID-19 cases, while bracing themselves for the annual influenza season, mounting pressure on national governments and health systems risks driving attention away from the principles of timely equitable access to new COVID-19 tools and the global solution that the world needs to end this crisis. COVID-19 cannot be beaten by any one country acting alone.

A substantial injection of financial support is needed from the international community to reverse the increasing risk of access gaps and disparities between high- and low-income countries, and to prevent a prolonging of the human and economic devastation caused by this crisis.

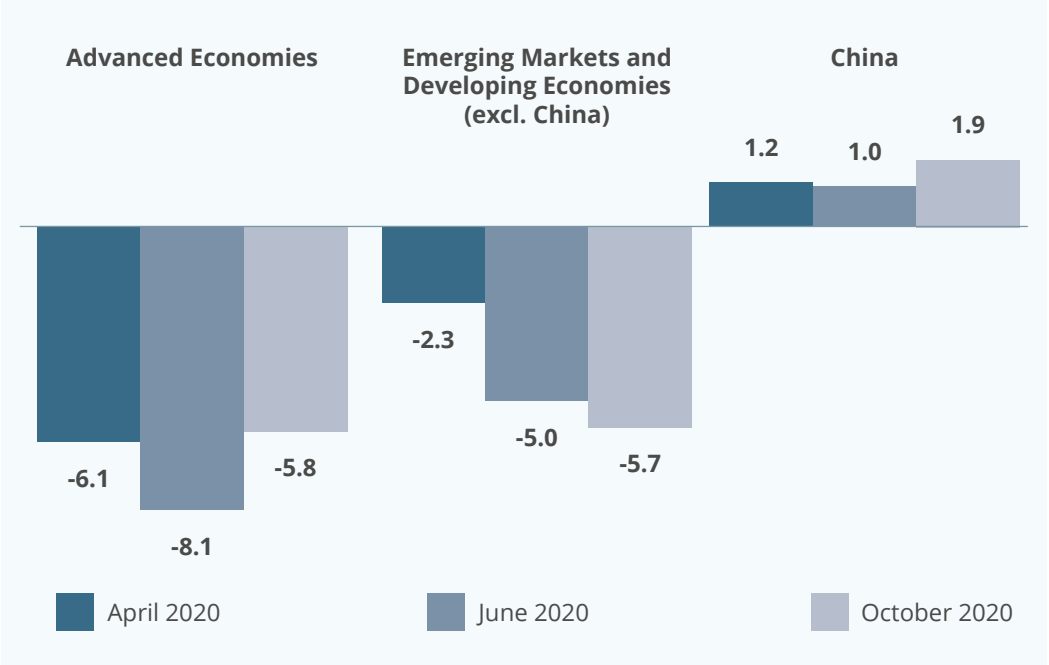
Powerful new economic insights argue that fast and universal access to COVID-19 tools would increase global income by US$ 9 trillion by the end of 2025

Despite signs of relief for some G20 economies in recent months, and a decrease in mortality rates overall, the global health and economic outlook remains deeply troubling. As countries in the northern hemisphere experience their second wave of COVID-19, with a worsening epidemiological landscape and anticipated economic impact, the imperative for reversing the pandemic is escalating rapidly. Swift action is needed.

In its latest World Economic Outlook, the International Monetary Fund (IMF) forecasts a contraction in the global economy of 4.4% in 2020, a modest improvement from the 5.2% contraction predicted in June. Such an improvement does not reflect, however, the inequalities in recovery between countries: better outlooks are mostly concentrated in China and in advanced economies (see Figure 3). Furthermore, the expected economic rebound in 2021 has been downgraded from 5.4% to 5.2%, leading to a global cumulative loss of output of US$ 11 trillion in 2020 and 2021. By end 2025, it is estimated that the world could lose US$ 28 trillion in gross domestic product (GDP).[2]

These devastating economic consequences are also causing major setbacks to human capital development. An estimated 90 million more people are at risk of being thrust into poverty in 2020 alone.[3]

Figure 3: Downgraded IMF forecast for Emerging Market and Developing Economies, reaching recession levels for Advanced Economies [4]



[2] Based on the scenario where local transmission is assumed to be brought to low levels everywhere by the end of 2022.
[3] Living on less than US$ 1 per day.
[4] IMFBlog. A Long, Uneven and Uncertain Ascent. https://blogs.imf.org/2020/10/13/a-long-uneven-and-uncertain-ascent/, accessed 21 October 2020.

The magnitude of these losses further emphasizes the need to accelerate the end of this health and economic crisis by addressing its root cause: uncontrolled COVID-19 transmission. According to the IMF, key to effectively combatting this health crisis is to ensure that all innovations (in tests, treatments and vaccines) are produced at scale for the benefit of all countries. If medical solutions can be made available faster and more widely, the IMF estimates it could lead to a cumulative increase in global income of almost US$ 9 trillion by the end of 2025 and reduce income divergence in all countries.

The ACT-Accelerator works to ensure that COVID-19 tools will be delivered rapidly and equitably. While the overall costs of the ACT-Accelerator are substantial, they are a fraction of what governments are injecting into their economies to counter the recession (US$ 12 trillion invested to date in G20 countries alone). In addition, there is strong support among the general public for investing in the ACT-Accelerator and its fundamental principles of fair and equitable access.[5]

It is in every economy's interest to finance a global solution, as all economies are interdependent through mobility and global trade.[6] Fully financing the ACT-Accelerator, to contribute to a shortening of the duration of this crisis, would be paid back in less than 36 hours once global mobility and trade are restored.[7] Even with the most optimistic forecasts for 2020, the investment in the ACT-Accelerator would be recouped in 3 days.

The urgency being applied to the discovery and development of new COVID-19 tools must now be matched with advances in market preparedness, manufacturing and country readiness capacities to ensure the effective deployment and delivery of these tools as soon as they are approved. Equitable scale-up of the COVID-19 tools that are already available is severely lagging. Any delays due to an unprepared or under-funded deployment effort has colossal costs: for each month lost in scaling up access to COVID-19 tools, the world is currently losing 120,000 lives,[8] US$ 460 billion in economic output[9], and US$ 600 billion in global trade revenue.[10]

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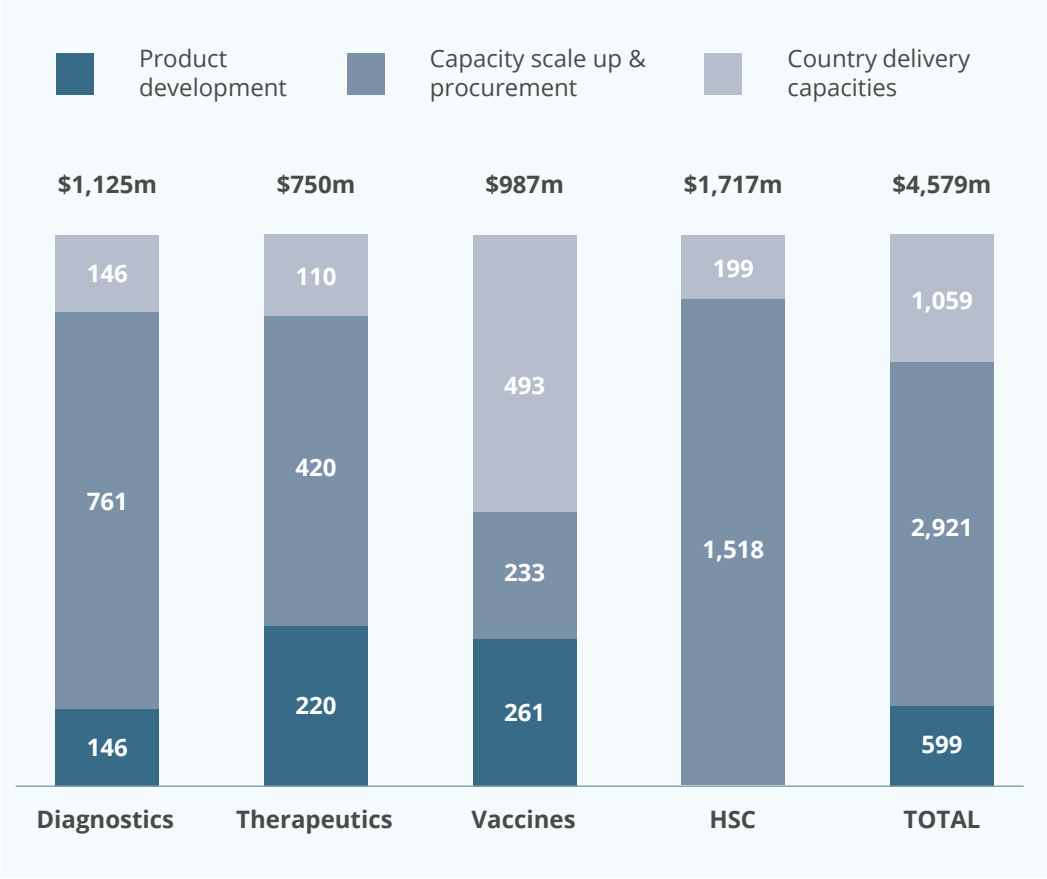
[5] Polling of more than 6,000 adults in the UK, USA, Germany and France showed strong public support for treatments and vaccines to be first made available to those who need them most. https://wellcome.org/reports/what-people-think-about-global-access-covid-19-treatments-and-vaccines.
[6] In 2015, both developed and developing economies had the same rate of global value chain participation – estimated to be 41.4% of their total exports. "This reflects the global nature of production networks which rely on the participation of a number of economies"; Source : WTO, World Trade Statistical Review 2019, p. 42.
[7] An Economic Investment Case and Financing Requirements for the ACT Accelerator. https://www.who.int/publications/i/item/an-economic-investment-case-financing-requirements.
[8] Lives lost in the last 30 days, as of 21 October, Source: WHO Coronavirus disease (COVID-19) dashboard [online database]. Geneva: World Health Organization; 2020. https://covid19.who.int/, accessed 21 October 2020.
[9] US$ 11 Trillion in GDP expected to be lost in 24 months, in 2020-21, Source: IMF World Economic Outlook October 2020, IMFBlog. https://blogs.imf.org/2020/10/13/a-long-uneven-and-uncertain-ascent/.
[10] US$ 12 Trillion estimated revenue losses in international sectors over 18 months, in 2020-2021, Source: WTO, WTTC, BCG analysis.

Rapidly closing the ACT-Accelerator's urgent US$4.6 billion financing gap will allow us to fast-track critical areas of work and near-term deliverables through March 2021, for the greatest possible impact

Reflecting the rapidly evolving landscape for COVID-19 tools, and recognizing the urgent concerns about growing gaps in equitable access, the ACT-Accelerator Pillars have sharpened their priorities and near-term deliverables to clearly articulate the immediate funding requirements for delivering on their goals and enhancing impact. **US$ 4.6 billion is urgently needed**. This financing will allow the Pillars to implement key activities across the areas of diagnostics, therapeutics, vaccines, and health systems strengthening that will contribute substantially to accelerating the exit of all countries from the acute phase of the pandemic. Figure 4 below summarizes the urgent funding required by each Pillar to deliver on their targets as outlined in the subsequent sub-sections.

Figure 4: Urgent ACT-Accelerator financing needs for near-term deliverables is US$ 4,579 million to support priority clinical trials and product assessments, the scale-up of production capacities, product procurement, and crucial country readiness and delivery activities



ACT-Accelerator Pillar priorities and urgent financing requirements to accelerate product development and delivery at-scale

Diagnostics

Test & live: living with COVID-19 requires testing for everyone, everywhere

Testing saves lives. Effective test-trace-isolate strategies were key to successfully bringing the first wave of the pandemic under control in many countries. If countries are to protect the gains achieved through painful lockdowns, bring second waves of COVID-19 under control and prevent future waves, a sustained focus on testing is crucial. The second wave is already stretching testing capacity to the limit once again, and in many countries the waiting time for a result has now been prolonged to 4–6 days.

Significant progress in COVID-19 diagnostics has been made in record time. The ACT-Accelerator has been instrumental in making quality rapid antigen tests available within just 8 months (including 120 million tests reserved for LMIC purchase) – light speed when compared with the 5 years it took to achieve this milestone in HIV. These rapid tests enable COVID-19 diagnosis outside of a laboratory, an essential complement to the gold-standard laboratory-based (molecular/PCR) tests.

Looking to the immediate future and for the years ahead, while the global population will not be fully protected against the virus, our testing arsenal must be further expanded so that the world has the tools it needs to live with COVID-19 and to restore our economies.

*By March 2021, have the first **self-tests ready for production, massively expand testing** outside of laboratories, and **200 million tests procured** for use in LMICs (of 500 million 2021 target)*

Transformative innovation is urgently needed to develop the tools to test everyone, everywhere; tests that get us back to our workplaces, get our children back to school, allow us to congregate in large and small gatherings, and to open borders – in safety. Tests to help protect vulnerable populations and health workers. Tests that can move us from overwhelmed health systems and long waits for results, to a world in which testing is as simple and easy as brushing our teeth.

No country can be left behind as we make this vision a reality; the Diagnostics Pillar will provide critical support to countries unable to shoulder the cost burden on their own, so that everyone can access the tests we have today and those we need tomorrow.

Without US$ 1.1 billion in funding now, further progress by the Diagnostics Pillar will be in jeopardy

The Diagnostics Pillar requires total funding of US$ 6 billion, of which US$ 1.1 billion is needed immediately to:

- **Accelerate the diagnostic innovation needed to rebuild lives and restore economies** by driving development of transformative, low-cost self-tests and digital solutions (US$ 146 million),
- **Catalyze equitable deployment** by ensuring countries, businesses and people can take up these products effectively (US$ 218 million), and
- **Support countries that cannot shoulder the costs alone** by providing procurement funding (US$ 761 million).

Beyond March 2021, the focus will be on making a mass-produced, US$ 0.50 test available to everyone, everywhere, with 500 million tests deployed to LMICs by the end of 2021 (details in Appendix B).

Figure 5: The Diagnostics Pillar total gap is US$ 5.3 billion, of which over US$ 1.1 billion is needed urgently

Pillar	Immediate Gap	Balance of 2021 Gap	**Total Gap**
Diagnostics	1.1	4.2	**5.3**

In US$ billion

Therapeutics

The immediate priorities for the Therapeutics Pillar are to intensify efforts on monoclonal antibodies (mAbs) while scaling up dexamethasone use and maintaining flexibility to support other promising therapeutics in the areas of new antivirals and repurposed products.

In the initial phase of the ACT-Accelerator work, the key focus of the Therapeutics Pillar was on supporting the discovery of successful products across three asset classes: mAbs, novel antivirals, and repurposed therapeutics. This strategy has been successful in identifying dexamethasone as the first proven life-saving therapy for hospitalized patients (~21% reduction of mortality)[11], and in identifying promising mAbs for pre- or post-exposure prophylaxis or as early treatment for non-hospitalized patients (preliminary results

[11] WHO Rapid Evidence Appraisal for COVID-19 Therapies (REACT) Working Group, Sterne JAC, Murthy S, Diaz JV, Slutsky AS, Villar J et al. Association between administration of systemic corticosteroids and mortality among critically ill patients with COVID-19: a meta-analysis. JAMA. 2020;324:1330-1341. doi: 10.1001/jama.2020.17023.

By March 2021, transform the treatment landscape by ***accelerating availability and use of dexamethasone*** *and* ***other medicines that prove effective, including monoclonal antibodies*** *(especially for LICs/LMICs)*

showing up to 80% relative reduction in hospitalization). Therapeutics Pillar partners have secured dexamethasone courses for up to 2.9 million patients in LMICs through an advance purchase agreement and have further secured initial mAbs production capacity for LMICs in 2021 and 2022.

While access remains limited, given the potential game-changing impact of mAbs therapy technologies, the Therapeutics Pillar is sharpening its focus on preparing the different pathways needed to support access to mAbs in LMICs, while monitoring the pipeline and maintaining flexibility to invest in and support other promising therapeutics.

The Therapeutics Pillar requires a total of **US$ 6.6 billion** through end-2021[12], of which **US$ 750 million is needed immediately to directly support LMIC access to mAbs including**:

- **Dosing and formulation research efforts** (US$ 200 million),
- **Market preparation for mAbs** usage in LMICs (US$ 110 million), and
- **Procurement of mAbs courses** for which 2021 capacity has been secured (US$ 320 million).

The remaining US$ 120 million includes:

- **Funds to support ongoing trial platforms** for ensuring the applicability of treatments to LMICs (including but not limited to mAbs – US$ 20 million), and
- **Flexible funding** to be leveraged for initial procurement conversations for assets with expected clinical readouts in early 2021 (US$ 100 million).

The Therapeutics Pillar investment case beyond March 2021 is built to enable flexible support for R&D, market preparation, and deployment at-scale for any therapeutics assets with positive clinical data (details in Appendix C).

Figure 6: The Therapeutics Pillar total funding gap is US$ 6.1 billion, of which US$ 0.75 billion is needed urgently

Pillar	Immediate Gap	Balance of 2021 Gap	**Total Gap**
Therapeutics	0.75	5.4	**6.1**

In US$ billion

[12] The Therapeutics Pillars anticipates a further US$0.6 billion may be required in 2022.

Vaccines

Securing agreements with manufacturers while investing in delivery preparedness and progressing vaccine candidate clinical trials

To date, 94 higher-income economies have already signed up to the COVAX Facility as self-financing members, joining 92 lower-income economies who will have their participation supported by the Gavi COVAX Advance Market Commitment (AMC). The COVAX Facility is the global mechanism to source COVID-19 vaccines, through which COVAX will ensure fair and equitable access to vaccines for each participating economy, using an allocation framework formulated by WHO. The COVAX Facility will do this by pooling buying power from participating economies and providing volume guarantees across a range of promising vaccine candidates, accelerating and securing doses from manufacturers whose expertise is essential to large scale production of the new vaccines – providing participating countries and economies with the best chance at rapid access to doses of a successful COVID-19 vaccine.

By early 2021, ***launch the rollout of safe, effective and quality-assured COVID-19 vaccines worldwide****, with an initial target of 2 billion doses secured by the COVAX facility*

The critical focus now is on securing agreements with manufacturers to: (i) invest in technology transfer, scale-up, and manufacturing reservation fees to increase global manufacturing capacity, and (ii) secure doses via Advance Purchase Agreements (APA) for all participating economies. At the same time, COVAX is urgently focusing on ensuring country readiness so that equitable delivery of vaccines for lower-income countries will be a reality. The inequity clock will start to tick as soon as high-income countries begin to use the first COVID-19 vaccine, which could be imminent.

In parallel, there remains a need for R&D financing to progress the most promising vaccine candidates to critical late stage clinical trials, to demonstrate they are safe and protect against COVID-19. With some candidates nearing phase 3 trial completion, the first vaccines may be available in the coming months. None of these will be available in sufficient quantities to supply the world, nor will the first products necessarily provide optimal protection and impact. Investments are needed for clinical trials of additional priority candidates to assure a portfolio of vaccines that can address the scope and magnitude of the pandemic.

By end the of 2020, the Vaccines Pillar requires at least US$ 1 billion for R&D, the Gavi COVAX AMC and delivery preparedness

The Vaccines Pillar requires a total of US$ 11.1 billion and has an outstanding funding gap of ~US$ 7.8 billion, of which at least US$ 1.0 billion is needed immediately before the end of 2020 for:

- **R&D** - US$ 261 million are needed by the end of the year with an additional ~US$ 0.8 billion early in 2021 to ensure CEPI is able to accelerate late-stage clinical trials for priority vaccine candidates, as well as to allow WHO to facilitate the global Solidarity phase III trial.

- **Gavi COVAX AMC** - The Gavi COVAX AMC aims to secure at least US$ 233 million in additional financing by end 2020, and will need at least an additional US$ 5 billion in 2021 to ensure that lower-income countries will have access to vaccines through the COVAX Facility.

- **Delivery preparedness** - For country readiness and delivery, including guidance, tools, coordination, technical expertise and support, US$ 492 million are needed now with an additional ~US$ 1 billion in 2021 to ensure the promise of R&D and the Gavi COVAX AMC for COVID-19 vaccines will be realized.

(details in Appendix D)

Figure 7: The Vaccines Pillar total funding gap is US$ 7.8 billion, of which US$ 1 billion is needed urgently

Pillar	Immediate Gap	Balance of 2021 Gap	**Total Gap**
Vaccines	1.0	6.8	**7.8**

In US$ billion

Health Systems Connector

A sharp focus on integrated country plans to address system bottlenecks, and critical health systems tools

The Health Systems Connector (HSC) focuses on cross-cutting aspects of health systems to support the rapid deployment of new COVID-19 tools as they become available. These include capacities and infrastructure that need to be radically scaled or upgraded to deploy COVID-19 tools (vaccines, therapeutics, and diagnostics), in addition to (non-product) system investments that will be required to complement the new tools. The HSC also aims to ensure sufficient supplies of essential Personal Protective Equipment (PPE) and medical oxygen in LICs/LMICs to protect frontline health care workers and to enhance the capacity of health systems to save lives.

Health system strengthening efforts are very country-specific and can only be addressed on that level. The HSC is supporting these critical efforts through a tailored country-context approach of translating global knowledge to address local problems. The primary role of the ACT-Accelerator HSC is not to provide a direct source of financing, but rather to promote a coordinated approach to implementation and follow-up to country readiness assessments, and link to the existing country projects and platforms of various partners, such as the World Bank's Multiphase Programmatic Approach (MPA).

By March 2021, ***unlock the health systems bottlenecks*** *to the scale-up and delivery of new and existing COVID-19 tools, including* ***vital supplies of PPE and Oxygen*** *for LICs/LMICs*

The Health Systems Connector requires US$ 1.7 billion by end January 2021 to prepare health systems & deliver impact

The immediate focus of the HSC is to help countries unlock the health systems bottlenecks that are hampering the delivery and implementation of new and expanded COVID-19 tools, through the following key activities:

- Support to countries on inclusive local processes for implementing **integrated country** readiness assessments to support the introduction of new COVID-19 tools,
- Development and delivery of guidance, products, tools, and technical support to countries to address identified gaps and **strengthen their capacities to deploy new COVID-19 tools effectively**,[13]
- Support for the **non-product investments** required to complement the COVID-19 tools, including in collaboration with ACT-A Pillars; and,[14]
- Accelerate availability of two critical tools not provided by the other pillars, **oxygen and personal protective equipment**, as high priority commodities.

The HSC requires a total of US$ 9.5 billion (of which US$ 1.6 billion is required in the near-term to facilitate access to PPE and oxygen). As country readiness is an absolute prerequisite to the equitable scale-up of other COVID-19 tools, US$ 89 million is needed urgently to support these health systems activities (details in Appendix F).

Figure 8: The Health Systems Connector total funding gap is US$ 9.1 billion, of which US$ 1.7 billion is needed urgently

Pillar	Immediate Gap	Balance of 2021 Gap	**Total Gap**
HSC	1.7	7.5	**9.1**

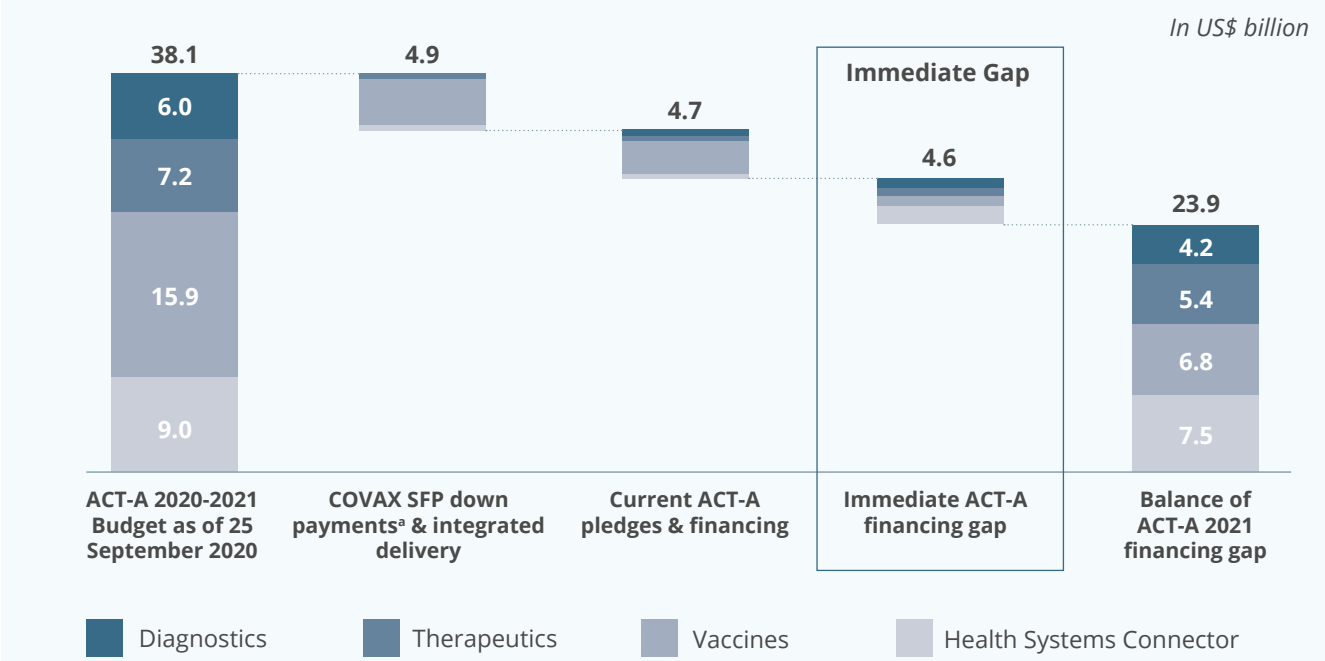
In US$ billion

[13] In addition to country preparedness activities led by the other ACT-A pillars.
[14] Service packages are being developed through 7 workstreams: Health finance, In-country supply chains, Data/health services monitoring, Protecting frontline health workers, Clinical care, Community responses and Private sectors.

While significant progress has been made in financing the ACT-Accelerator's overall budget of US$ 38.1 billion, urgent action is needed to address the immediate financing gap of US$ 4.6 billion and the remaining US$ 23.9 billion balance for 2021

The initial ACT-Accelerator investment case that was published in September 2020 outlined a total requirement of US$ 38.1 billion to fully fund the ACT-Accelerator to deliver on its promise. Since then, this overall envelope has been reduced through a combination of self-financing country commitments to the COVAX Facility, costing adjustments, and financial pledges. As of 1 November 2020, US$ 4.6[15] billion is urgently needed to accelerate immediate progress, and US$ 23.9 billion is needed to finance activities through the remainder of 2021 (see Figure 9).

Figure 9: Of the US$ 38.1 billion ACT-Accelerator budget, US$ 4.6 billion is urgently needed, with a balance of US$ 23.9 billion in 2021



[a] *COVAX Facility manufacturing and procurement cost for self-financing participants (SFP) financed via the respective Facility participation. Latest list of SFPs: https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_19-10.pdf.*

In Figure 9 above, the first column provides a recap of the total ACT-Accelerator Budget for 2020-2021 as detailed in the *ACT-Accelerator Economic Investment Case Financing Requirements*, released on 25 September 2020. The second column reflects the reduction in financing gap due to down payments to the COVAX Facility by self-financing participants and budget adjustments to facilitate integrated delivery of COVID-19 tools through the work of the HSC. The third column summarizes the ACT-Accelerator donor pledges and financing to date, as detailed in the *ACT-Accelerator Commitment Tracker*. The fourth column highlights the urgent investments needed to enable the full scale-up and positioning of the ACT-Accelerator to change the course of the pandemic. The final column provides an overview of the financing gap for the balance of the 2021 costs, including the large-scale procurement of new COVID-19 tools (e.g. self-tests and vaccines).

[15] including US$ 15 million in costs to support the ACT-A Hub and the design of the Global Allocation Framework.

LIST OF APPENDICES

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Appendix A – Pillar co-conveners & leads

The ACT-Accelerator draws on the expertise of multilateral and global health institutions, as well as close engagement with industry and innovators and manufacturers. Among these organizations, the ACT-Accelerator conveners bring world-class knowledge and know-how in R&D, manufacturing, policy, regulatory activities, market shaping, procurement and delivery.

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

The **Wellcome Trust** and **Unitaid** are co-conveners for the **Therapeutics Pillar**. 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. 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 also ensures access to critical health products women and children, making it a world-class downstream convener for Therapeutics.

FIND and the **Global Fund** are co-conveners for the **Diagnostics Pillar**. FIND, a global diagnostics alliance, has over 17 years of deep technical and practical experience in the definition of needs, development of fit-for-purpose products, generation of evidence for regulators and policymakers, analysis of market dynamics, the introduction of new products, and strengthening of laboratory systems. FIND has been instrumental in the development of 24 new diagnostic tools, and over 50 million FIND-supported products have been provided to LMICs in the last 5 years. 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. 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.

The **World Bank**, the **Global Fund** and **WHO** are co-conveners for the **Health Systems Connector**. The World Bank works to help nations build healthier, more equitable societies and to improve fiscal performance and country competitiveness. Over the last decade, the International Development Association (IDA) has provided $US 13.5 billion 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 health systems strengthening. The World Bank has mounted the largest, broadest and fasted financing platform for supporting countries in the emergency COVID-19 health response, including through its Global Health Multi-Phase Approach program, approving $7.6 billion for 111 countries within 3 months, as part of its $160 billion broad commitment to addressing the global pandemic over the next 15 months. WHO is the leading and directing authority for global health within the UN and international health and development system.

WHO is leading ACT-Accelerator's work on global **access and allocation** and regulatory processes (including WHO prequalification). WHO also co-leads all of the product Pillars, providing normative, policy and technical guidance for the development of Pillar-specific deliverables (e.g. clinical use guidelines for each of ACT-Accelerator products). WHO also hosts the **ACT-Accelerator Hub** which is facilitating and coordinating work across the Pillars and Health Systems Connector.

Appendix B
ACT-A Diagnostics Pillar near-term and overall deliverables & funding gaps

In US$ million	Main deliverables	Urgent needs[1]		Balance of 2021 Gap		Totals		
		Target	Gap	Target	Gap	Target	Confirmed	Gap
Innovation & capacity building	Drive development, wide availability and affordability of **transformative, easy-to-use and digitally connected tests, including self-tests**[2]	200	146	200	200	400	54	346
	Build in-country capacity & capabilities by strengthening laboratories and training healthcare workers and lab technicians	225	171	225	225	450	54	396
	Conduct operational research, including innovation delivery models, to support country policies, ensuring effective uptake	75	47	75	75	150	28	122
Delivery & Impact	**Procure 85m** tests to cover immediate LMICs need; **500m for 12 months**	1300	761	3700	3700	5000	539	4461
TOTAL		**1800**	**1125**	**4200**	**4200**	**6000**	**675**	**5325**

[1] Urgent needs milestones are until end of February 2021; [2] Includes evaluation studies directed by FIND, as well as Target Product Profiles, International Standards & Emergency Use Listing (EUL) process by WHO

Appendix C
ACT-A Therapeutics Pillar near-term and overall deliverables & funding gaps

In US$ million	Urgent needs[1]		Balance of 2021 Gap		Totals		
	Main deliverables	**Gap**	**Main deliverables**	**Gap**	**Target[10]**	**Confirmed**	**Gap**
Innovation & Capacity Building	R&D *(e.g., trials for mAbs, LMIC work; incl. Anticov trial)*	220[2]	R&D *(for mAbs, novel antivirals, and repurposed therapeutics)*	600[8]	1120	300	820
	Procurement[3] *(2021 mAbs supply from Fuji capacity reservations)*	320[4]	Procurement[3] *(rapid response to positive clinical data; 25% of total procurement ask)*	1100	1420	0	1420
	Manufacturing scale-up *(Fuji mAbs capacity reservation[5])*	0	Manufacturing scale-up *(incl. remaining 2022 mAbs capacity payment & other activities as needed)*	200[9]	340	140	200
	Market preparation[6]	110	Market preparation *(activities depending on candidate needs)*	200[9]	310	0	310
Delivery & Impact	Procurement[3] *(for Tx supported by positive clinical data that become recommended for use in COVID-19)*	100[7]	Procurement[3] *(for Tx supported by positive clinical data that become recommended for use in COVID-19; 75% of total procurement ask)*	3300	3400	0	3400
TOTAL		**750**		**5400**	**6590[11]**	**440**	**6150**

[1] Urgent needs milestones are until end of February 2021; [2] $20M to replenish Unitaid bridge funding for Anticov trial; $200M for support of 5-10 additional mAbs trials; [3] Including funding of activities related to procurement preparation and distribution; [4] Assuming upper-range procurement cost estimate for 4M mAbs courses at $80 per treatment course; [5] Payments made to-date covering 2021 mAbs capacity reservation cost and partial 2022 mAbs capacity reservation cost; [6] Covering operational research, early market introduction registration support, capacity mapping, demand forecasting, and licensing / deep tech transfer as relevant; [7] Assumed funding required on hand to begin procurement discussions with manufacturers, for procurement to begin Q2 2021+; based on proportional costs for mAbs capacity reservations; [8] Based on analog of spend from Tx Accelerator (excl. $0.6B to be spent in 2022); [9] $400M funding needs equally split across manufacturing scale-up (e.g., volume guarantees, market shaping) and market preparation (e.g., operational research, demand forecasting); exact split between these deliverables pending requirements from relevant candidates with positive clinical data and interplay between demand / supply side partners; [10] Funding estimates based on upper range boundaries for procurement and market preparation activities; [11] Excluding $0.6B R&D funding to be spent in 2022.

Appendix D
ACT-A Vaccines Pillar near-term and overall deliverables & funding gaps

In US$ million	Main deliverables	2020 needs		2021 needs		Totals	
		Target	Gap	Target	Gap	Target	Gap
Innovation & capacity building	Ensure support and funding for **research and clinical trials to accelerate vaccine development to licensure**	1517	220	600	600	2117	820
	Facilitate **global Solidarity phase III trial** for up to 10 vaccine candidates	77	41	248	248	325	289
	Support **NRAs and regulatory networks** as well as **oversight of regulatory activities**	1	1	7	7	8	8
	Invest **upfront in manufacturers** to reserve doses now and **procure doses** post-approval **for the 92 AMC eligible economies (COVAX AMC**[1]**)**	At least 2000	233	At least 5,000	5000	At least 7000	5233
	Ensure **global, fair and equitable allocation**, incl. creation of **global ethical guidelines**, and **provide policy guidance**	<1	<1	2	2	2	2
Delivery & Impact	Ensure **country readiness and equitable delivery** of vaccine for low-income countries	543	453	981	981	1524	1434
	Provide **global, regional and country level technical support** as well as mobilize expertise	99	39	-	-	99	39
TOTAL		**4237**	**987**	**6838**	**6838**	**11075**	**7825**

Excluding COVAX Facility costs financed by self-financing participants (SFP)[2]

[1] The COVAX Advance Market Commitment (AMC) is the financing instrument that will support 92 lower-middle and low-income economies in the COVAX Facility. Latest list of pledges made to AMC: https://www.gavi.org/sites/default/files/covid/covax/COVAX-AMC-Donors-Table-08.10.2020.pdf; [2] COVAX Facility manufacturing and procurement cost for self-financing participants (SFP) financed via the respective Facility participation. Latest list of SFPs: https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_19-10.pdf.

Appendix E
ACT-A Health Systems Connector near-term and overall deliverables & funding gaps

In US$ million	Main deliverables	Urgent needs[1]		Balance of 2021 Gap[2]		Totals		
		Target	Gap	Target	Gap	Target	Confirmed	Gap
Innovation & capacity building	Innovation, training, and management systems	50	50	0	0	50	0	50
	Innovation, training, and management for O_2	50	50	0	0	50	0	50
	Infection prevention and control (IPC) for health facilities[3]	10	10	92	92	102	0	102
	Supply Chain[3]	0	0	198	198	198	0	198
	Global coordination costs	89	89	100	100	189	0	189
	Community response[3]	0	0	200	200	200	0	200
	Clinical Care[3]	0	0	211	211	211	0	211
Delivery & Impact	Basic and full PPE procurement[4]	1480	1178	5420	5420	6900	302	6598
	O_2 procurement[4]	340	340	1260	1260	1600	-	1600
TOTAL		**2019**	**1717**	**7481**	**7481**	**9500**	**302**	**9198**

[1] Urgent needs milestones are until end of January 2021.
[2] Numbers represent initial estimates and will be further refined based on country assessments and plans.
[3] These amounts are catalytic funds that represent only a fraction of the entire need.
[4] These costs exclude domestically resourced procurement.

Gavi
The Vaccine Alliance

CEPI

World Health
Organization

wellcome

BILL & MELINDA
GATES foundation

FIND
Because diagnosis matters

The Global Fund

Unitaid