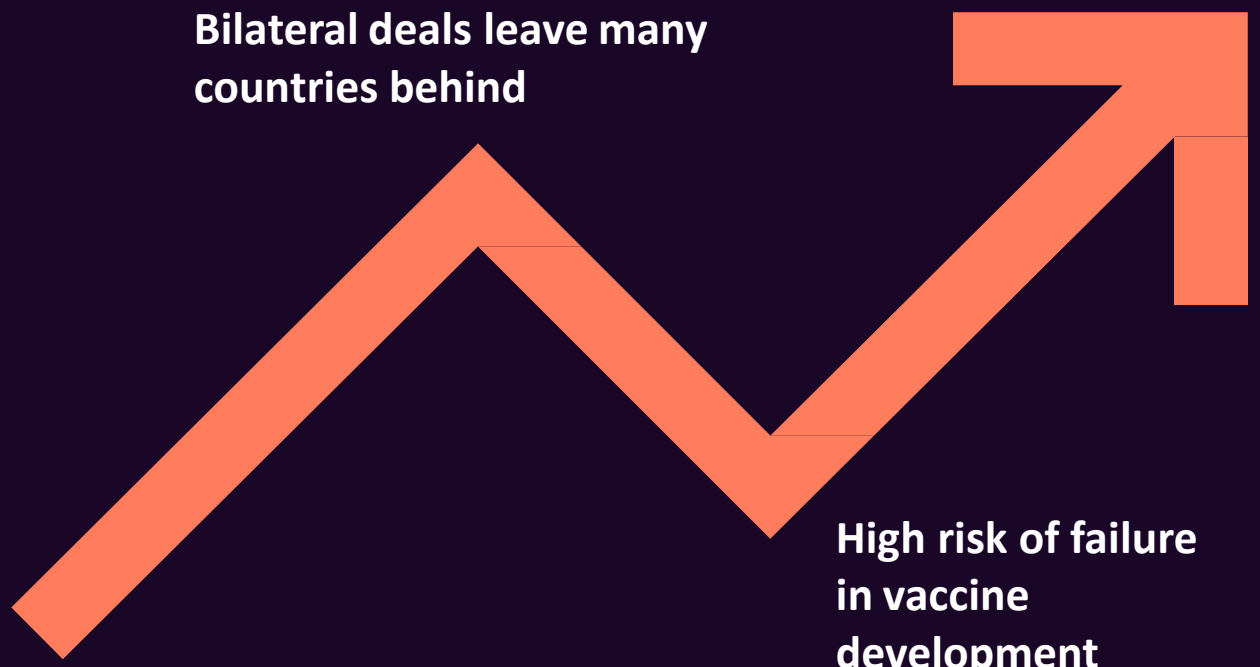
# COVAX Facility
# Background information for self-financing participants

August 2020

# Scene-setting and benefits of the COVAX approach

# Why we need COVAX

With a fast-moving pandemic, no one is safe, unless everyone is safe




- Today, historic scientific collaboration, with currently over 200 vaccine candidates in varying stages of development
- Unprecedented commitment from industry to work together in the interest of the global public good
- Under a business as usual approach, it could take years to develop effective vaccines and decades to ensure they reach everyone that needs them
- US$375 billion lost to the global economy each month

# The COVID-19 pandemic: Facts at a glance

STATUS AS OF AUGUST 10

**COVID-19 is the biggest threat to global health security in a century**

**19.5M**
Confirmed COVID-19 cases globally[1]

**722k**
COVID-19 related deaths globally[1]

**188**
Affected countries and territories globally[1]

**$9T**
Global economic cumulative losses in 2020 and 2021[2]

**COVID-19 vaccine development is advancing at an unprecedented pace**

**160+**
COVID-19 vaccines in development[3]

**26**
COVID-19 vaccines in clinical trials[3]

**But development and manufacturing are complex, long and risky**

**7% / 17%**
Probability of success for preclinical/ clinical vaccine programs[4]

**$137M - 1.1B**
Average R&D costs to develop a vaccine[5]

**12-18 months**
expected supply constraints after approval of the first COVID-19 vaccine

Source: 1 WHO Coronavirus Disease (COVID-19) Dashboard, status August 10, 2020; 2 IMF; 3 WHO, status July 31, 2020; 4 Pronker et al., PLoS One, 2013; 5 Gouglas et al.,The Lancet , 2018

# Our goals

To support the largest actively managed portfolio of vaccine candidates globally

To deliver 2 billion doses by end of 2021

To offer a compelling return on investment by delivering COVID-19 vaccines as quickly as possible

To guarantee fair and equitable access to COVID-19 vaccines for all participants

To end the acute phase of the pandemic by the end of 2021

# COVAX: an end-to-end solution

**Bold ideas and brilliant innovation for the worst global health crisis in 100 years**

# COVAX and the ACT Accelerator

Part of a worldwide effort to develop and deploy Advanced COVID Tools across vaccines, therapeutics and diagnostics

# ACT-A Facilitation Council

**Vaccines**

2 billion doses to the world by the end of 2021

CEPI · Gavi The Vaccine Alliance · World Health Organization

**Therapeutics**

245 million courses to LMICs by mid-2021

wellcome · Bill & Melinda Gates foundation · Unitaid Innovation in Global Health

**Diagnostics**

500 million tests to LMICs by mid-2021

FIND Because diagnosis matters · The Global Fund

**Health Systems Connector**

*Delivery Partners*

THE WORLD BANK IBRD • IDA | WORLD BANK GROUP · The Global Fund

# One world, protected.

## Together we are stronger than we are apart

| | |
|---|---|
| CEPI | Supporting vaccine research and development from the lab to the production facility |
| Gavi The Vaccine Alliance | Pooling procurement and incentivizing manufacturing expansion to secure rapid supply of safe and efficacious vaccines for countries and territories |
| World Health Organization | Providing normative guidance on vaccine policies, safety, regulation, and allocation |

# Status of expressions of interest

STATUS AS OF AUGUST 10

**High income:** 41 EOIs, 0.5+ B people

**Upper middle income:** 39 EOIs, 1.0+ B people

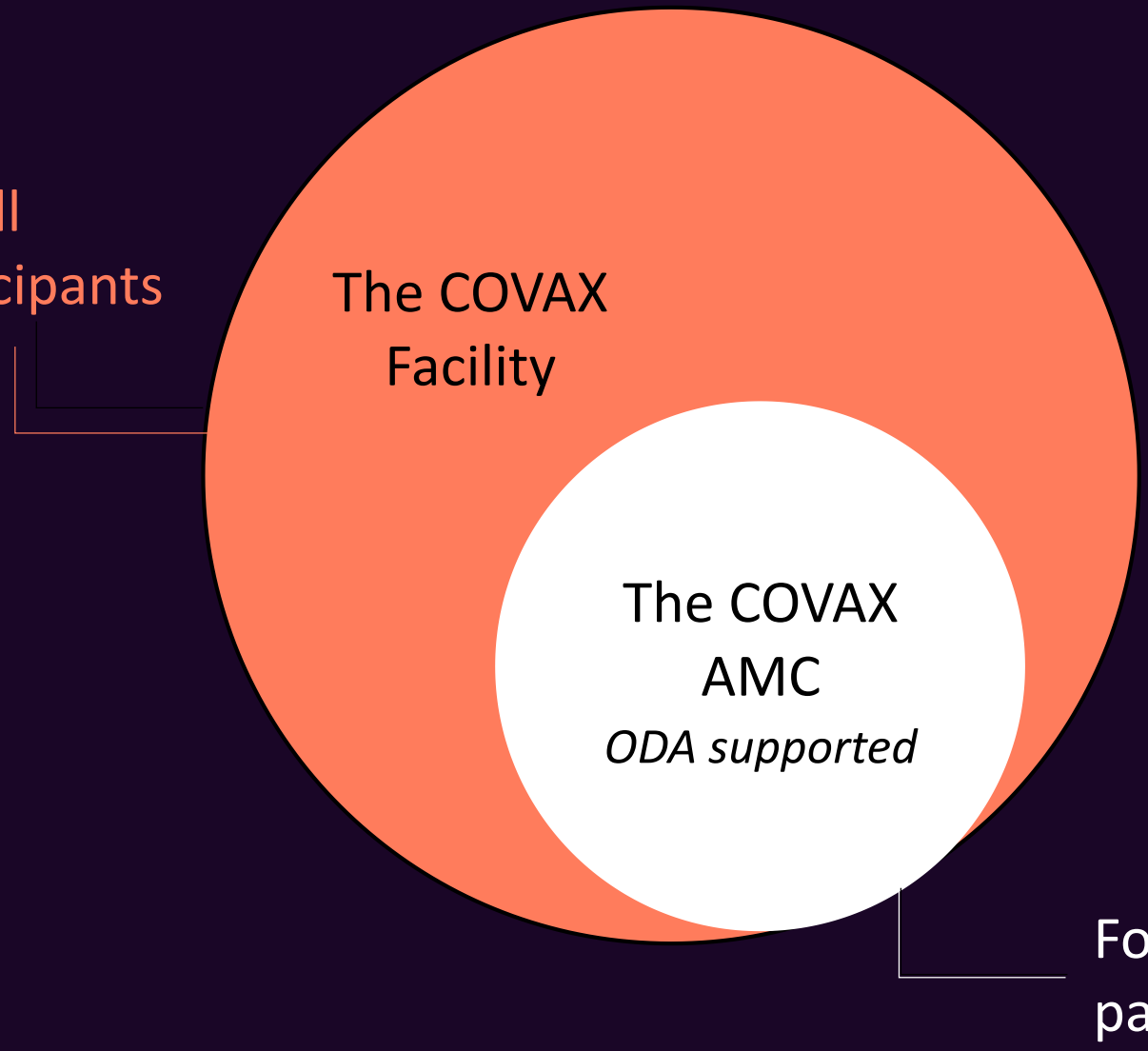
**Low income / lower middle income:** 92 AMC-eligible economies[1], 3.9+ B people

1. AMC-eligible economies are not required to submit an expression of interest; includes 12 IDA-eligible upper middle income economies

# Facility overview and the benefits of pooled procurement

# The COVAX Facility serves all participants

The COVAX AMC is an instrument for ODA-eligible countries



# The Facility connects a pool of demand to a pool of supply

Bold ideas and brilliant innovation for the worst global health crisis in 100 years


Consolidates buying power and provides participants access to a broad and actively-managed portfolio

Provides manufacturers access to a massive, demand-assured market

# Binding commitments to the Facility in exchange for access to doses

## Participants

Joining involves making several commitments…

- Financial commitment to purchase a pre-defined number of doses
- Additionally provide an upfront payment so the Facility can accelerate development and manufacturing
- Contribute data (e.g. epidemiological) to global information repositories
- Support for accelerated regulatory pathways

## The COVAX Facility

…and receiving benefits in return

- Allocation of doses sufficient to cover 20% of the population; once 20% is covered, additional doses can be allocated
- Diversified vaccine candidate portfolio, including candidates that may be better suited for specific subpopulations
- Accelerated access to doses
- Access to Facility-negotiated price including benefits from economies of scale
- Reduced competitive dynamics among countries

# The Facility provides demand certainty to manufacturers in exchange for timely dose supply

## The COVAX Facility

The Facility makes an offer to manufacturers…

- Financing to accelerate manufacturing scale-up
- Commitment to procure a pre-defined number of doses
- Payment conditional on regulatory approval, WHO prequalification, etc.
  - Manufacturer-specific volume guarantees as strong, tailored demand signal
  - Market-wide demand guarantee to signal long-term market viability and support continued vaccine development

## Manufacturers

…and receives secured supply in return

- Make the necessary investments in capacity to provide the agreed volumes
- Supply reserved doses for the Facility in a timely manner
- Negotiate price under the expectation to seek minimal return during the acute phase of the pandemic
- Provide transparency on funding received and relevant contract terms to enable complementary investments

# Gavi, the Vaccine Alliance: implementing innovative solutions to immunization challenges


## The Alliance operating at scale …

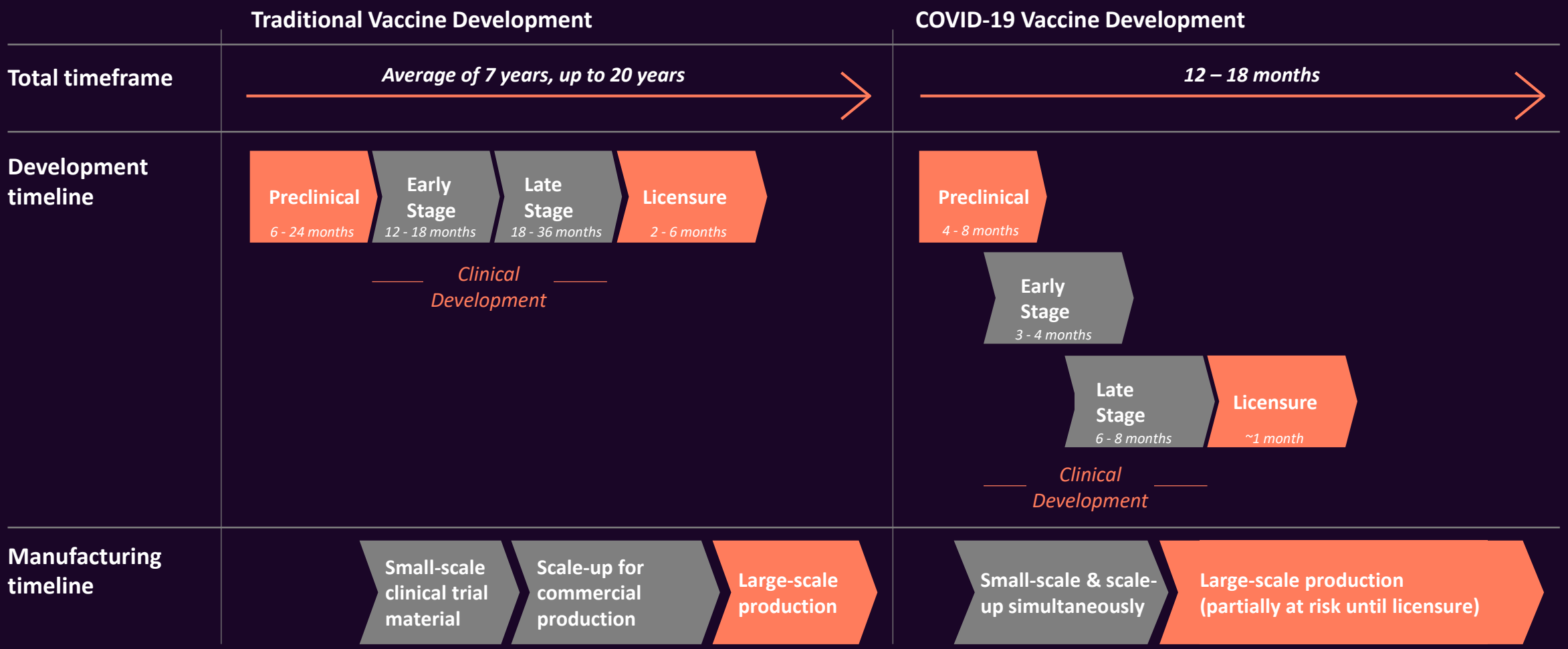
- 60% of the world's birth cohort
- > 822 million children vaccinated
- Manufacturer base grown from 5 to 17
- 5 bn doses procured ($9 bn) since 2012

Text

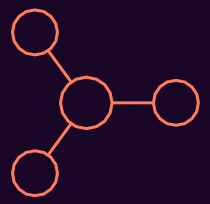
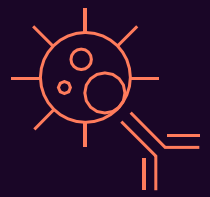
# COVAX candidates and deals with manufacturers

# Paradigm shift was required to accelerate COVID-19 vaccine development and manufacturing

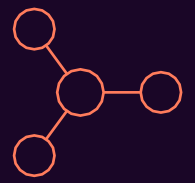
HIGHLY ILLUSTRATIVE



# Different vaccine technologies are under development

| Technology | | Description | Example candidates *(not exhaustive)* |
|---|---|---|---|
|  | **Protein** | **Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response | Clover Biopharmaceuticals, NOVAVAX, The University Of Queensland Australia, CSL |
|  | **Nucleic Acid** | **Genetically engineered plasmid containing the DNA sequence** containing sequence for disease-specific antigen<br>**Messenger RNA** containing sequence for a disease-specific antigen | inovio, CUREVAC, moderna, BIONTECH |
|  | **Viral vector** | **Chemically weakened viruses to carry DNA**, containing sequence for disease-specific antigen, into human cells | MERCK, THEMIS, University of Oxford, AstraZeneca |
|  | **Inactivated** | **Chemically "killed" virus or subunits of the virus** grown under controlled conditions | sinovac, SINOPHARM |

# The technologies have different advantages

| Technology | | Advantages | Comparative cost per dose |
|---|---|---|---|
|  | **Protein** | Vaccine technology is widely used<br>Proteins are versatile and customizable<br>No use of viruses, so no risk of biological contamination | $$ |
|  | **Nucleic Acid** | Preparation and formulation is simple<br>Fast to produce and to adapt<br>Production can be easily repurposed for other Vx | $$$ |
|  | **Viral vector** | Produces strong response in immune system<br>Genes can enter host cells easily<br>Genes go directly to target cells | $ |
|  | **Inactivated** | Vaccine technology is widely used<br>Less risk of adverse effects<br>Very suitable for some populations (e.g., elderly, people with immunodeficiency) | $ |

**One vaccine may be more suitable for a target group and/or a specific region than another**

**A diversified portfolio allows to utilize advantages across technologies**

# Portfolio candidates are selected based on five assessment criteria and a granular due diligence

1. **Identify candidates**
2. **Shortlist candidates based on assessment criteria**
3. **Perform Due Diligence on shortlisted candidate(s)**
4. **Negotiate contracts with selected candidate(s)**
5. **Sign-on candidate(s) to the portfolio**

## 2 Assessment criteria

Shortlisted candidates are assessed on five assessment criteria

- **Efficacy/Immunogenicity** (Preclinical studies and dose)
- **Safety** (Toxicity and clinical safety profile)
- **Technical** (Scalability, Speed, Formulation and Quality)
- **Access/regulatory** (fair global allocation and regulatory pathway)
- **Partnership** (awardee capability/resources and strategic positioning)

# Dose availability can be accelerated through two types of investments – COVAX needs both

## Two types of investments to accelerate dose availability

1 **Dose manufacturing parallel to clinical development (at-risk)**

Invest in manufacturing vaccine doses before approval to accelerate dose availability

2 **Volume guarantees**

Incentivize manufacturers through volume guarantees and a guaranteed market to ensure dose availability

## Why COVAX needs both

- ✓ To **maximize our chance of success,** we need to invest manufacturing in a wide-range of candidates already today
- ✓ To **ensure sustainable dose availability**, volume guarantees create a guaranteed market to manufacturers
- ✓ To **accelerate timelines as much as possible**, both investments together create the strongest incentive

# Allocation, policy, regulatory, safety & monitoring

# Three components inform the formulation of vaccination strategies

## 2: Strategic Advisory Group of Experts (SAGE)

*Provides guidance and policy advice in the context of specific candidates, e.g. on vaccination strategies*

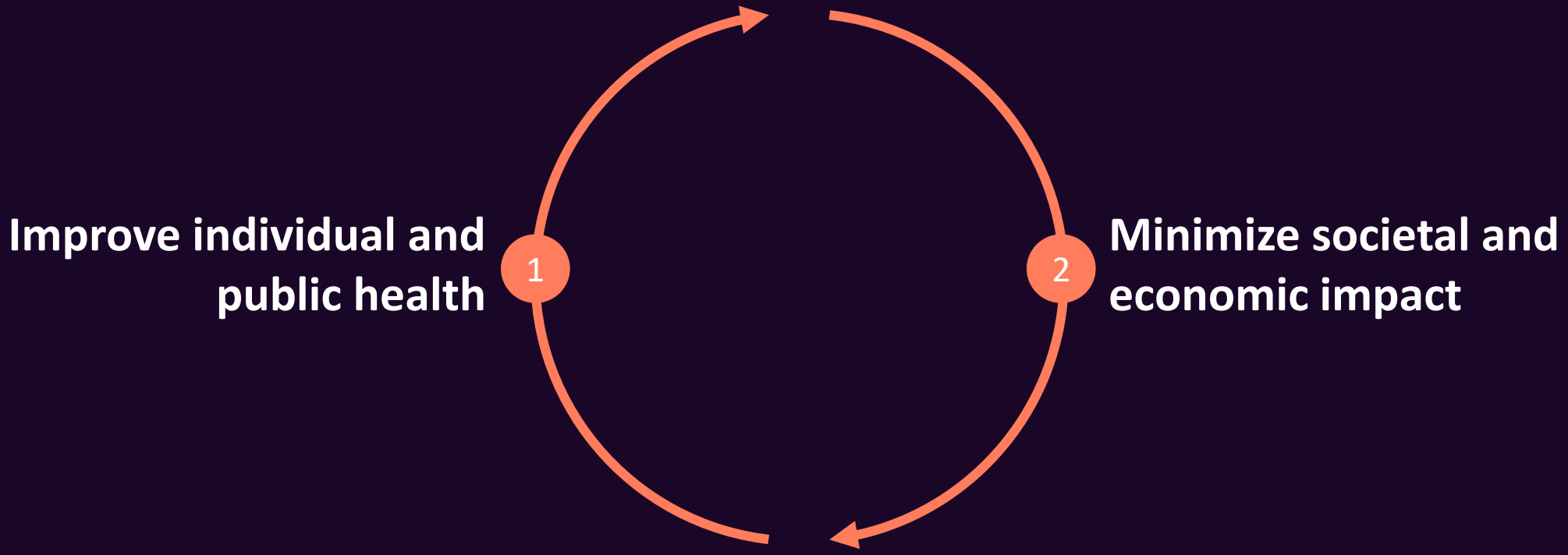
## 1: Allocation Framework

*Sets frame for overarching public health goals and priorities (candidate independent)*

## 3: Regulatory, Safety & Monitoring

*Provides guidance on regulatory issues, safety and monitoring both for candidate specific and system specific approaches*

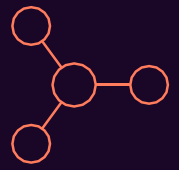
# 1: The two main goals of a vaccination program are inextricably linked




To significantly reduce the impacts of COVID-19 in the safest, quickest and most effective way, it is not necessary to vaccinate the entire population

# 2: Vx candidates use different technology platforms with implications for how they can be used

## Different technologies …



**Protein**

**Nucleic Acid**

**Viral vector**

**Inactivated**

## … with different characteristics

**Vaccine characteristics and study settings (e.g. trial population or regional setting) affect deployment:**

- Immunogenicity (e.g. sub-optimal effect on elderly populations)
- Safety profile (e.g. women of childbearing age)
- Ability to scale-up manufacturing
- Cold chain requirement (e.g. -70C°)
- …

One vaccine may be **more suitable for a target group and/or a specific region than another**

Vaccines are **unlikely to be interchangeable**

**Need for guidance and policy advice for specific vaccine candidates**

# 2: Strategic Advisory Group of Experts (SAGE) on Immunization: Introduction and setup

**SAGE is the principal advisory group to WHO for vaccines, providing guidance and policy advice for specific vaccine candidates**

1. Providing **continuous review** of the available evidence on the progress of specific vaccine candidate
2. Providing **guidance** for the development of prediction models to determine the optimal age groups and target populations for the introduction of a specific vaccine candidate
3. Preparing **policy advice** on the accelerated use of vaccine candidates, including recommendations for early allocation of vaccines when vaccine supply is still limited
4. Providing **guidance** to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available

## Sub-working groups

SAGE's review, guidance and policy advice is informed by three sub-working groups:

- **Vaccination goals & prioritization**
- **Evidence gathering on vaccines in clinical trials**
- **Vaccine impact modelling**

# 3: The situation is unique from a regulatory approval and safety & monitoring perspective

| | Regulatory approval | Safety & Monitoring |
|---|---|---|
| **What makes this situation unique** | • Need for global regulatory alignment at **high speed**<br>• **Need to manage massive workloads** before and after regulatory approval processes<br>• **Need for simultaneous regulatory approval in high number of jurisdictions** with different regulatory contexts | • **High number of novel platforms** in the race (e.g. mRNA)<br>• **High speed from development to scaled mass vaccine delivery** (e.g., tens of thousands subject in clinic and tens to hundreds of millions of vaccinations in few months) |
| **What COVAX is doing to address these issues** | • **We are working with regulators**, including FDA and EMA, on several topics and specific products | • **We are working with a number of organisations and advisory committees** on how best **to define and prepare for safety and monitoring** for adverse events to inform vaccine delivery |

# Terms of participation - agreements with the Facility

# Clearly defined participation principles will support the ambitious undertaking of the Facility

| | |
|---|---|
| **Global access** | • Ensure everyone can secure access to safe and efficacious vaccine to protect health security globally<br>• Open to all, no one is prevented from participating due to income |
| **Impact orientation and transparency** | • Single minded in its goal to ensure equitable access to COVID-19 vaccines<br>• Coordinated strategy for vaccination as supply constrained in the short term |
| **Solidarity and collective ownership** | • Commitment of participants to collaborative global effort - everybody contributes so that everyone can benefit<br>• Clear political and financial commitments - all participants asked to contribute based on their capacities |
| **Complementarity with other funding** | • End to end solution – complementary investments to drive rapid availability of supply at scale<br>• Manufacturers requested to disclose third party funding for R&D or manufacturing, which will be considered in contractual conditions<br>• Vaccines from any manufacturer considered including those not in the CEPI/BMGF portfolio |

# Overview of the participation agreements

## Commitment Agreements

These will be participant-specific and will set out the specific financial commitment to be made by the participant to the Facility. Sections will be included on expected doses to be made available for procurement.

## Principles of Participation

These principles will provide the basis on which self-financing participants join the Facility. The Principles will be attached to and referenced in the Commitment Agreements.

# Non-financial commitments

# For discussion: Non-financial commitments

| | |
|---|---|
| **Ensure unrestricted movement of vaccine doses from domestic manufacturers** | Participants agree to **not impose embargoes** or any **impediments to access**, **support timely National Regulatory Authority (NRA) release**, **import/export** of vaccines, and prioritize cargo space for vaccine shipments |
| **Facilitate regulatory clearance** | Participants are encouraged to promote and leverage **regulatory convergence, collaboration and reliance** as much as possible **to fast-track the path to vaccine licensure** |
| **Contribute to global information repository** | Participants agree to **contribute data** (e.g. epidemiological and virological) **to global information repositories** to build the overall body of knowledge (e.g. to inform vaccine development and vaccination strategies) to the benefit of all |
| **Provide transparency on bilateral supply agreements** | Participants commit to **being open and transparent about their own COVID-19 vaccine supply agreements with the Facility**, which will help the Facility optimizing its portfolio of investments to the benefit of all |

# The global pandemic requires an aligned approach on issues relating to liability and indemnification for COVID-19 vaccines under COVAX

The global pandemic presents **unprecedented circumstances** in terms of the speed of development and the scale of use of COVID-19 vaccines

There is an **unknown risk of potential liability** arising from COVID-19 vaccines

**Mechanism to compensate** persons who have sustained unexpected SAEs following vaccination

There is a **high urgency to avoid a potential delay** to widespread vaccine delivery

The Liability Task Force which sits within COVAX is looking at these issues. The Task Force will engage with multiple stakeholders involved and affected by these issues to understand the issues and identify potential solutions.


CEPI


Gavi
The Vaccine Alliance


World Health
Organization