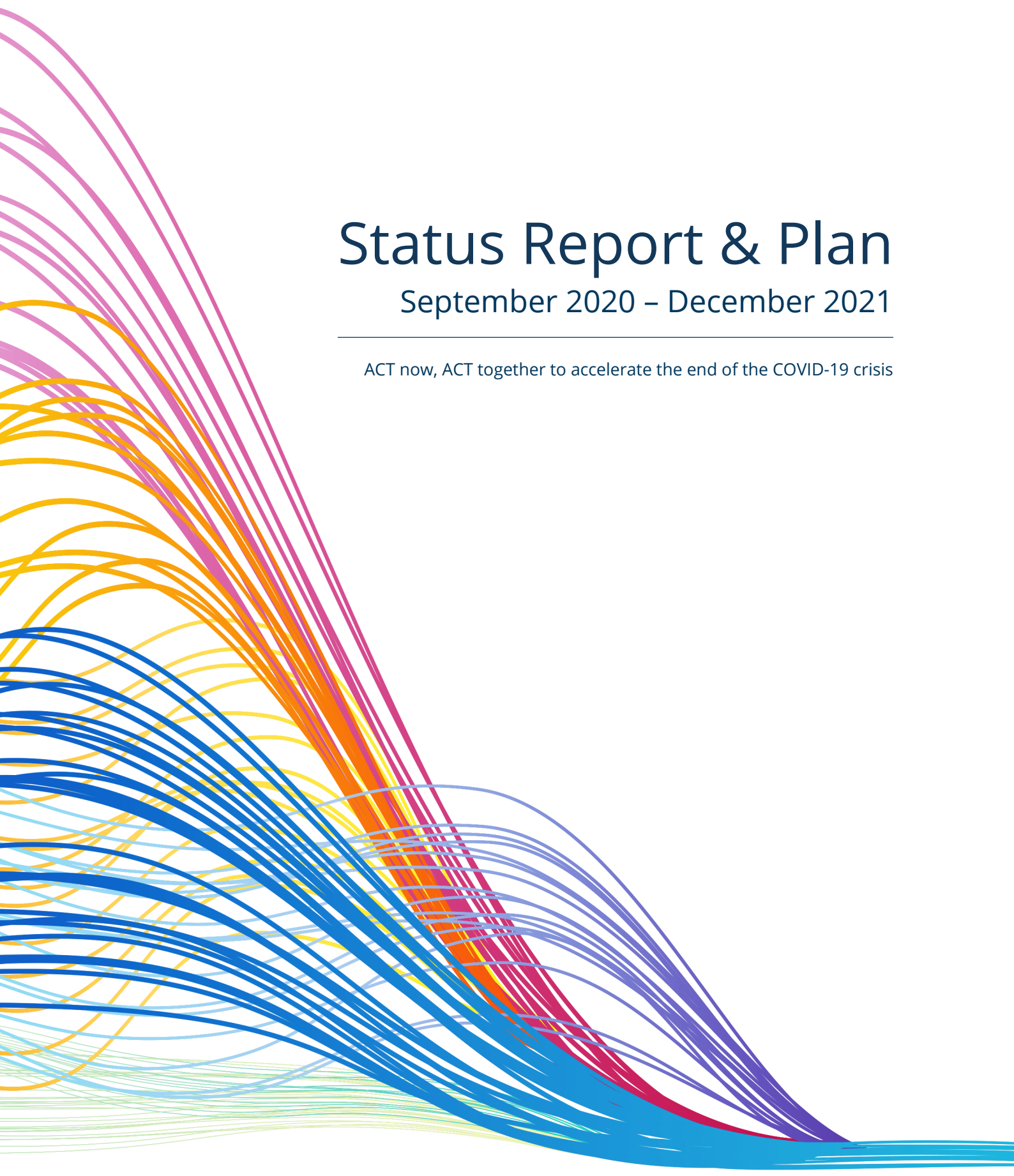
ACTaccelerator
ACCESS TO COVID-19 TOOLS

Status Report & Plan

September 2020 – December 2021

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



25 September 2020

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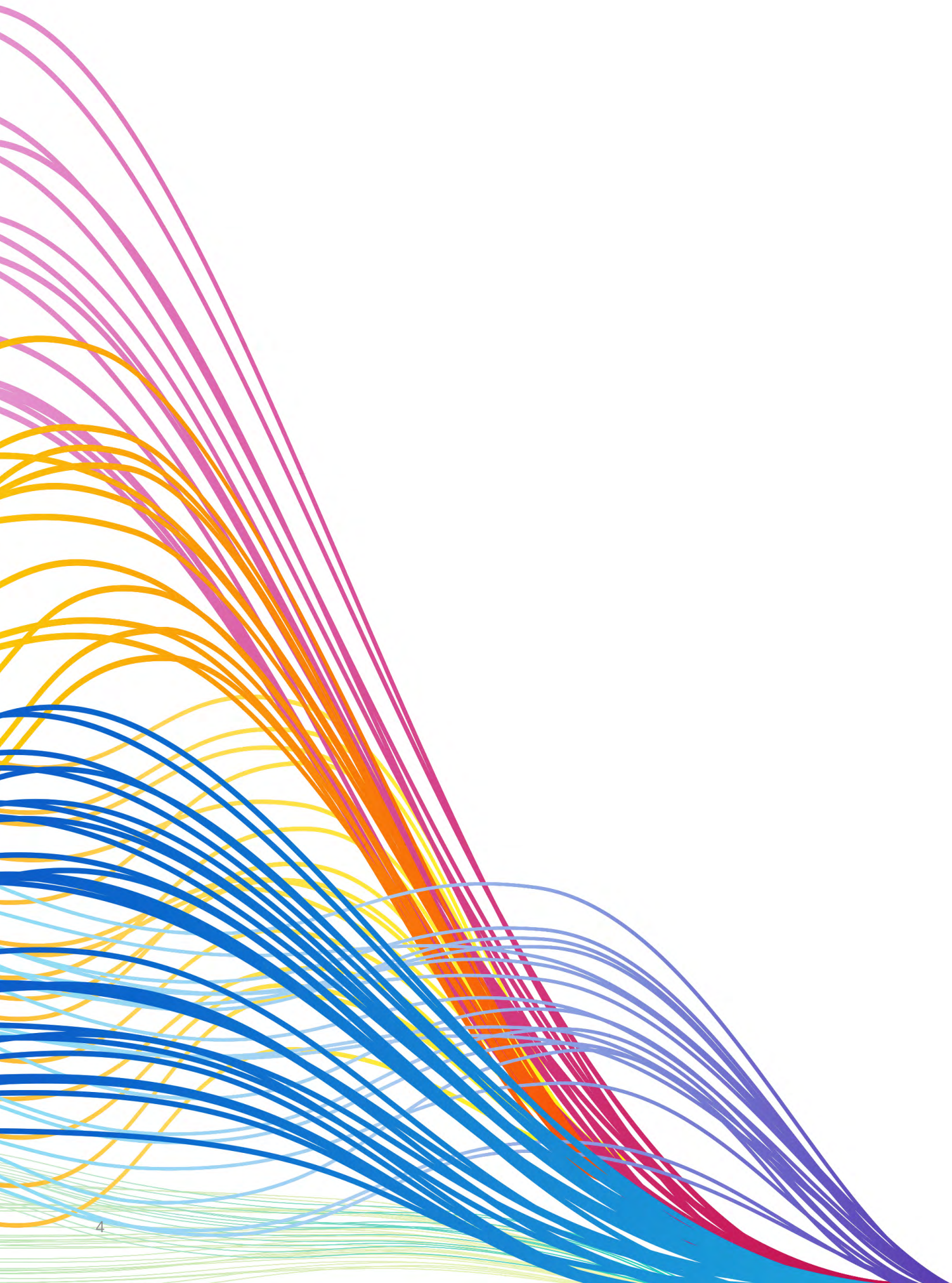

01

PURPOSE OF THIS DOCUMENT

This document outlines the aspiration, achievements to date, and plan for the Access to COVID-19 Tools Accelerator (ACT-Accelerator). It is complemented by an Investment Case document that provides an economic rationale for investing in ACT-Accelerator and gives an overview of the funding requirements for each of the Pillars and Health Systems Connector.

This document ("ACT-Accelerator Status Report & Plan") has four main objectives:

1. Reaffirm what ACT-Accelerator was set up to achieve

2. Present ACT-Accelerator's accomplishments to date

3. Outline the immediate priorities on the critical path

4. Highlight the step changes required for ACT-Accelerator to move from start-up to impact

The ACT-Accelerator Status Report & Plan will be updated as work progresses, and as knowledge about the global pandemic and the efficacy of tools available to fight it develops.

02

EXECUTIVE SUMMARY

COVID-19 is a human, social, and economic tragedy that, as of 23 September 2020, has cost more than 960,000 lives globally and will contract global GDP by $US 7 trillion in 2020.[1]

Approaches taken so far have relied on testing strategies that have been limited by quality, availability and accessibility, coupled with societal interventions such as physical distancing, hand washing and mask wearing. These approaches have been effective in flattening the curve to lower the burden on health systems and reduce morbidity and mortality – but they are not a sustainable solution. Stringent physical distancing measures come at a very high cost, essentially freezing social and economic life around the world, and in many low- and middle-income country settings they cannot be executed effectively.

Only by tackling the pandemic itself, globally, and at the same time, will lives and livelihoods be restored and catastrophe in the poorest countries averted. Unless it is defeated everywhere, COVID-19 can still strike anywhere.

ACT-Accelerator was launched on 24 April 2020, with the vision of creating a global solution to expedite the end of the COVID-19 pandemic. Uniquely, ACT-Accelerator combines public and private sector expertise and institutions from around the world to accelerate the development, regulatory approval, scale-up, delivery and equitable allocation of COVID-19 tests, treatments and vaccines.[2]

ACT-Accelerator has ambitious targets: to provide 2 billion vaccine doses to the world by the end of 2021, 245 million courses of treatment and 500 million diagnostic tests to LMICs in 2021.

Ensuring global equitable allocation is key. Unless effective tools are made available to all, populations and health systems will remain at risk and the globally interconnected economy we all depend on will not be able to fully recover. Lack of confidence in public safety and future prospects will further delay the resumption of social and economic activity in the short-term, and potential subsequent waves may cause even more economic and humanitarian losses.

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[1] World Bank Global Economic Prospects – Pandemic, Recession: The Global Economy in Crisis, https://www.worldbank.org/en/publication/global-economic-prospects

[2] It was preceded by a Vaccine Development and Financing Task Force, co-convened by CEPI and the World Bank with participation of WHO, GAVI, Bill & Melinda Gates Foundation, Wellcome Trust and others.

Within just 5 months of its launch, ACT-Accelerator has harnessed the international public health ecosystem in a nimble structure that is already delivering concrete results, accelerating the development and testing of vaccine candidates, evaluating over 50 new diagnostics and supporting the development of urgently needed rapid tests, scaling up a new treatment for severe COVID disease, and establishing increasing consensus on the global allocation of these products.

ACT-Accelerator has a fully costed global plan. It is the only global initiative offering an ambitious end-to-end solution that covers critical activities (i.e. R&D, manufacturing, regulatory assessment and pathways, procurement, and delivery) for essential tools needed to expedite the end of the pandemic.[3]

The period of September to December 2020 presents a crucial, time-limited window of opportunity to scale-up and transition ACT-Accelerator out of its start-up phase and to position it for global impact. By December, we will have a much firmer understanding of which treatments and vaccines may have early success.

During this critical period, ACT-Accelerator must ensure that manufacturing capacities are set up, safety and quality are assured, procurement agreements are established, health systems are geared up for the safe and effective delivery of new tools and innovations, and that fair and concrete allocation mechanisms are in place.

To realize ACT-Accelerator's goal of ending the acute phase of the pandemic, $US 38 billion is required. This is a fraction of what governments have already spent on domestic stimulus to mitigate the consequences of the first wave ($US 10.7 trillion). While $US 2.6 billion has been mobilized to enable ACT-Accelerator's start-up phase, there is now an urgent need to secure the remaining $US 35 billion needed to enable it to scale up for global impact.

In addition, an increasing number of bilateral and multilateral deals for scarce products (e.g. vaccines) are putting equitable allocation, and a global health and economic solution, at risk.

ACT-Accelerator now needs an urgent step change in investment and advocacy to deliver on its promise. Funding and advocating for ACT-Accelerator and fully enabling the equitable allocation framework will be vital to ensure that the health, societal and economic costs of the pandemic in 2021 are lower than those in 2020.

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[3] Fully exploiting this solution requires additional country-level investments to optimise delivery

03

WHAT ACT-ACCELERATOR AIMS TO ACHIEVE

The world is facing an unprecedented challenge in COVID-19, and the case for bringing a rapid end to the acute phase of this crisis cannot be overstated. Current approaches have relied on testing strategies that have been limited by quality, availability and accessibility, coupled with societal interventions such as stringent physical distancing measures, hand washing and mask wearing. These measures, particularly physical distancing measures, come at an enormous cost – effectively freezing social and economic life around the world – and are not a sustainable solution for ending the pandemic.

ACT-Accelerator was launched on 24 April 2020, building on the commitment made by G20 leaders to the Coronavirus Global Response on 26 March in order to present a united front against the pandemic. Its vision is to create an end-to-end global solution to expedite the end of the COVID-19 pandemic by developing, scaling and enabling equitable global access to tests, treatments and vaccines needed to reduce the severity of COVID-19 disease.

Accelerating the development of new tools

Primary reliance on societal measures such as stringent physical distancing has proven virtually impossible to uphold, and even unimplementable in some settings. Moreover, these measures do nothing to address the fear and lack of public confidence brought about by the pandemic. Instead, the root causes of the crisis – the severity of impact of the virus – must be confronted in order to overcome the health and economic challenges the pandemic has created.

The world urgently needs to be equipped with effective tools that can end this COVID-19 crisis rather than simply alleviate its consequences. Releasing the virus' grip on society and improving public health will require an integrated solution.

Simple, high-quality, affordable rapid diagnostic tests are needed to detect the disease, interrupt transmission chains and enable targeted use of treatments to avert severe disease. Treatments will be needed to prevent transmission and reduce the severity of disease. Vaccines need to be deployed to induce immunity in populations, protect from disease and death and ideally suppress transmission. Finally, personal protective equipment (PPE) and oxygen needs to be available and deployed in health systems to enable all other tools to be safely and effectively deployed.

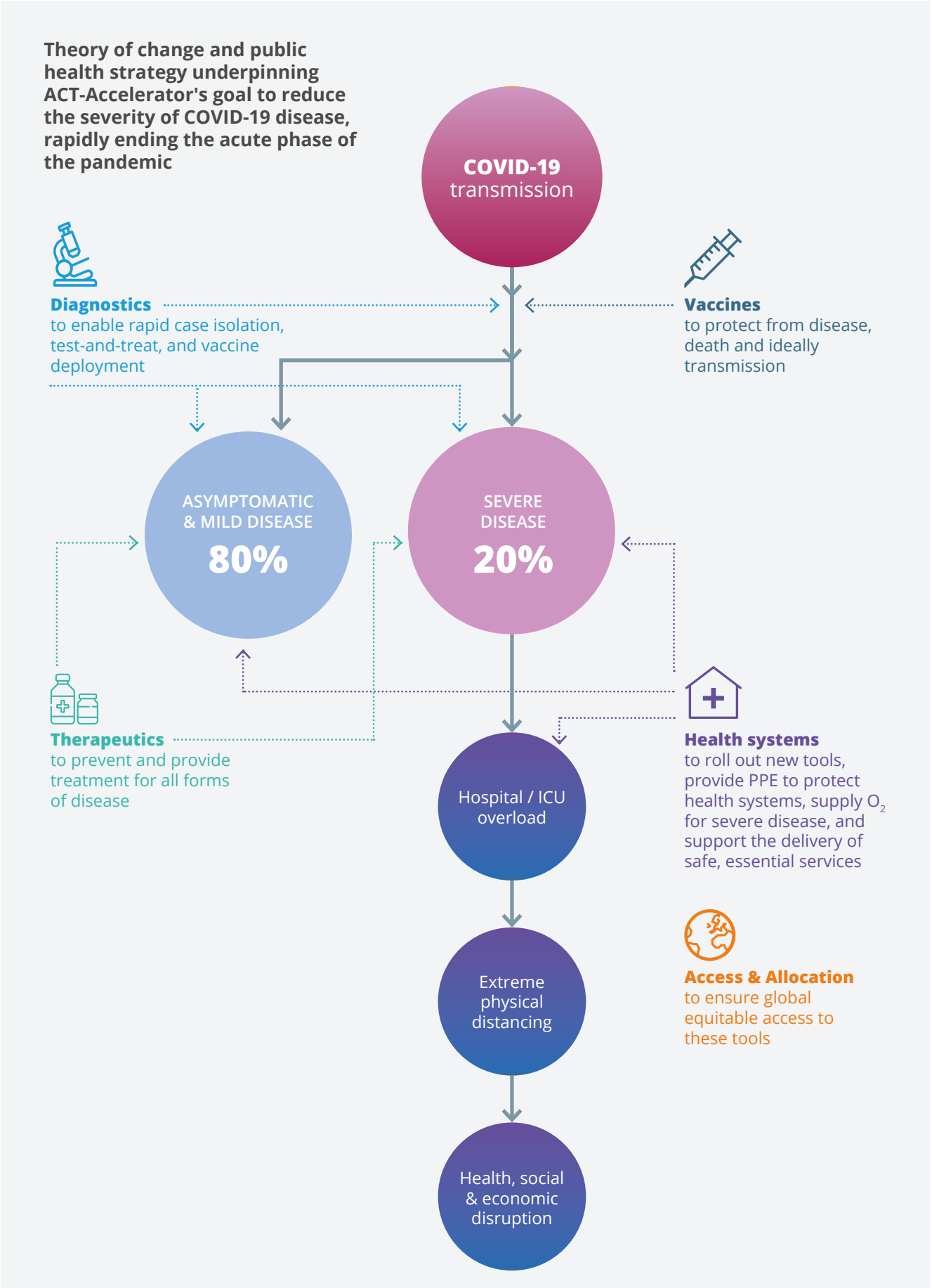

Theory of change and public health strategy underpinning ACT-Accelerator's goal to reduce the severity of COVID-19 disease, rapidly ending the acute phase of the pandemic
COVID-19 transmission
Diagnostics to enable rapid case isolation, test-and-treat, and vaccine deployment
Vaccines to protect from disease, death and ideally transmission
ASYMPTOMATIC & MILD DISEASE 80%
SEVERE DISEASE 20%
Therapeutics to prevent and provide treatment for all forms of disease
Health systems to roll out new tools, provide PPE to protect health systems, supply O_2 for severe disease, and support the delivery of safe, essential services
Hospital / ICU overload
Extreme physical distancing
Access & Allocation to ensure global equitable access to these tools
Health, social & economic disruption

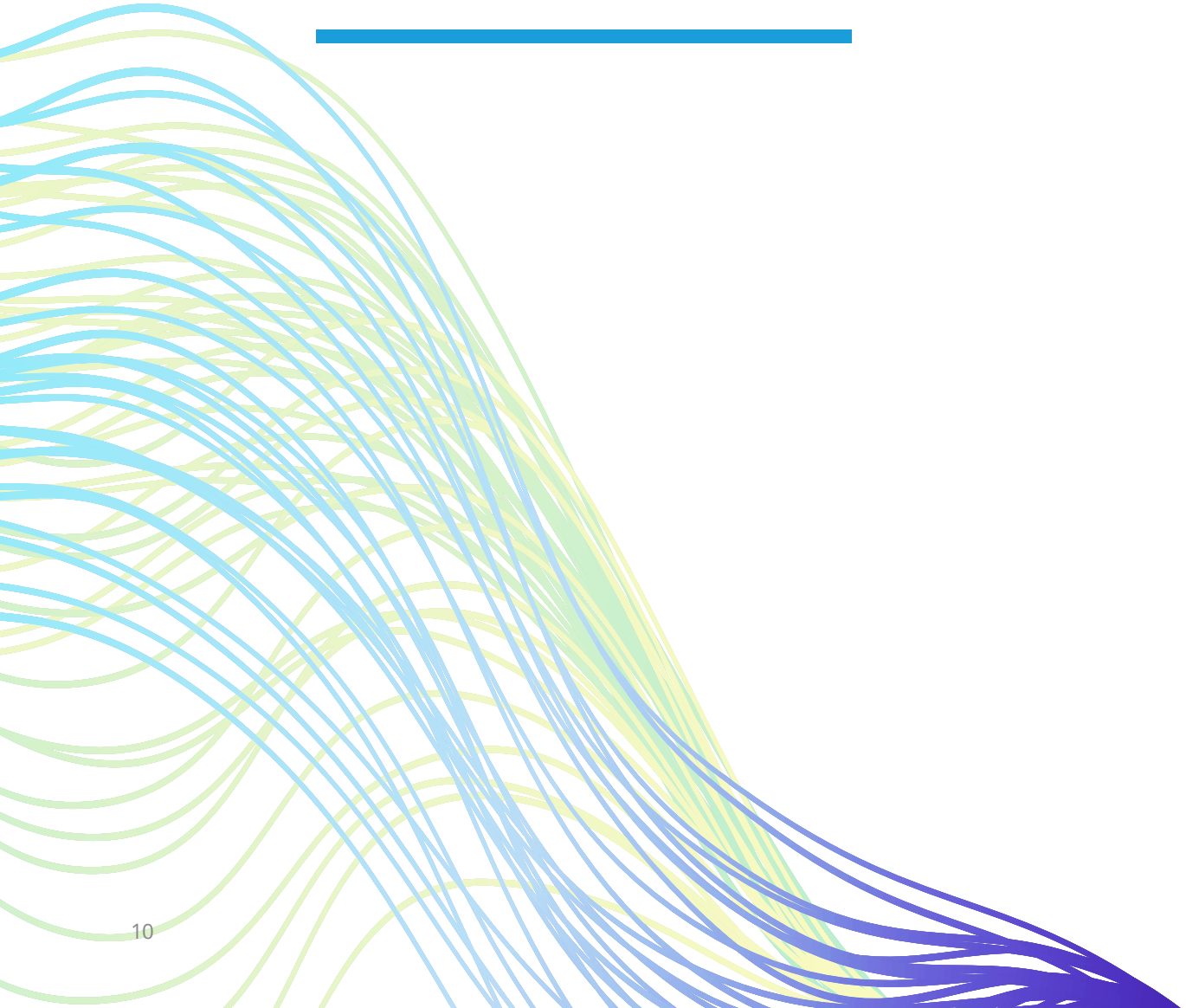
Figure 1

Together, these tools can reduce the severity of COVID-19 disease in the short term and facilitate high-level control of the disease in the medium term. This will reduce pressure on health systems, ensure that stringent physical distancing measures can be relaxed safely and restore public confidence, thereby enabling economies and societies to recover.

Why is ACT-Accelerator well placed to accelerate development of COVID-19 tools?

ACT-Accelerator is built on the philosophy that no country can beat COVID-19 alone. By focusing investments globally, ACT-Accelerator shapes the market for tools and incentivizes manufacturers to invest in development and manufacturing of critical tools, while enabling governments to access a portfolio that spreads the risk of failure of individual candidates, as well as access to other tools should one of them prove not to be viable. It also shares the reward of complex test, treatment and vaccine development programmes in multiple geographies and across multiple technical platforms.

While clear progress is being made, available rapid diagnostic tests are not yet as accurate as we need them to be, and despite encouraging success on new therapeutics, we are still lacking sufficient effective treatments for COVID-19. Of the more than 200 vaccine candidates under review, many will fail. Identifying and developing appropriate and viable COVID-19 tests, treatments, and vaccines will require large investments at a high level of risk. Given the need to deploy these tools together, countries would either need to make several individual high-risk bets or collaborate to support a portfolio of tools.



Catalyzing and scaling access to tools

The development of new COVID-19 tools will not be enough on its own. These tools need to gain regulatory approval quickly and be manufactured at scale so that they are readily available when and where they are needed. Moreover, health systems must be ready to adopt them in their battle against COVID-19. Currently, access to key commodities and tools, such as PPE and oxygen, and bottlenecks in key areas of health systems, such as financing, data, workforce, clinical care, and supply chains, are all limiting factors to effective deployment of COVID-19 tools, especially in LMICs. Finally, local communities must have confidence in their safety and effectiveness to ensure uptake and the private sector must be engaged globally and locally.

Why is ACT-Accelerator the right solution to scale access to tools?

ACT-Accelerator is an ambitious investment that can catalyse access to safe, efficacious and affordable tools on a global scale, by bringing together the R&D, manufacturing, regulatory, commercialization, procurement and delivery efforts needed. This end-to-end integration makes innovative approaches possible. For example, procurement can be used as an acceleration motor early on by leveraging pooled resources as a demand guarantee to sustain R&D and manufacturing, and to obtain affordable tools at the scale required.

The ACT-Accelerator partnership convenes leading organisations with the expertise to bring these efforts to bear, as well as the in-country presence and experience to roll out these tools at scale. Together, the partners can also accelerate acceptance and bring legitimacy to the process to increase public confidence in the safety and efficacy of these tools.

To overcome these barriers, governments and markets must be urgently prepared to accelerate implementation as soon as viable new products become available, and to enable delivery of COVID-19 tools to those who need them most. This requires significant resources across the value chain – more than most countries could and should pay individually.

Enabling global equitable allocation

COVID-19 needs to be addressed at the global level in order to protect the global economy, ensure sustained reduction in cases, and restore confidence in public safety and future prospects. We know that as long as anyone is at risk from this virus, the entire world is at risk. Even when there is a low case count, economies are struggling to revive global sectors such as airlines, tourism, commodities, and manufacturing as overseas trading partners are in the depths of the pandemic and their own domestic shocks. Lack of confidence in the future will also hold back economic recovery. In the end, due to the interdependencies of our societies and economies, no country can recover until all of them do.

What role can ACT-Accelerator play in enabling equitable allocation?

ACT-Accelerator aims to facilitate fair and equitable global allocation of tools to ensure nobody is left behind. ACT-Accelerator offers an integrated and global approach so that all safe and effective tools to fight COVID-19 can be deployed as fast as possible to all those in need, not only to those who can pay the most.

On a broader note, the investments made by ACT-Accelerator into strengthening health systems infrastructure and service delivery in LMICs will have positive long-term implications for global health (e.g. protecting the gains of recent decades in key diseases such as Tuberculosis). Indirectly, this will also benefit all countries; as inequalities reduce, future global health threats can be better managed.

ACT-Accelerator goals are supported by concrete targets

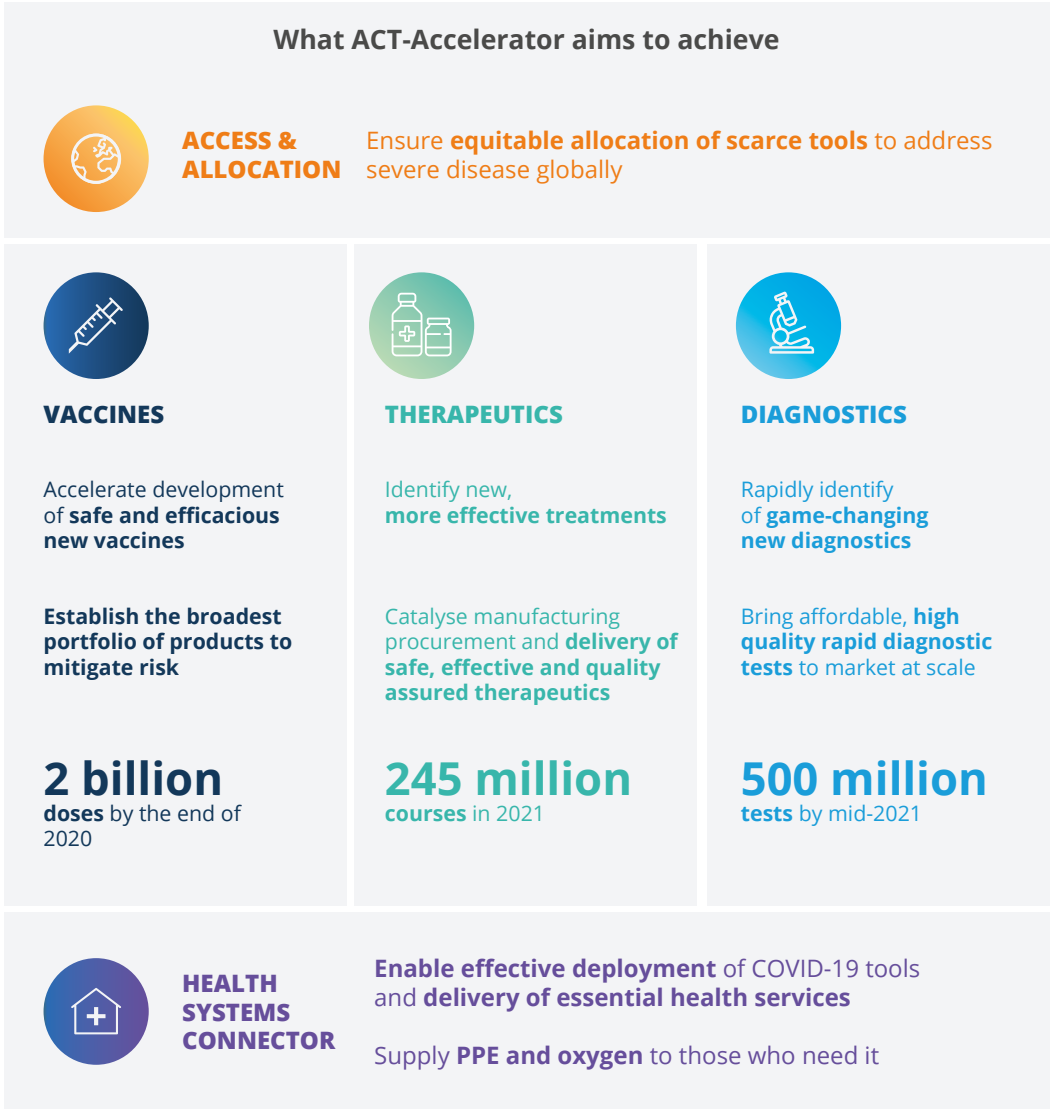


Figure 2

ACT-Accelerator 's ambitious goal to accelerate the end of the crisis is supported by concrete targets.

These targets are not an end in themselves – the path to achieving them will in itself deliver other novel tools and approaches that will boost the overall global COVID-19 response. It will also leave a legacy of stronger global health action beyond this pandemic.

Vaccines: ~2 billion doses of vaccines fairly distributed by the end of 2021

Development of vaccines is usually long, complex, risky and expensive. The vast majority of vaccines in early development fail. There are also significant supply constraints. When a new COVID-19 vaccine is successfully developed there will be greater demand than there is supply. Excess demand and competition for supply is already creating a disorderly market subject to price gouging as individual buyers (national governments) seek to secure scarce resources for themselves, with those most able to make upfront financial commitments at a distinct advantage. This is the kind of market failure that only a globally coordinated approach can solve.

ACT-Accelerator's main goal in the context of vaccines is to accelerate access to vaccines for all countries and provide them with enough to immunize health care workers and the vulnerable in 2021 (i.e. ~2 billion doses).

Goals include supporting the development of the most promising candidates while, in parallel, securing supply, scaling up manufacturing capacity, establishing an allocation mechanism, formulating vaccine use policy, and rapidly establishing the readiness for delivery at scale. Other critical goals include working to ensure that regulatory conditions and coordination are in place to allow the smoothest, most efficient, and safest transitions between early stages of development through to licensure, large-scale use and long-term safety and post-deployment impact monitoring. Given the rapid development of these vaccines, the post-authorization monitoring in the routine use setting is critical for further guiding their optimal use.

Therapeutics: ~245 million treatment courses delivered to LMICs in 2021

Therapeutics can play a role in all stages of the disease: to prevent infection in most-at-risk groups, to suppress and prevent symptoms and the spread of infection to others; to treat mild disease and prevent progression to moderate or severe symptoms; to speed up recovery and save lives for severe disease cases. Even when an effective vaccine exists, COVID-19 cases will continue to occur and require treatment as vaccines may not protect all population groups (e.g. the elderly), some people will not take them, and for others it may not provide 100% protection.

ACT-Accelerator's main goals in the area of therapeutics are to accelerate the development of new, safe and effective therapeutics of assured quality, appropriate for all countries including LMICs; and to ensure manufacturing, procurement and delivery of successful candidates for LMICs.

Diagnostics: ~500 million simple, accurate and affordable diagnostic tests used in LMICs by mid-2021

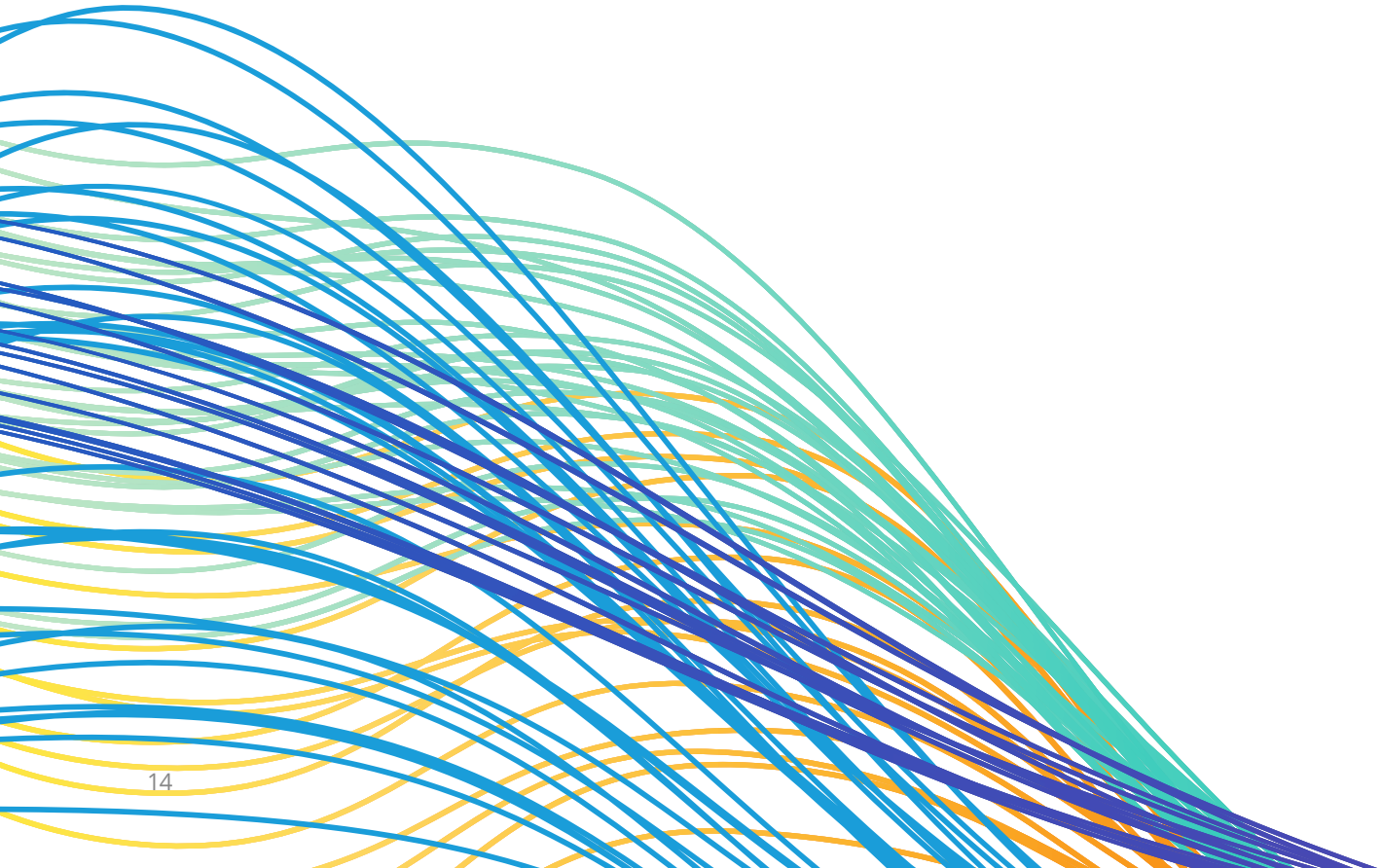
Diagnostics to help control the pandemic are in our hands today. Widely available tests are a prerequisite for fully resuming international mobility, travel and trade, but there is a clear danger that LMICs will miss out. Diagnostic capacity is also critical to enabling test-and-treat strategies, and roll out of targeted vaccination campaigns.

The main goal of ACT-Accelerator in the area of diagnostics is to enable access to simple, accurate and affordable tests which will be game changers for the COVID-19 response. This will include developing 2–3 affordable, well-performing antigen (Ag) rapid diagnostic tests (RDTs), and building a supplier base to meet global needs with substantial price reductions. Furthermore, 500 million tests will be procured for LMICs for the next 12 months, and laboratories will be strengthened in 20+ countries to support the operational introduction of these new types of tests.

Establishing equitable access to simple, accurate and affordable diagnostic tests will save 9 million lives and avoid 1.6 billion further infections.

Health Systems Connector: support the delivery of existing and new COVID-19 tools and safe, essential health services, including by strengthening the provision of PPE and oxygen

Lessons from previous epidemics have highlighted that alongside the development of innovative tools, it is essential to strengthen health systems and capacities to ensure that interventions can be deployed and delivered to ensure access and mitigate the collateral impact on other health outcomes.



The vision for a Health Systems Connector is to act as a "connector" between the three Pillars. ACT-Accelerator's main goal under the Health Systems Connector is to make two critical tools not provided by the other pillars – oxygen and personal protective equipment – available as high priority commodities. In addition, the connector aims to support countries to build the required capacity and support health systems to deploy new tools effectively and efficiently when available.

Countries will be supported on key enablers, such as community engagement, front-line service delivery capacity, supply chains, integrated monitoring of service capacity in highly affected countries, health financing, private sector engagement and integrated clinical care. Further details will be worked out in a road map.

Health system strengthening efforts are very country specific and are better addressed at that level. The adequate resourcing of those enablers is critical, and they should receive support through complementary funding channels including the national Strategic Preparedness and Response Plans[4] and the United Nations Global Humanitarian Response Plan[5]. Knowledge-sharing, coordination and best practice transfers between countries will help to develop more effective responses.

Access & Allocation: Attain a fair and equitable allocation

The main objective of this workstream is to enable equitable access and fair allocation of COVID-19 tools through the recognition of overarching principles, a global allocation framework, and product-specific mechanisms to allocate each of the tools where they are needed the most. This will allow vulnerable groups and others to get the protection and help they need, wherever they are. This global allocation will also be key to enabling economic recovery, which will only be possible if all interconnected economies are able to restart.

[4] Strategic Preparedness and Response plan: https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus
[5] United Nations Global Humanitarian Response Plan: https://www.unocha.org/sites/unocha/files/GHRP-COVID19_July_update.pdf

04

ACT-ACCELERATOR IMPACT TO DATE

Within just 5 months of its launch, ACT-Accelerator's start-up phase has proven its potential and importance. It has harnessed the international public health ecosystem in a nimble structure that is already delivering concrete results by accelerating access to new tools, and by establishing increasing consensus on their fair and global allocation.

A bold structure driving unprecedented collaboration

Ending the pandemic requires a strong and coordinated response from institutions across and beyond the global public health sphere. ACT-Accelerator is not only an unparalleled effort in joining governments, scientists, businesses, civil societies, and philanthropists, but it also brings together leading partners in the development and deployment of novel tests, treatments and vaccines to fight the pandemic. With these close partnerships, ACT-Accelerator has reshaped the global public health architecture, and promoted the technological advancement of the tools it is invested in.

ACT-Accelerator joins four Pillars (Vaccines, Therapeutics, Diagnostics and the foundational Health System Connector) with a support structure in a nimble collaboration (Figure 3).

Additionally, cross-cutting workstreams further facilitate the work of the Pillars, such as Access & Allocation, that aims to ensure equitable access to tools across ACT-Accelerator, as well as support on topics such as norms & standards, regulatory/prequalification, and policy & technical guidance.

ACT-Accelerator is a bold structure, driving unprecedented collaboration
World Health Organization
Gavi
The Vaccine Alliance
CEPI
FIND
Because diagnosis matters
ACCESS & ALLOCATION
VACCINES
DIAGNOSTICS
Working with:
GOVERNMENTS
CIVIL SOCIETY
INDUSTRY
THERAPEUTICS
The Global Fund
Unitaid
HEALTH SYSTEMS CONNECTOR
WORLD BANK GROUP
wellcome

Figure 3

The Pillars are co-convened from 9 leading partners, who drive the product work and are fully responsible and accountable for implementing Pillar scopes of work. ACT-Accelerator leverages the existing public health infrastructure, with each partner being a key player in their respective domain – access to R&D (CEPI, FIND, Wellcome), regulatory and standard setting expertise (WHO), procurement experience (Unitaid, The Global Fund, Gavi), as well as Health Systems and Delivery (World Bank, WHO and others).

Formal governance for the Pillars is provided by the Boards and governing bodies of the co-convened delivery partners. ACT-Accelerator is not a new legal or decision-making entity and is envisaged to be ramped-down after ~18 months.

Finally, ACT-Accelerator has been set up as a light and simple support structure. It enables the work of the delivery partners and facilitate cross-cutting knowledge sharing, rather than constituting a formal governance mechanism. Additional ACT-Accelerator supporting structures include the ACT-Accelerator Facilitation Council (composed of government members that represent regional and economic cooperation groups, founding donors of ACT-Accelerator, and market shapers, with non-government partners and civil society and industry representatives as invitees) and the Hub (hosted by WHO).

The ACT-Accelerator Facilitation Council will provide the Pillars with support and guidance on key strategic, policy, and financial issues to ensure delivery, financing, and equitable access. The Council will also communicate progress of the ACT-Accelerator pillars to a broad range of interested stakeholders.

The Hub supports the Council and enables the work of the partners in each pillar, recognizing the interlinked nature of treatment, testing and vaccination, and the critical role of health systems.

The Hub coordinates across partners, recognizing the interlinked nature of tests, treatments and vaccines, and the critical role of health systems.

Integrated fast-tracked process for all tools

The delivery partners have committed to ambitious targets on delivering tests, treatments and vaccines to the world. In order to achieve them within the next 9-18 months, ACT-Accelerator has organized a clear plan in 4 key phases across the pillars: R&D, manufacturing, procurement & supply chain, and delivery of each of the tools.

The efforts in R&D are focused on discovering, developing and approving an array of safe and efficacious tools, while within manufacturing the co-conveners are focusing on building sufficient capacity to produce safe and quality assured tools at global scale. Commercialization is also being supported early on, through promoting affordability, accelerating country registration and licensing to expand the supply base. In procurement & supply chain, resources and intelligence are being pooled into acquiring tools and building adequate supply chains to deploy these tools to countries. And finally, looking at delivery, in-country capacity and capability is being built to ensure the tools can be used and reach their recipients.

Traditionally these phases are conducted in sequence. ACT-Accelerator is accelerating the phases by running them in parallel to ensure that tools can be quickly approved, scaled up and deployed without compromising on safety and efficacy (see Figure 4).

ACT-Accelerator's critical path uses accelerated & parallel workstreams to rapidly achieve its goal

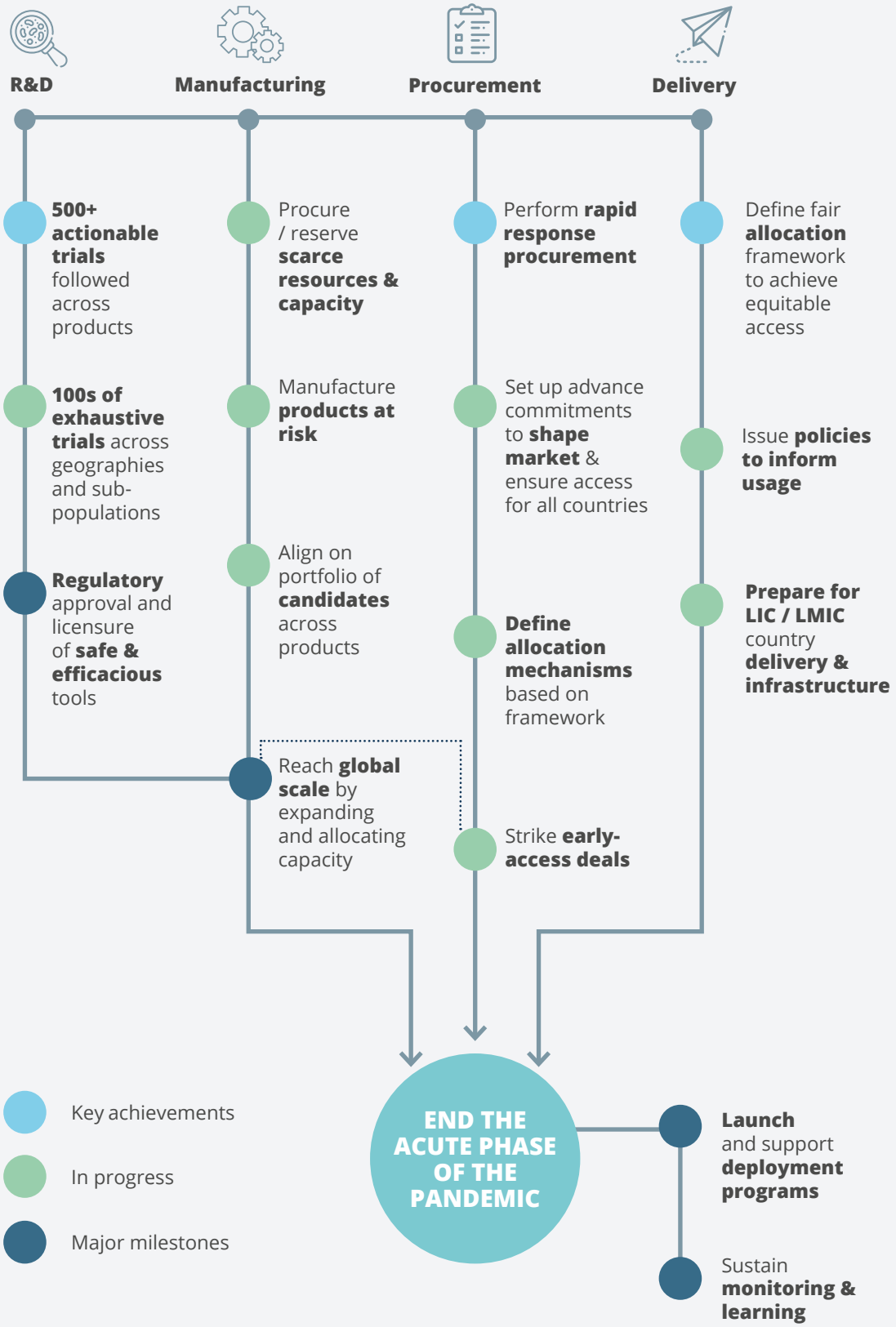


Figure 4

Proof of principle in each of the Pillars

The early proof of ACT-Accelerator's potential is compelling and includes tangible results in each of the Pillars and cross-cutting work areas.

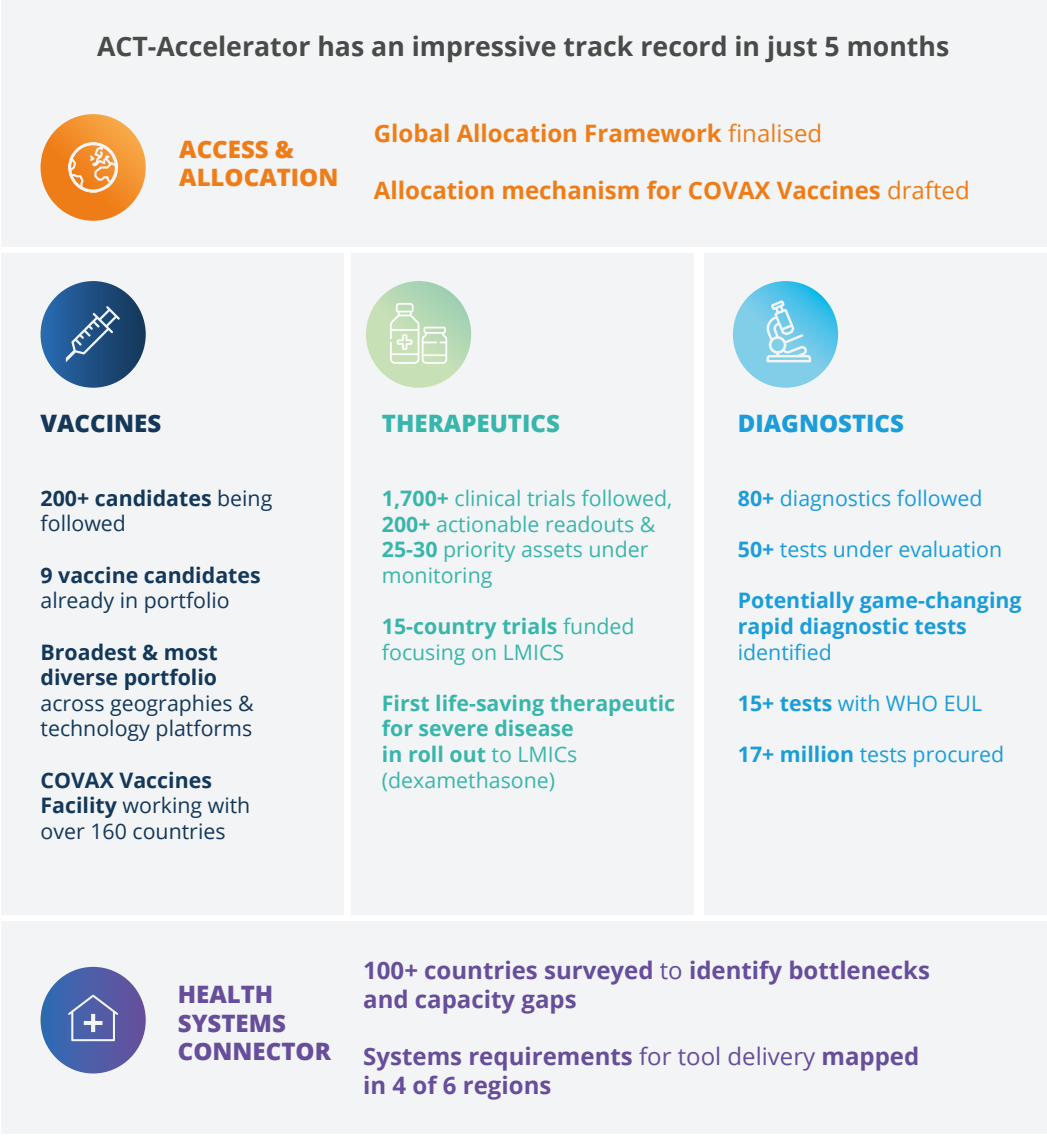


Figure 5

Vaccines: A world-leading portfolio is contributing to global access mechanism

The broadest vaccine portfolio in the world has been established, with 9 candidates already in the CEPI portfolio across 4 platform technologies, with work underway to add more (target: 15). Furthermore, vaccines will also be purchased with advance purchase agreements. A global solution for equitable allocation has been launched with the COVAX Global Vaccines

Facility – with total of 161 economies (69 self-financing economies and 92 with support from the Gavi COVAX AMC), representing nearly two-thirds of the global population, now committed to or eligible to receive vaccines through the Facility, and with more commitments coming in. A COVID-19 global policy on vaccine use is already under development, before we even have results of the phase III clinical trials, and the work on delivery at scale is underway at the global level, in all regions, and in many countries.

Therapeutics: A proven treatment is being scaled up with more on the horizon

Results from clinical trials showed evidence of efficacy of dexamethasone in severely ill COVID-19 patients, and efforts are currently being made by the international community for scaling up its production and delivery to cover up to 50% of needs in LMICs. The Pillar has also designed an advanced market intervention to secure prompt access to novel therapeutics (monoclonal antibodies and new antivirals) if they prove successful. It has also analysed and prioritized the most promising therapeutics being evaluated in more than 1,700 clinical trials, complementing research as needed through R&D efforts, and preparing market base-line for 25-30 priority assets, including intellectual property, regulatory and manufacturing aspects, to allow rapid reaction and delivery of safe and quality assured treatments in the shortest time lag as possible after clinical information is generated.

Diagnostics: A new game-changing rapid diagnostic test is about to be scaled up

Over 17 million laboratory tests have already been procured to support countries in their immediate COVID-19 response, with 18 new laboratory tests added to the WHO Emergency Use Listing Procedure (EUL). In addition, over 50 diagnostic tests are being evaluated, including several potentially game-changing Ag RDTs that can provide rapid results to health workers in clinics and communities. Vital progress is being made to ensure country readiness to implement new tools, including training and capacity building. This work will leave a lasting legacy of stronger laboratory systems. This acceleration of R&D, manufacturing scale-up and country readiness for deployment of RDTs could fundamentally change our capacity to identify the virus and break the chain of transmission.

Health Systems Connector: Requirements mapped and process in place

The minimum component requirements for delivery of COVID-19 tools have been mapped in 4 of 6 regions; 105 countries have been surveyed to identify potential bottlenecks and capacity gaps/needs for informing planning, and 10-15 countries have been identified for early roll out, testing and refinement of the overall approach. Guidance documents have also been developed for clinical care, including the use of oxygen, and the procurement, deployment and disposal of PPE.

Access & Allocation: A global allocation framework has been finalised

A comprehensive framework and mechanism for ensuring the equitable allocation of COVID-19 vaccines has been developed under broad consultation; this is already driving the planning for vaccine allocation through the COVAX Facility. An allocation mechanism is also already in place to enable the equitable allocation of diagnostics for LMICs. The continuous deep engagement of countries on the allocation framework through regular WHO Member State consultations, reinforces the urgency of this element and its relevance.

05

IMMEDIATE PRIORITIES ON THE ACT-ACCELERATOR CRITICAL PATH

ACT-Accelerator has laid out a critical path towards accelerating the end of the pandemic. Emerging risks are being meticulously mitigated, and an efficient process has been set up to track achievements and priorities. The period of September to December 2020 is emerging as a unique opportunity for ACT-Accelerator to be poised for impact.

Critical path for each Pillar

ACT-Accelerator's vision and goals have informed the choice of key milestones and priority deliverables across Pillars, which are reflected in detailed timelines and take into account Pillar-specific considerations (see subsequent pages).

The Vaccines Pillar is working under the possibility that there will be an authorized vaccine candidate by Q4 2020 – Q1 2021. Major milestones along the way include finalizing an allocation mechanism in September 2020 and supporting production scale-up and technical transfer of frontrunner candidates in August/September. On 18 September, self-financing countries joined the COVAX Facility on legally binding terms. The Pillar is in planning phase to support a global, platform-based adaptive vaccine trial to test multiple vaccine candidates in an efficient and timely manner. Policy recommendations on prioritized use of the first authorized candidate will be issued as soon as data are available for review from the clinical trials. To be ready to achieve delivery at scale of vaccines in 2021, a thorough vaccine delivery, supply, monitoring, and logistics strategy will be put in place by December with country readiness dashboards, checklists and guidance, tools and training packages being rolled out step-by-step between September and December. Planning for post-authorization safety and impact assessments is being established and will need to be resourced so that policies and programmes can be optimized as knowledge grows.

The Therapeutics Pillar is working towards the adequate deployment of 245 million effective therapeutic courses at scale in LMICs by 2021 with the aim of realizing rapid global and equitable access to the most appropriate, safe and effective treatment options for COVID-19 patients. In achieving this, key milestones include: executing market interventions at risk for novel therapeutics (monoclonal antibodies and new antivirals) that prove successful – with manufacturing capacity reservation and volume guarantees starting in 2020 to secure access to these promising life-saving tools in LMICs. Furthermore, rapid procurement of the first lifesaving therapeutic is ongoing in 2020 and will be extended to additional products in

2021. Evidence generation and evaluation efforts for priority products is ongoing, as well as the development of regulatory pathways. A supply operations team will be established to coordinate procurement across countries as relevant and a defined allocation mechanism for product deployment in countries by end of 2020.

The Diagnostics Pillar is urgently working towards expanding access of existing tools in LMICs and supporting the development and deployment at scale of critical rapid tests by Q4 2020, with an emphasis on Ag RDTs. Major milestones to achieve this include product development and validation by mid-September, market preparation including regulatory approval by mid-October, training healthcare workers and strengthening laboratory services by mid-October, and rolling out tens of millions of Ag RDTs by Q4 2020. Following initial deployment, the Diagnostics Pillar is already starting to develop the evidence base on how to use tests most effectively, expand access, continually improve test performance and lower prices.

The deliverables for the Health Systems Connector have been grouped into eight workstreams. The finalized workplan is being integrated into the overall ACT-Accelerator plan. Key priorities are to ensure PPE is made available to all health care workers, including those on the frontline and to ensure access to oxygen supplies. Further work focuses on supporting basic infrastructure, building health work force capacities, and strengthening community-based health services. Useful and readable data will be collected in the form of a dashboard. Countries will be assisted in investment making, starting with a guidance note on health financing in November 2020. Countries will be engaged throughout the process, in 5 countries by December 2020, expanding to more thereafter. Finally, following country surveys, the private sector will be mapped and tapped to public capacity needs. Much of this work is country specific and will be led by countries themselves in partnership with other partners and funders, in particular through support to national Strategic Preparedness and Response Plans.[6]

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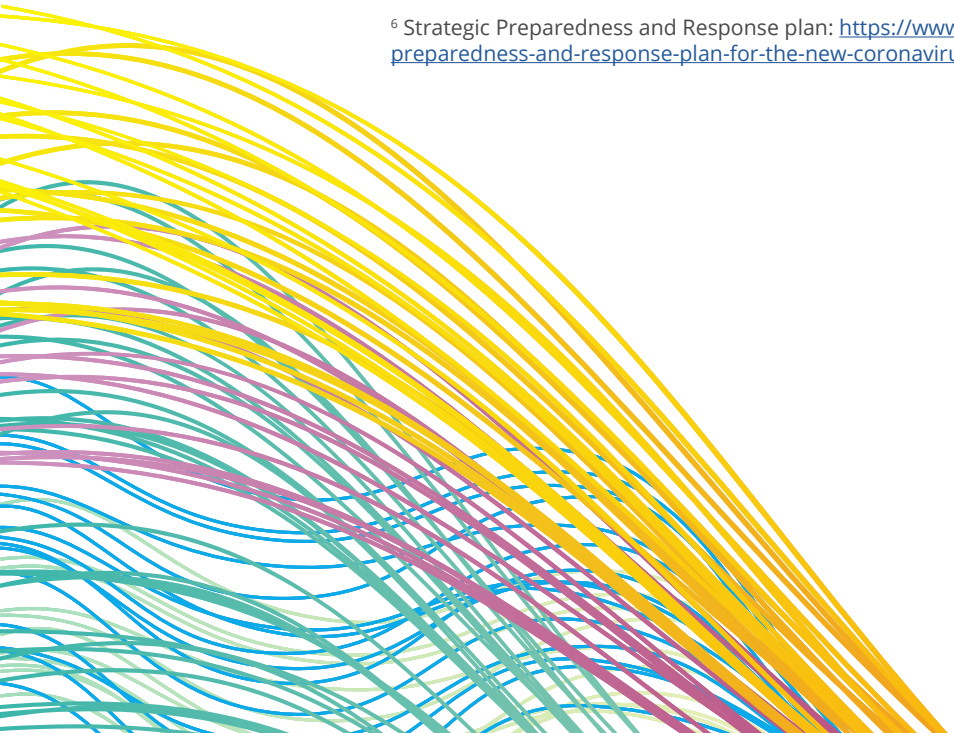
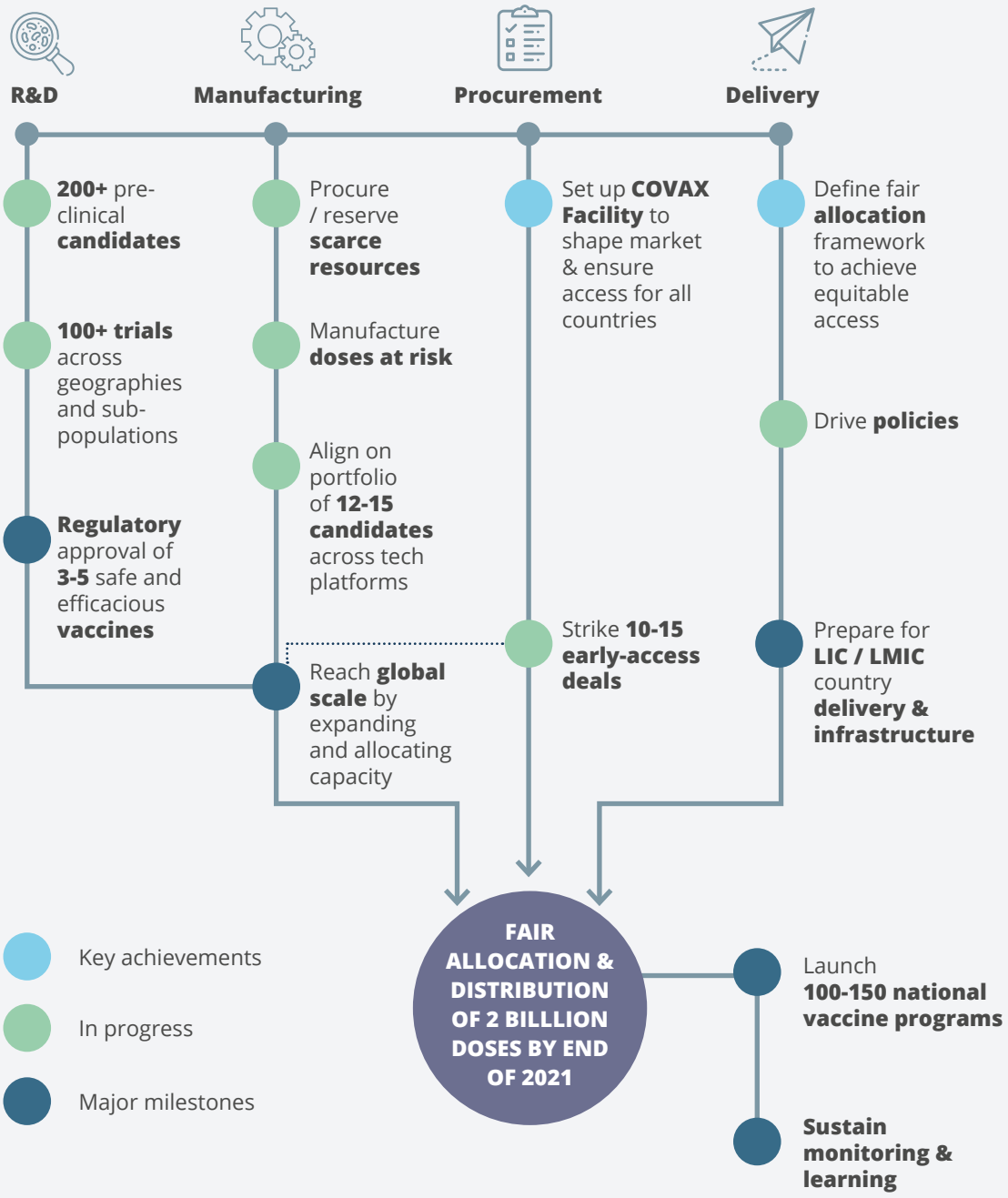
[6] Strategic Preparedness and Response plan: https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus

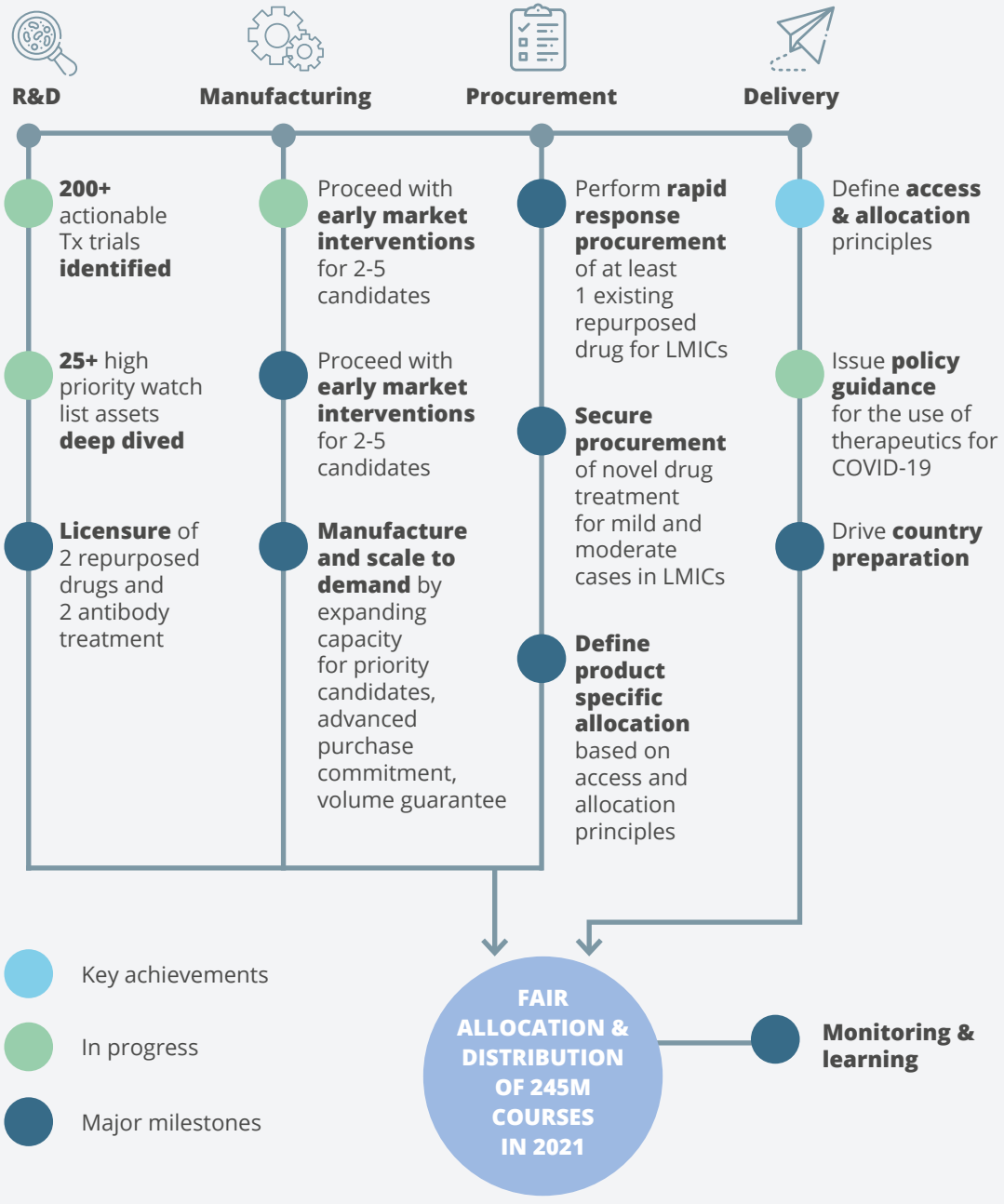


ACT-ACCELERATOR'S VACCINES PILLAR (COVAX) WILL BRING 2 BILLION DOSES OF VACCINES TO THE WORLD

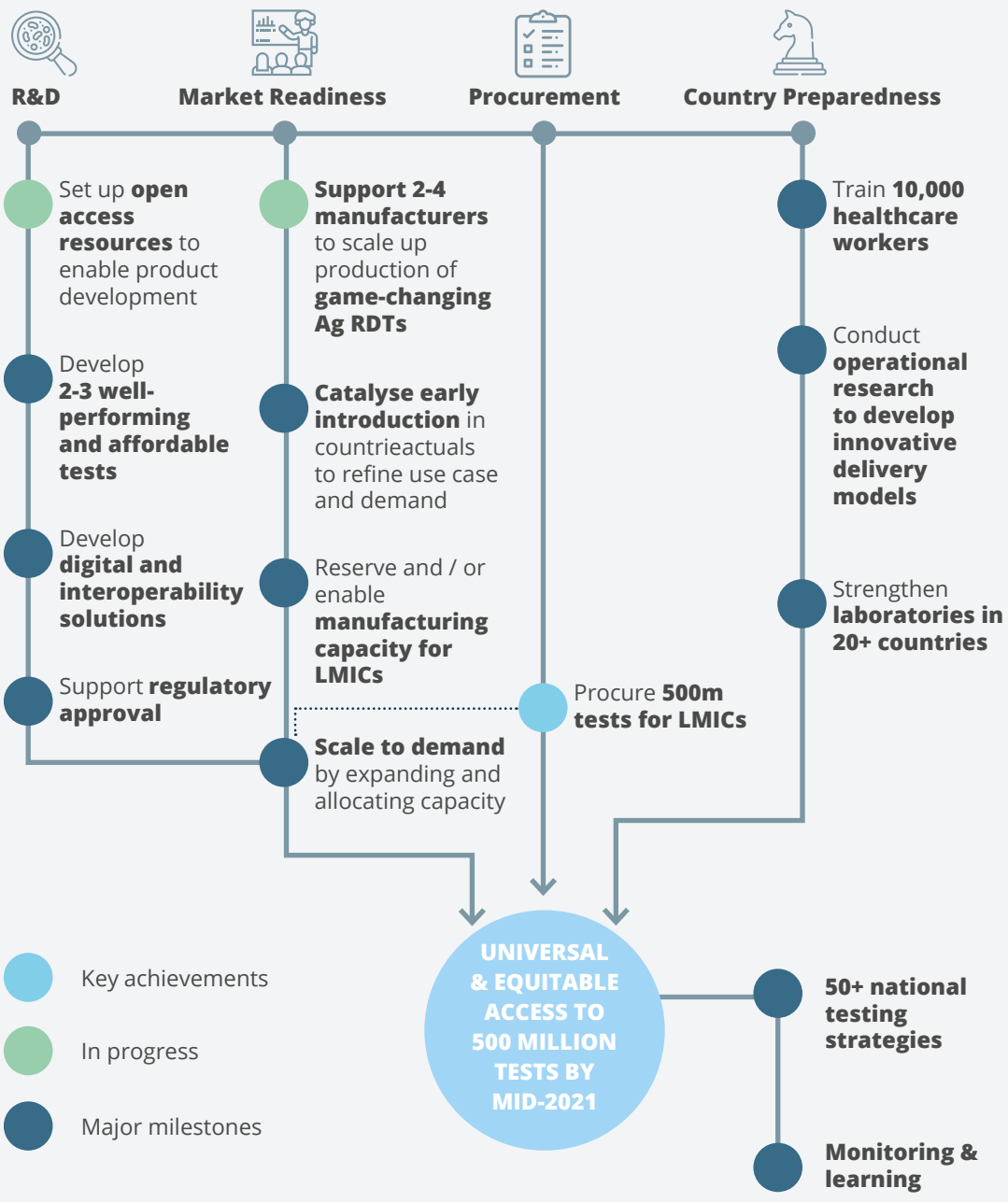


CEPI Gavi The Vaccine Alliance World Health Organization

ACT-ACCELERATOR'S THERAPEUTICS PILLAR WILL DEVELOP AND SCALE UP SAFE, EFFECTIVE AND QUALITY-ASSURED THERAPEUTICS



ACT-ACCELERATOR'S DIAGNOSTICS PILLAR WILL BRING 500M TESTS TO LMICS



Ambiguity and risks are being mitigated and anticipated meticulously

ACT-Accelerator is operating within an ambiguous context with significant unknowns about the epidemiology of the virus and viability and efficacy of possible tools. Given the risks such a broad endeavour entails, ACT-Accelerator has instituted forums to continuously mitigate emerging and anticipated risks. ACT-Accelerator instituted regular cross-cutting meetings at the functional and leadership level aimed at uncovering and mitigating risks. These meetings ensure early detection and a coordinated response across all partners.

Addressing anticipated risks in developing a solution to COVID-19, ACT-Accelerator's latest understanding frames risks in three categories: firstly, risks related to the disease itself; secondly, product development and delivery risks; and lastly, risks related to perception, behaviour and actions of society. Anticipating these risks to mitigate or adapt the ACT-Accelerator's plan and delivery approach is key to successfully achieving the goals of ACT-Accelerator.

To address disease-related risks (such as mutation of the virus or shift in infectious pattern): ACT-Accelerator has the legitimacy and weight to engage the best scientific bodies from all over the world to closely monitor the virus evolution. If major shifts in virus behaviour require a change in tact with respect to the characteristics of tools needed to overcome it, ACT-Accelerator's role as an integrator with all relevant stakeholders will accelerate this pivot, adapting the delivery partners' work accordingly, and reallocating resources as needed.

To address product development and delivery risks (such as limited efficacy and safety of tools or supply shortages or inadequate use of tools due to strained healthcare systems): ACT-Accelerator will apply an array of strategies. These include diversifying its portfolio of tools and supporting parallel development, facilitating tech-transfers to maximize global manufacturing capacity, and working with health systems to prepare for tool deployment as they become available. While recognizing that meeting these targets on an accelerated timeline is a real challenge, ACT-Accelerator can leverage its monitoring and assessment strategies to minimize execution risk, especially at key decision-making milestones.

To address risks related to the perception, behaviour and actions of society (such as vaccine hesitancy or declining acceptance of Non-Pharmaceutical Interventions): the Pillars and Health Systems Connector will support health promotion efforts on COVID-19, and engage communities to increase buy-in and uptake of tools. In addition, ACT-Accelerator is also continuing to facilitate a unified and consistent message among WHO Member States and engaging with civil society and community-based organizations to ensure legitimacy and buy-in among the general public.

Tracking our progress against these milestones in real time

The approach taken by the delivery partners is constantly updated, consequently as the situation evolves and new scientific insights become available, achievements, priorities and funding needs are being periodically updated.

These rolling quarterly reviews are being used to highlight near-term spending needs and urgent funding gaps for priority deliverables, outline what happens if sufficient investment is not made, identify milestones requiring critical input, and showcase ACT-Accelerator's achievements to date. This is essential to distil complexity in a fast-evolving landscape and drive strategic discussions across ACT-A. These quarterly updates are a crucial tool in communicating with all relevant stakeholders.

Upcoming results in the period Sep to Dec 2020 will be pivotal

ACT-Accelerator must be positioned to act on them

The period September to December 2020 presents a crucial period to scale-up the impressive success of ACT-Accelerator's start-up phase and to position it for global impact.

By December we will have a much firmer understanding of which treatments and vaccines will have early success. During this time, ACT-Accelerator must be positioned to act on these to ensure that manufacturing capacities are set up, procurement deals are established, and fair and concrete allocation mechanisms are in place, and plans to ensure country and health systems readiness are well underway.

In Vaccines, advanced purchase agreements need to be made to secure manufacturing capacity and ultimately vaccine doses to the COVAX Facility, even before any vaccines are licensed. Without these, the global supply of vaccine will be secured by a small number of wealthy economies, and no vaccine will be available for the majority of countries or populations worldwide. Phase II/III readouts from some candidates will also be critical to trigger procurement deals, establish the basis for vaccine-specific policy recommendations that will guide their use, and move the allocation mechanism, procurement, and vaccine programme delivery preparation into an accelerated phase anchored on the realities of one or more specific vaccines.

In Therapeutics, a number of clinical trials for priority assets including novel and repurposed therapeutics will have read-outs in the coming months. To start, a number of key read-outs for new monoclonal antibodies expected for September / October, and new antivirals Phase III read-outs expected in December 2020 and Q1 2021, will allow the partnership to determine and select molecules for utilizing the initial wave of reserved capacity for production. For repurposed medicines and combinations regimens, the Pillar is looking at potential market interventions (such as the ones undertaken with Dexamethasone) for several products and combinations of antivirals with read-outs expected for Q4 2020. A new wave of products will have read-outs in 2021, with actions and investments to be determined depending on the first wave of results and interdependencies with other Pillars.

In Diagnostics, we are at a crucial juncture to ensure diagnostic capacity is available so that everyone in the world who needs a test can get one. Countries without their own production lines are in great danger of missing out as manufacturing capacity of existing and emerging tests is rapidly being reserved. Diagnostic tests are of immediate importance to ensure test-and-treat strategies can be implemented, and to monitor the efficacy of other effective public health measures. As new tools are developed, testing will be critical for the roll-out of vaccination campaigns. In LMICs, a successful COVID-19 response hinges on simple, accurate and affordable Ag RDTs that can be used anywhere, and promising recent developments indicate that the first effective tests could be ready for use in the coming weeks. These RDTs are also paving the way for potential self-testing approaches that would be game changing for high- and low-income countries alike.

Pre-empting regulatory and prequalification processes will be key

Lessons from previous public health emergencies have shown that regulatory work must begin early and fast in order for new tests, treatments, and vaccines to be made available in a timely fashion. In therapeutics for example, ongoing work to tackle emerging regulatory challenges and intellectual property issues must be ramped up now – otherwise, access to promising repurposed and new treatments, whether small molecules or complex biological products, would be significantly delayed. In vaccines, harmonization and cooperation of standards and methods for rapid, aligned reviews of dossiers are key for breaking through potential delays in deployment of vaccines across more than 100 countries in a short number of months.

Building manufacturing capacity will be critical

Investments in tech transfers and manufacturing scale-up/-out must be pursued immediately in order to maximize manufacturing capacity for both existing and promising new tools (such as the Ag RDT that will be ready in the coming weeks) as well and the supportive technologies or products they need (e.g. syringes). Failing this, production would be delayed, and availability of medical products will be in volumes far below those needed. In addition, inventory reservations must be made to ensure LMICs have access to future tools before global capacity is fully reserved by others.

Securing procurement and volume guarantees will be essential

In the coming months, additional advance purchase agreements must be struck with manufacturers in order to secure tools and signal strong market demand. Failing to do this at scale will lead to a less competitive and inequitable global market, where manufacturers produce insufficient volumes, and what is available is secured by a handful of individual countries while the others are left without.

Delivery and readiness issues must be anticipated

As supply of tools is secured, preparations must be made to ensure they can be delivered and deployed in countries. For example, as additional details on promising vaccine candidates emerge, cold-chain capacity needs to be scaled ahead of time to ensure these doses can be deployed. In addition, antibody-detecting rapid diagnostic tests will need to be deployed in very different ways than polymerase chain reaction diagnostics (e.g., decentralized, outside of labs). Finally, innovative delivery models are needed, and healthcare workers must be trained immediately to ensure countries have the capabilities needed to safely and effectively deploy new tests, treatments and vaccines. Training on safety monitoring, development of data systems, planning for community mobilization, and methods to monitor product uptake are all needed now.

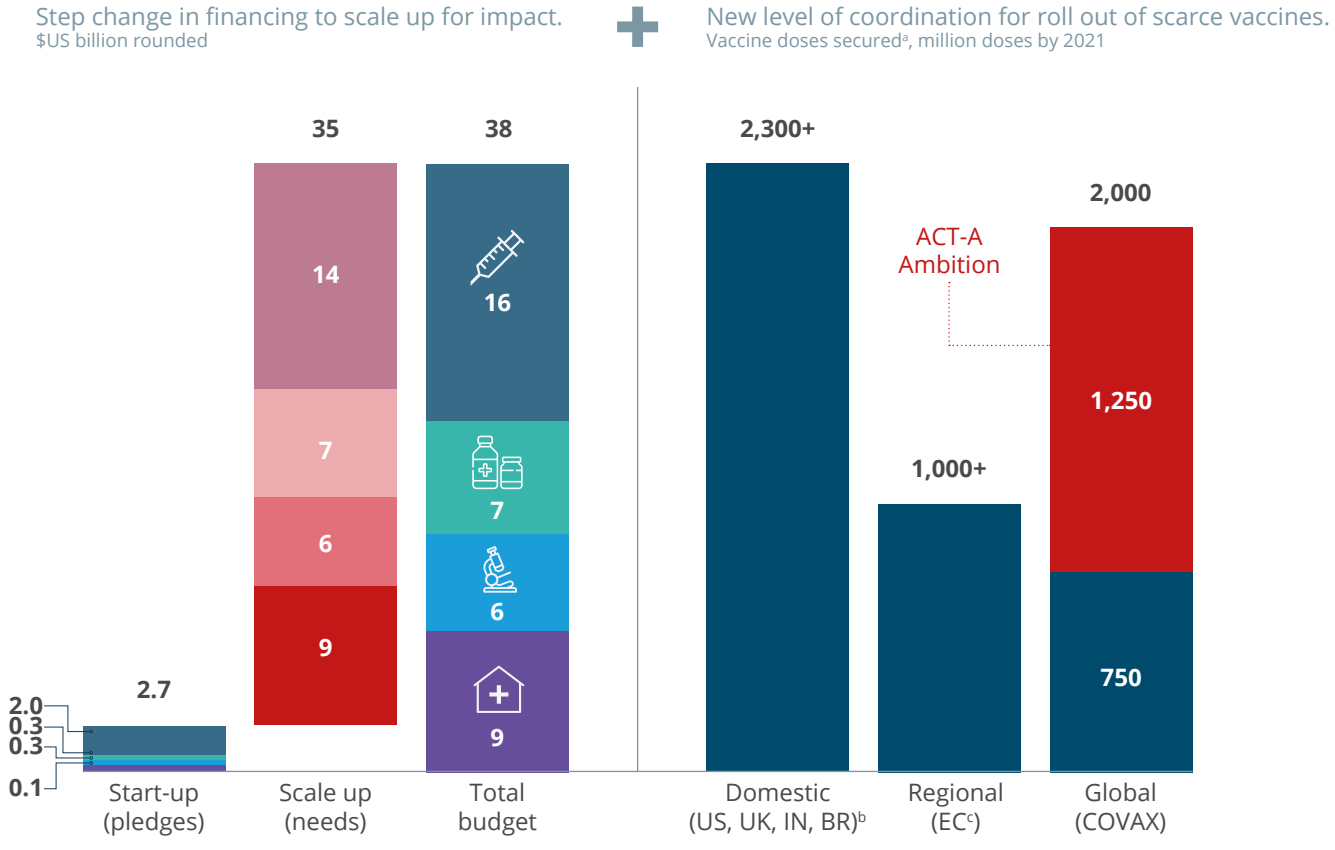
06

SCALING UP TO POSITION ACT-ACCELERATOR FOR GLOBAL IMPACT

While ACT-Accelerator's initial funding has helped achieve significant results in its start-up phase, it must now massively scale up in order to position for global impact and realize its goal.

A major step change in investment and advocacy for ACT-Accelerator is now needed, first to close the remaining ACT-Accelerator financing gap of $US 35 billion and second to galvanize global political solidarity needed to ensure equitable allocation of ACT-Accelerator's tools.

Step changes needed for ACT-Accelerator (figures as of 7 September 2020)



SOURCE: IMF Estimates; Press releases; OECD; WHO; World Bank; The Economist Intelligence Unit

Figure 6

[a] Based on publicly disclosed agreements
[b] Cumulative numbers
[c] European Commission Inclusive Vaccines Alliance

Two major challenges threaten the promise of ACT-Accelerator

Current funding is insufficient for ACT-Accelerator to seize imminent opportunities

Within just 5 months, ACT-Accelerator has already delivered concrete results, accelerating the testing of vaccine candidates, evaluating over 50 new diagnostics, scaling up a new therapeutic and establishing increasing consensus on international allocation of these products. This has been achieved with initial funding of $US 2.6 billion, but this is just 7% of ACT-Accelerator's total estimated funding needs.

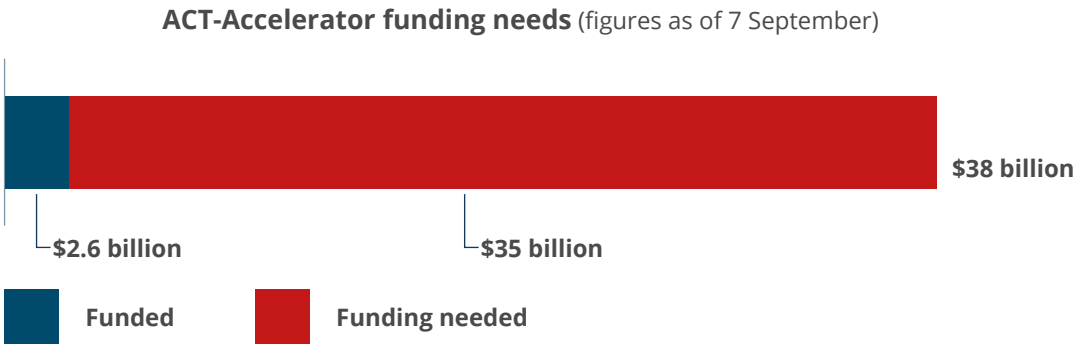


Figure 7

Funds raised to date fall short of the $US 38 billion required in total, leaving a gap of $US 35 billion.

The period of September to December 2020 is a crucial period to scale up these early achievements, and position ACT-Accelerator for global impact. Without additional financing, ACT-Accelerator will not be able to ensure that manufacturing capacities are set up, that adequate procurement deals are established, and fair and concrete allocation mechanisms are in place. Without these, ACT-Accelerator's vision of accelerating the end of the pandemic is at risk.

National and regional interests could compromise the optimum use of scarce COVID-19 products

Global approaches are crucial to optimize the impact and minimize the development risks and financial costs of new COVID-19 tests, treatments and vaccines. ACT-Accelerator established the COVAX Global Vaccines Facility and aligned with the Diagnostics Consortium to pool risk and purchasing power while optimizing distribution. An allocation mechanism for COVID-19 vaccines has been finalised and is being developed for other tools. For vaccines, this has meant establishing international consensus that all countries should receive vaccines at the same rate until a minimum of 20% of their populations is covered.

As an increasing number of HICs are establishing bilateral and multilateral deals for vaccines, it is vital that the use of these products be aligned with the global allocation framework, and

coordinated with the COVAX Global Vaccines Facility, to optimize impact and the possibility of restarting the global economy as rapidly and efficiently as possible. Recognizing this risk WHO has undertaken extensive and ongoing discussions with its Member States, and negotiations with the European Commission, to ensure such deals are aligned with WHO's Equitable Allocation Framework.

This situation is also relevant for other tools – for example, demand from HICs for antibody-detecting RDTs is escalating and is threatening to limit access for LMICs.

A step change in support is key to realize ACT-Accelerator's goal

Immediate and long-term funding is required

Achieving ACT-Accelerator's targets costs $US 38 billion. Without this, it is impossible to deliver ACT-Accelerator's goal of ending the acute phase of the pandemic by reducing severe disease through the development, scale up, procurement and delivery of new tools.

$US 2.6 billion have been raised so far. However, ACT-Accelerator is in dire need of support so as to not pass critical acceleration opportunities. This includes funding for critical investments required within the next 6 months to meet the ACT-Accelerator targets as well as the longer-term needs for the Vaccines, Therapeutics, and Diagnostics Pillars and Health Systems Connector.[7]

[7] The costs for the Health Systems Connector include costs for two critical tools not included in the other Pillars: PPE and oxygen. It does not cover all enabling Health Systems costs and is complementary to other funding needs such as SPRP and GHRP.

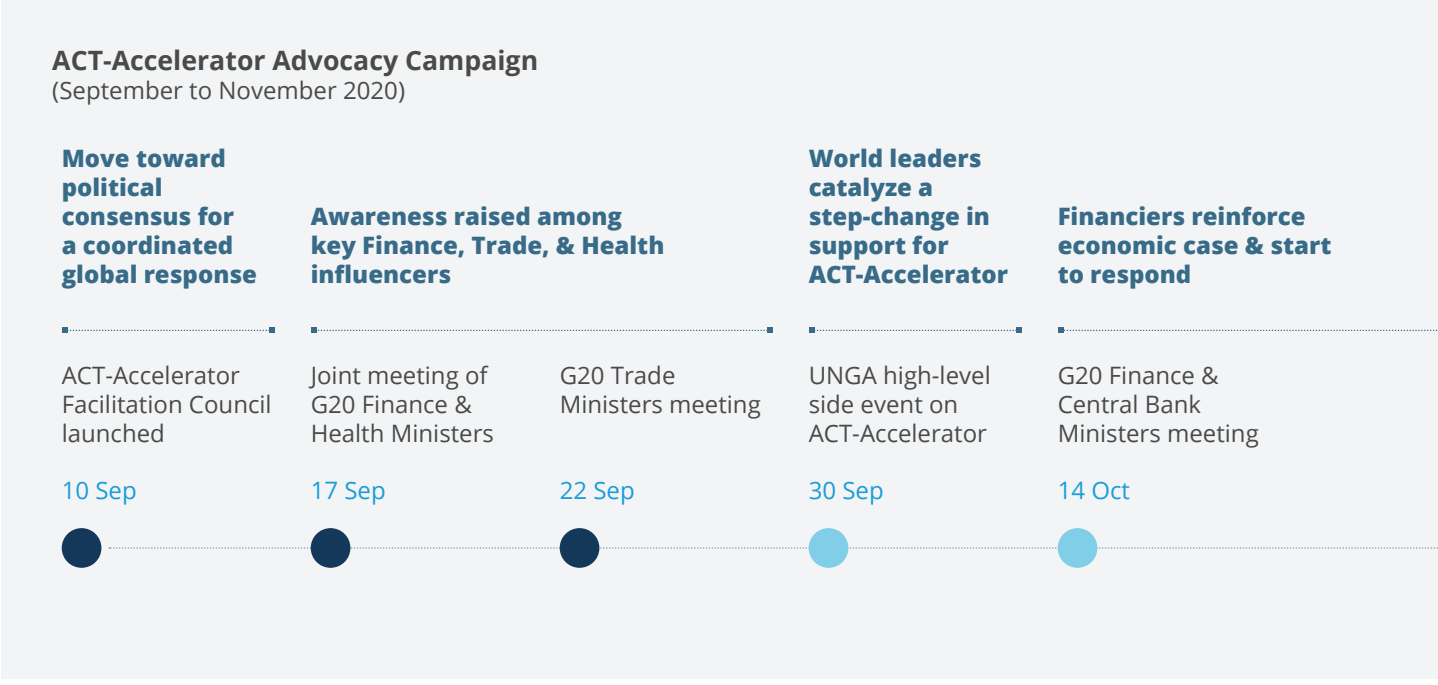


Figure 8

The sum required by ACT-Accelerator pales in comparison to the domestic stimulus investments already made and the $US 7 trillion economic contraction expected in 2020 if COVID-19 is left unabated.[8]

Political leadership and advocacy is essential

In addition to financing, ACT-Accelerator requires the direct engagement of leaders worldwide to translate the political commitments to equitable allocation of scarce COVID-19 tools into concrete mechanisms that assure their timely roll-out to all countries and highest risk populations.

Governments also need to actively participate in the work of ACT-Accelerator, for example to pool resources and build planning security for suppliers. This is an imperative for the mutually beneficial allocation mechanism to function.

Path forward

From September to November 2020, ACT-Accelerator envisages actively engaging with a series of high-level meetings, international events and global fora to gather support during this crucial period (Figure 8: ACT-Accelerator Advocacy Campaign).

Throughout this period, coordinated leadership action will be crucial to consistently promote and drive the health, economic and moral case to reposition ACT-Accelerator and secure solutions to its financing and allocation challenges.

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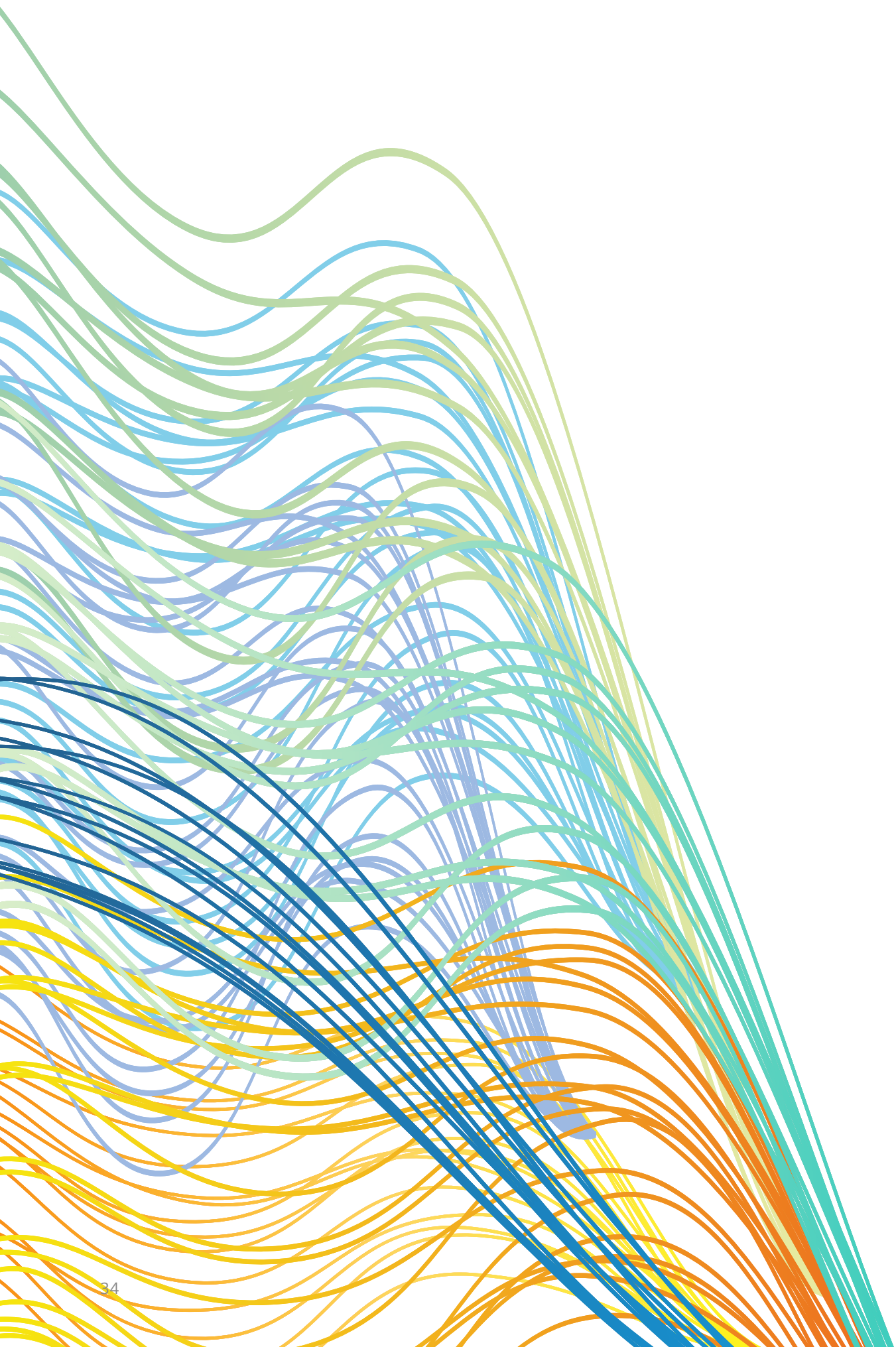
[8] World Bank Global Economic Prospects – Pandemic, Recession: The Global Economy in Crisis https://www.worldbank.org/en/publication/global-economic-prospects.



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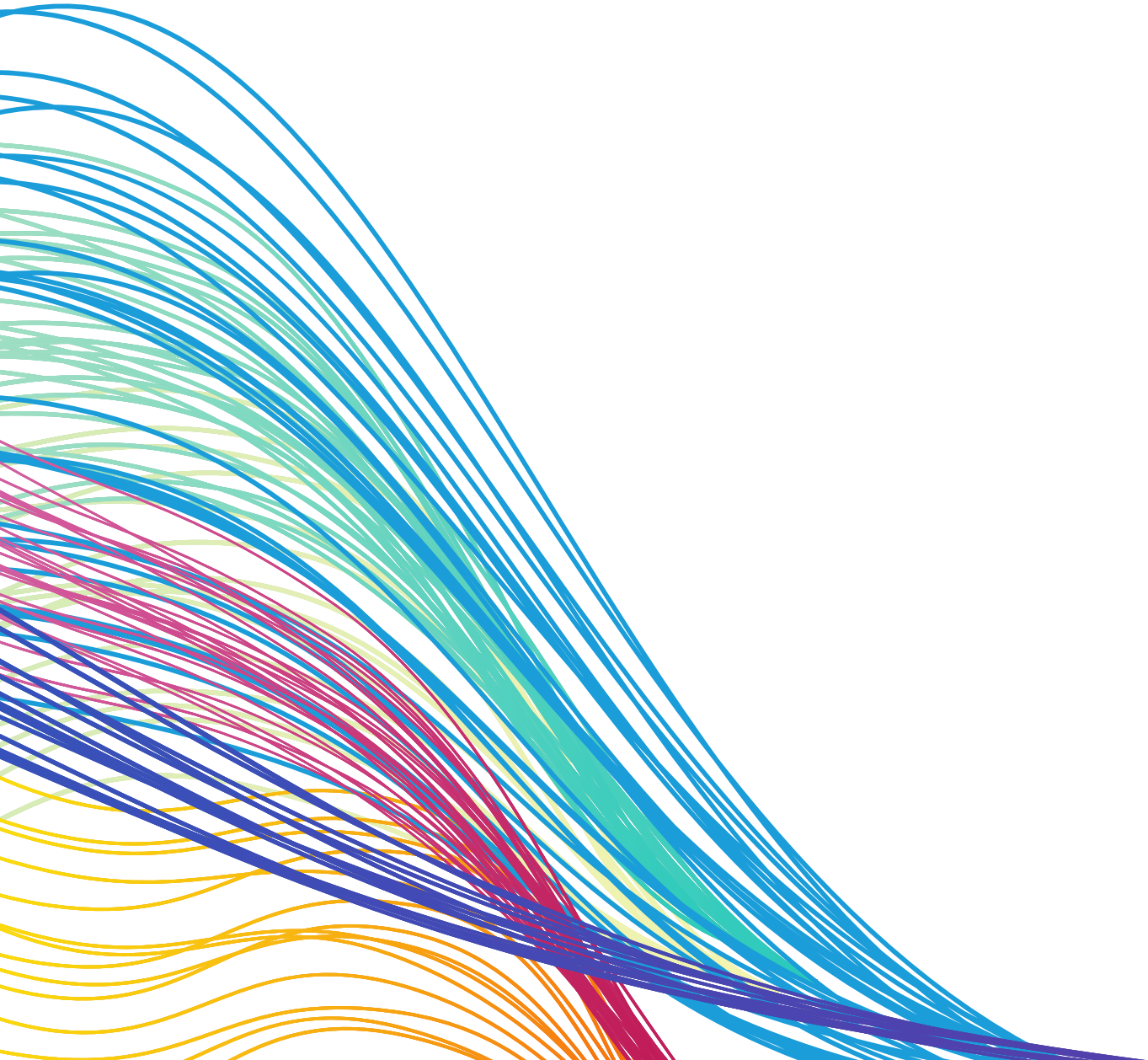
Ab	Antibody-detecting
Ag	Antigen-detecting
CEPI	Coalition for Epidemic Preparedness Innovations
FIND	The Foundation for Innovative New Diagnostics
GAVI	Global Alliance for Vaccines and Immunization
GHRP	Global Humanitarian Response Plan
HICs	High-Income Countries
IMF	International Monetary Fund
LICs	Low-Income Countries
LMICs	Low- and Middle-Income Countries
NPIs	Non-Pharmaceutical Interventions
ODA	Official Development Assistance
OECD	Organization for Economic Cooperation and Development
PPE	Personal protective equipment
PQ	Prequalification
RDT	Rapid Diagnostic Test
SPRP	COVID-19 Strategic Preparedness and Response Plan
WHO	World Health Organization