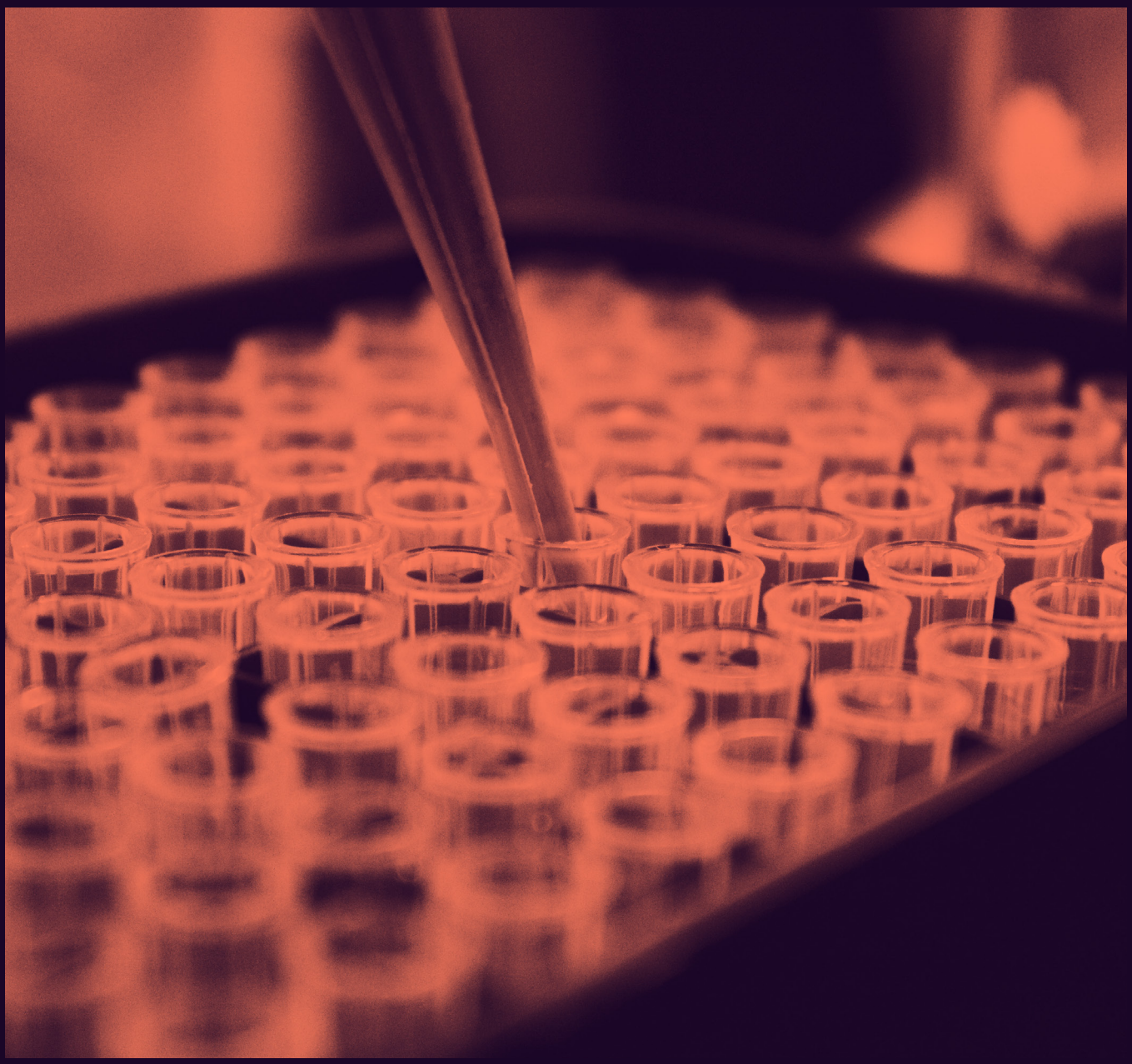
COVAX



COVAX, the act-accelerator vaccines pillar

Insuring accelerated vaccine development and manufacture

Introduction

Developing a vaccine against COVID-19 is the most pressing challenge of our time. The global pandemic has already caused the loss of hundreds of thousands of lives and disrupted the lives of billions more. As well as reducing the tragic loss of life, introduction of a vaccine will prevent the loss $375 B[1] to the global economy every month.

Developing one or more safe and effective vaccines is also one of the most complex challenges of our time. Unlike with past vaccine development, scaling up manufacturing and completion of human trials for vaccine candidates must be done in parallel. Even with accelerated investment in manufacturing, and the completion of trials to ensure vaccine candidates are safe and effective, there is no scenario in which supply over the next 18 months will exceed demand although at today's anticipated trajectory some vaccine candidates could become available within this time frame.

Governments are answerable to their populations and to their taxpayers, and with so many lives and livelihoods at stake some are understandably pursuing bilateral deals with manufacturers to secure access to scarce future vaccine supplies. As treasuries around the world seek to address unprecedented revenue shocks, such strategies bring hope and instill confidence. But they also bring risk. In normal times, vaccine development is long, complicated, and more often than not ends in failure; it is difficult to know which deals will actually result in getting any vaccine.

Many leaders have called for a global solution to address a global issue and for a shared endeavor that involves the best shared science to resolve in the shortest possible time a pandemic involving every region and territory on the planet.
The COVAX Pillar provides this solution: through portfolio diversification, pooling of financial and scientific resources, and economies of scale, participating governments and blocs can hedge the risk of backing unsuccessful candidates just as governments with limited or no ability to finance their own bilateral procurement can be assured access to life-saving vaccines that would otherwise have been beyond their reach.

The goal of the COVAX Pillar is to end the acute phase of the global pandemic by the end of 2021. If it succeeds in this goal, through the appropriate allocation of safe and effective doses of vaccines in phases determined by epidemiology and public health to slow and ultimately to stop the pandemic, it could save millions of lives and transform the economic prospects of governments and individuals.

The COVAX Pillar is an urgently needed approach to getting a safe and effective vaccine faster, through financing that shares the risks of development and creates the capacity for manufacturing vaccine doses now, in parallel with clinical development, and before they are shown to work. It will show how participating countries, by buying into a share of many vaccine candidates instead of just a few, will be able to insure themselves against the failure of any individual candidate and secure successful vaccines in a cost-effective, targeted way.

[1] IMF estimates, published on April 14 https://blogs.imf.org/2020/04/14/the-great-lockdown-worst-economic- downturn-since-the-great-depression/

COVAX: The Context

When a successful vaccine is found, worldwide demand will be in the billions of doses to address the epidemiologic needs. But initial supply will inevitably be limited. The current best-case estimate is that no more than a few hundred million doses will be available by December 2020 in the current environment, scaling to a cumulative 2 billion doses by end 2021.

It is difficult to predict which vaccine(s) will be successful. Indeed, the vast majority of vaccines in early development fail. The probability of success for a vaccine in early stage development is less than 20% prior to Phase 2 clinical trial.

This means that the best chance of success for any country is to diversify and access a broad portfolio of vaccine candidates. This increases the chances of success and allows the vaccines that are successful to be shared. Such an approach would enable every country to gain access to a much broader array of vaccines than they would otherwise have through multiple bilateral agreements with individual manufacturers. For countries with local development or manufacturing capacity, this 'portfolio approach' insures countries against the risk of their own candidates proving unsuccessful or less effective, or that domestic manufacturing capacity is unsuitable, leaving them with no vaccines at all.

Pooling risks not only means a greater chance at shared rewards through access to successful vaccine candidates, it also means lower prices as competition in a non-pooled risks scenario leads to a disorderly market with price gouging as individual buyers seek to outbid each other for limited resources.

Over time, there will be adequate doses available to vaccinate all who need vaccination, assuming a safe and effective vaccine is found, sufficient investment in manufacturing capacity is secured, and adequate market incentives are established for manufacturers. In the meantime, an allocation methodology is required that stratifies and prioritizes risk groups (for example, healthcare workers, elderly, vulnerable groups) for vaccination in such a way to reduce the spread of virus and the impact of the virus on lives, livelihoods, health systems and economies as quickly as possible.

The biggest challenge will be supply of vaccines for the period while supply is scaling up. While massive efforts are underway to establish large production capacity, initial supplies will need to be prioritized. The main allo- cation criteria are based on the most urgent goal of reducing mortality, protecting health systems and policy.

Priority populations will be determined based on the characteristics of the specific vaccine(s) that demonstrate safety and efficacy. Policy recommendations will lay out the priority populations with the first round of vac- cination likely to consider:

- Health care system workers (1% of global population)
- Adults over 65 years old (8% of global population
- Other high-risk adults with underlying conditions such as hypertension, diabetes, etc. (15%)

COVAX: The Act-Accelerator vaccines pillar

The ACT-Accelerator is a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines. It is a partnership of key stakeholders – political leaders, public and private sector partners, civil society, academia – that leverages each partner's strengths to drive towards accelerated and equitable access.

Within the ACT-Accelerator, COVAX, the vaccines pillar, is driving the work on vaccine development, manufacturing, procurement and delivery at scale, as well as policy and allocation, bringing it together into the type of agreement described above. It leverages the expertise of existing organisations (CEPI, Gavi and WHO) and industry partners in a new way to meet the challenge of a pandemic.

The COVAX Pillar also ensures that the required additional activities for the successful launch of vaccine are supported in parallel – including detailed demand and supply scenarios, the regulatory dialogue to avoid time lags, the setup of an allocation framework and mechanism and supporting the buildup of infrastructure and health systems preparedness.

A fully financed COVAX pillar could give all participating governments a guaranteed share of any future successful vaccine production.

The COVAX pillar will simultaneously address both pull financing (advance market commitments), and push financing (at-risk investments for R&D, manufacturing capacity reservation & inventory), and agree to do so now to drive investment at high speed, volume, and 'at risk', and to secure manufacturing inventory build-up and future supply. By combining the power and expertise of CEPI's R&D role on the push side with Gavi's procurement and allocation function on the pull side, the COVAX pillar is able to ensure the manufacturing of doses now, something neither organisation, government or financier could achieve entirely on its own. Supported by the World Health Organization in assuring effective regulation and optimal allocation, both CEPI and Gavi will use the depth and breadth of their partnerships with governments, private sector, academia, civil society, and financiers to achieve the accelerated impact the world needs from the COVAX pillar.

Why we need to act now

- **Mitigate economic damage** – for every month that this pandemic continues, $375 billion[1 is lost from the global economy. Acting now to accelerate development, manufacture, and distribution of a COVID-19 vaccine will save hundreds of thousands of lives and protect the livelihoods of millions more.
- **Accelerate availability of vaccine** – if we follow the traditional course of vaccine development, we could face years of delay. Such a delay will cost lives and trillions of dollars in economic damage. COVAX will enable at-risk investments in production capacity across several candidates now – to ensure that, upon regulatory approval, doses can be made immediately available at scale.
- **Ensure globally fair allocation and access for low and middle income countries (LMIC)** – nobody is safe from COVID-19 until everybody is safe. COVAX not only represents the best solution to end this pandemic, it is also the fairest way to allocate vaccine for all countries to ensure that access can be provided for every country.

The COVID-19 vaccine global access (COVAX) facility

When sufficiently capitalized, the COVAX pillar will immediately offer advance purchase agreements to vaccine candidates meeting technical threshold criteria. This will be done to produce vaccines at risk before we have results of efficacy trials. Offering between five to ten such contracts will allow a specially created financial instrument, the COVAX Facility, which sits within the pillar, to:

- procure cumulative 2 billion doses by end 2021, ensuring that participating countries receive allocations of vaccine as quickly as possible including an emergency buffer (10% of doses)
- procure the highest possible volume of vaccine from each manufacturer, resulting in the greatest number of doses at the most economically efficient price
- provide for globally fair and equitable allocation of vaccine, saving millions of lives, and protecting millions more livelihoods, and bringing the acute phase of the pandemic to an end in the most efficient fashion possible.

Initial capitalization would provide an equitable distribution of doses and begin to dent the epidemic in participating countries. The COVAX pillar is for all countries. It will include a fair and equitable allocation of limited supplies on the basis of ethical values and public health goals. Criteria will include population groups with higher risk of mortality, burden of disease, threat, vulnerability, product supply and logistics, country context, and global health security priorities. As further scale-up of production occurs, and the market is considered orderly, countries will have continued allocation of doses as needed, or could revert to bilateral deals where that makes sense for them to do so.

COVAX in numbers

Ending the acute phase of the COVID-19 pandemic as soon as possible will require large up-front capital. Commitments from high income and upper middle income countries (HIC, UMIC), are needed (1) to procure ~950 M doses through the COVAX Facility; and (2) to ensure that vaccine can be delivered at the greatest possible speed by underwriting the costs of manufacturing at risk are needed. $18.1 B is needed to cover these latter costs as well as the costs of procuring and delivering vaccine for low and middle income countries

(LMIC). Such investment will secure the development of, and fair access to, up to two billion doses of vaccine by the end of 2021, assuming a safe and effective vaccine is developed in the near future. Of this total, $11.3 B is needed urgently to cover investments within the next 6 months. This includes ~$2 B in funding for advance market commitments to secure doses for LMICs. It also accounts for an emergency buffer of doses with mixed funding sources.

These numbers are estimates and will become more precise once we get a better idea of, among other factors, the technology that the successful vaccine candidates will be based on, and the number of doses required.

Research & development	**$9.4 B**
Volume guarantees	**$5.5 B**
Delivery costs	**$3.2 B**
Of which is urgent need	**$11.3 B**

The total funding need of $18.1 B for 2020/2021 is made up of:

- **Research & development and manufacturing**
  Investment in R&D of $2.4 B ($1.5 B urgent need), tech transfer/scale-up and out of $1.7 B ($1.2 B urgent need), at-risk manufacturing of $5.3 B ($5.2 B urgent need) are required. ~$4.3 B from at-risk manufacturing is expected to be recovered as inventory value for successful candidates.

- **Volume guarantees/procurement**
  Significant amounts of capital will be required for manufacturer- specific and market-wide volume guarantees and advance procurement for countries of all income levels, including $5.5 B ($2.0 B urgent need for AMC) for immunizing for example healthcare workers and high risk population of LMICs through the Gavi Advance Market Commitment (AMC) and securing an emergency vaccine stockpile of ~200 M doses. In addition, a commitment from HIC and UMIC to procure ~950 M doses through the COVAX Facility is needed. The final cost will depend on the even-tual vaccines that are developed. Payments will only be made once candidates reach licensure or an equivalent regulatory milestone (e.g., recommendation of use). It is necessary to have funding and guarantees in place to protect volumes and encourage manufacturers to scale up and enter multilat- eral deals with the COVAX Facility.

- **Delivery costs**
  ~$3.2 B ($1.4 B urgent need) are needed for in-country delivery to build up supply chain capacity and carry out vaccine campaigns in LIC and LMIC as well as for global coordination and technical assistance. Delivery for UMIC and HIC is expected to be covered by domestic health budgets.

Against the human costs of the pandemic, and the estimated $375 B[1] impact on the global economy every month we delay, the imperative to **act now**, and to **act together**, and to **act boldly**, is clear.