COVAX Facility
Consultation with self-financing countries – Day 1

July 16, 2020

Welcome & objectives of the consultation

Objectives

1. **Clarify the COVAX offer - overview of the Facility, vaccine candidate portfolio, and how it will work**

2. **Provide an opportunity for countries to discuss, clarify, and come to common understanding on key issues related to participation, allocation, governance and design of COVAX**

Agenda & housekeeping

Meeting preparation – Day 1

Agenda for 16 July Country Consultations – ~3 h

Topic
Welcome & Objectives of the consultation
Agenda & housekeeping
Scene-setting, benefits of the COVAX approach
Deep dive 1: Value proposition and what participating countries can expect to receive
1. Facility overview and benefits of pooled procurement
2. COVAX candidates and the actively managed portfolio
3. Deals with manufacturers
4. Manufacturer support for Facility and perspective on the approach
Participant Discussion
5. Allocation, policy, regulatory, safety & monitoring
Participant Discussion

Meeting preparation – Day 2

Agenda for 17 July Country Consultations – ~3 h

Topic
Welcome and recap from Day 1
Participant discussion/ overflow questions from Day 1
Deep dive 2: Terms of participation - agreements between the Facility and countries
1. Overview of the different agreements
2. Financial commitments of countries
3. Non-financial commitments of countries
Participant discussion
Deep dive 3: COVAX Facility governance and how countries participate
Governance
Participant discussion
Timelines and next steps
1. What to expect – between now and 31 Aug
2. General questions for wrap-up of the consultation

Housekeeping

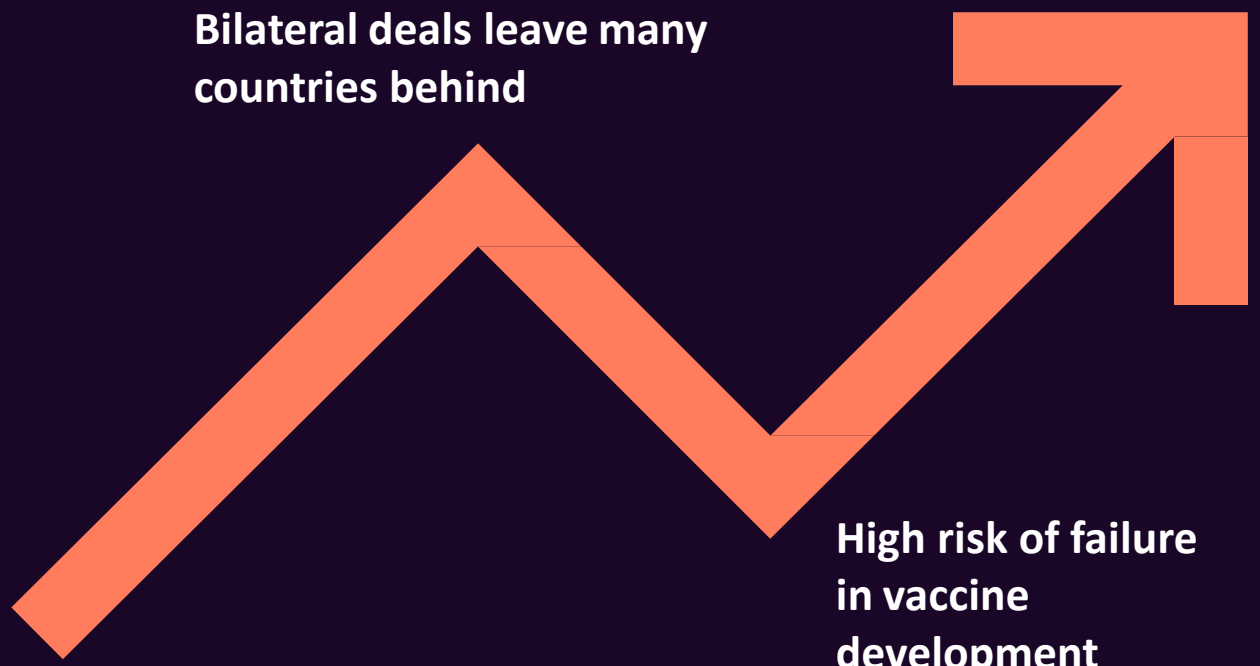
We **have a full house today, so we kindly ask you to…**

- **Please click the 'raise your hand' button** if you would like to speak. We **ask participants to share questions/comments verbally** during the Q&A as much as possible
- **Please state your name and country before sharing a comment or question**
- **Please save questions for the relevant part of the agenda** focusing comments on the topics currently being discussed
- Please make **time bound interventions.** Given the time constraints, we will proceed directly to the content and not have opening statements
- **Please respect Chatham House Rules** – none of the comments raised on the line should be attributed
- You are invited to use **informal forms of address**
- We anticipate convening additional sessions and following-up in writing to respond to unanswered questions over the next several weeks
- **Share any further input offline to covax@gavi.org**

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

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

13.1M

Confirmed COVID-19 cases globally[1]

573k

COVID-19 related deaths globally[1]

189

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]

23

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 July 15, 2020; 2 IMF; 3 WHO, status July 13, 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 participating countries

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

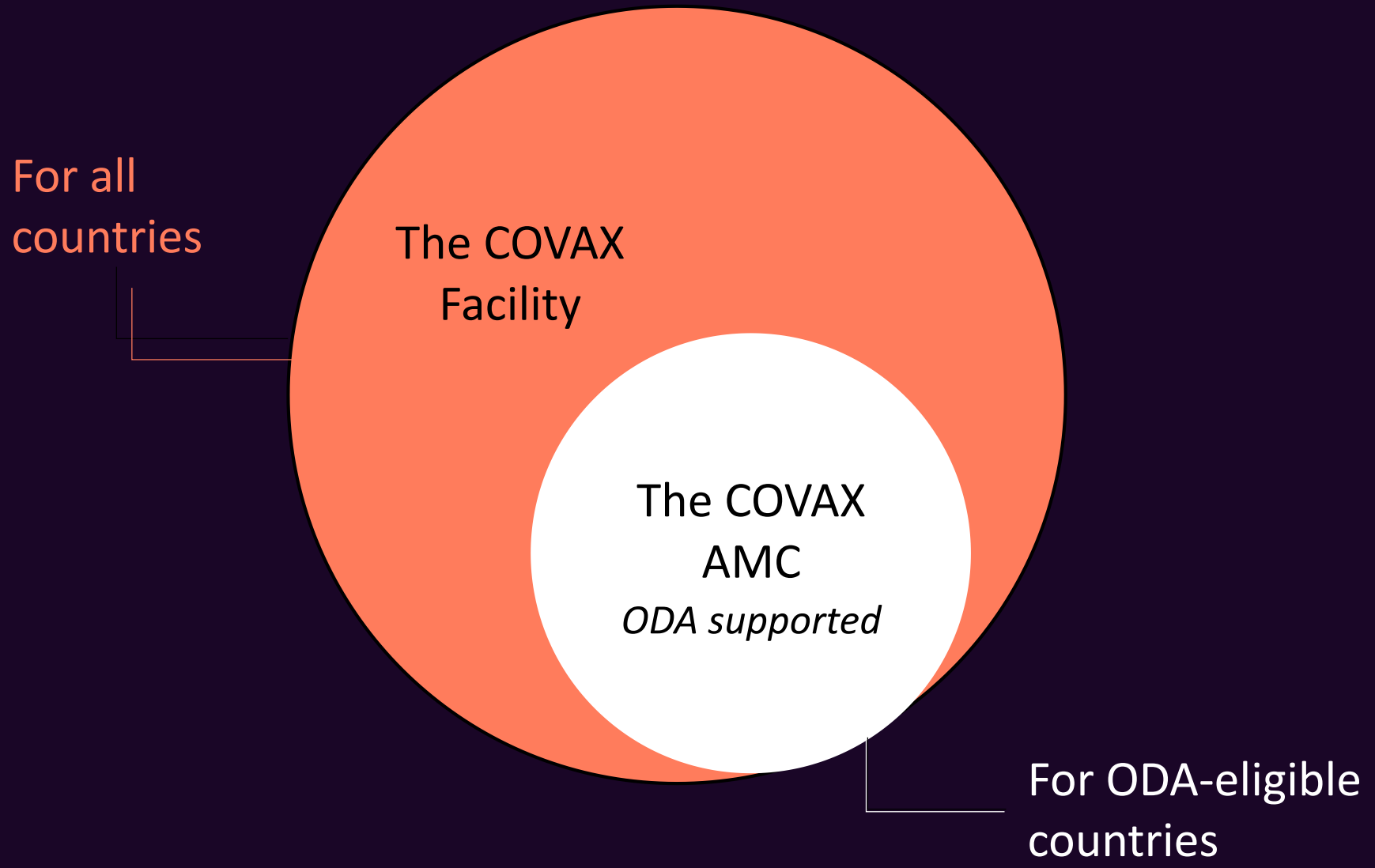
CEPI	Supporting vaccine research and development from the lab to the production facility
Gavi The Vaccine Alliance	Pooling procurement and incentivizing manufacturing expansion to secure rapid supply of safe and efficacious vaccines for countries
World Health Organization	Providing normative guidance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

Deep dive 1:
Value proposition and what participating countries can expect to receive

Facility overview and the benefits of pooled procurement

The COVAX Facility serves all countries

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

Pooled demand

Pooled supply

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

Provides manufacturers access to a massive, demand-assured market

Participating countries make binding commitments to the Facility in exchange for access to doses

Participating countries

By joining, countries make 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 receive benefits in return

- Allocation of doses sufficient to cover 20% of a country's 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 …

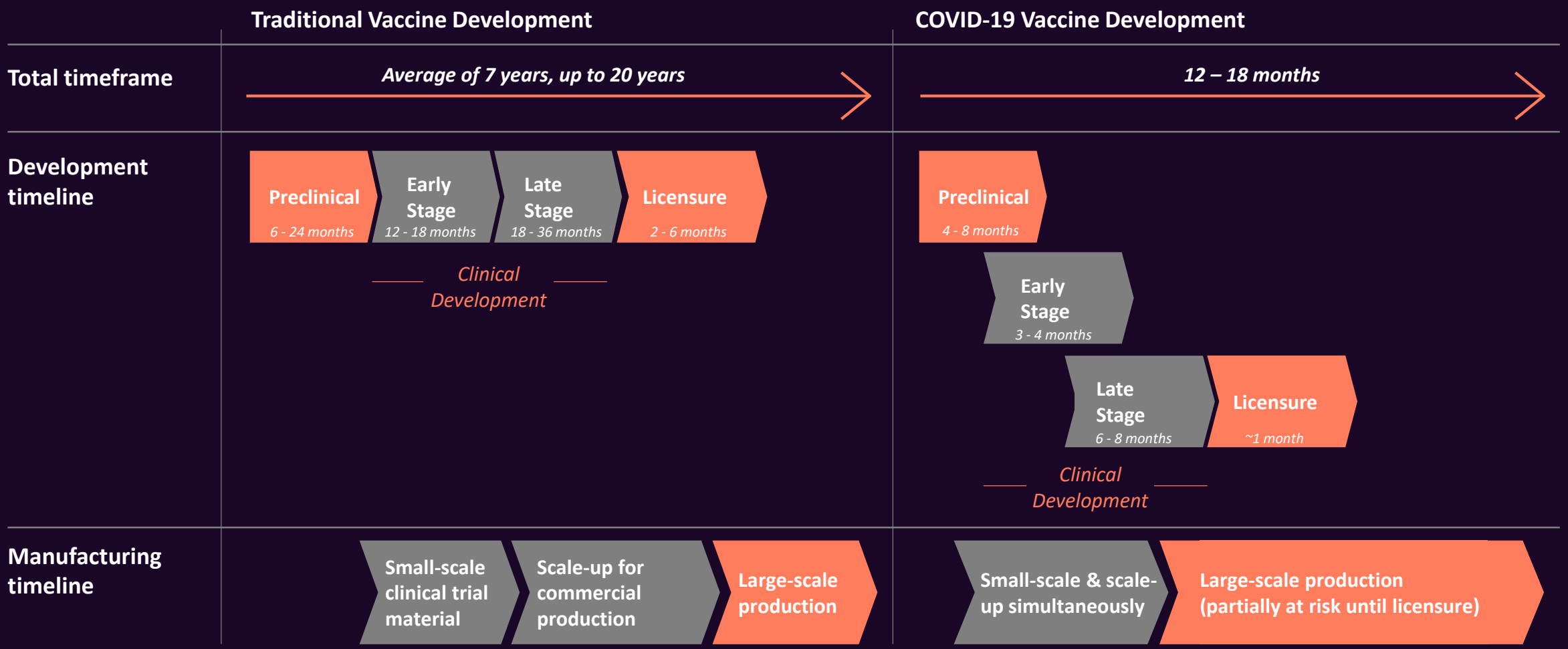
- 60% of the world's birth cohort
- > 822 million children vaccinated
- Manufacturer base grown from 5 to 17
- 5 bn doses procured ($9 bn) since 2012

Text

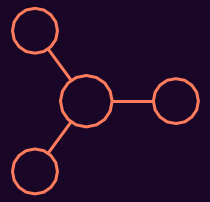
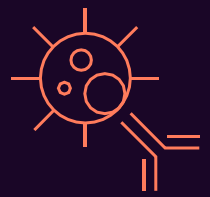
COVAX candidates and the actively managed portfolio

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

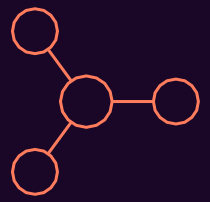
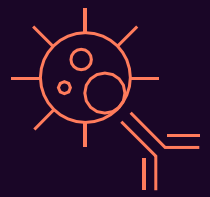
HIGHLY ILLUSTRATIVE



Different vaccine technologies are under development

Technology	Description	Portfolio candidates
 **Protein**	**Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response	NOVAVAX, Clover Biopharmaceuticals, The University Of Queensland, CSL
 **Nucleic Acid**	**Genetically engineered plasmid containing the DNA sequence** containing sequence for disease-specific antigen **Messenger RNA** containing sequence for a disease-specific antigen	inovio, CUREVAC, moderna
 **Viral vector**	**Chemically weakened viruses to carry DNA**, containing sequence for disease-specific antigen, into human cells	MERCK, THEMIS, University of Oxford, AstraZeneca

The technologies have different advantages

Technology		Advantages	Comparative cost per dose
	**Protein**	Vaccine technology is widely used Proteins are versatile and customizable No use of viruses, so no risk of biological contamination	$$
	**Nucleic Acid**	Preparation and formulation is simple Fast to produce and to adapt Production can be easily repurposed for other Vx	$$$
	**Viral vector**	Produces strong response in immune system Genes can enter host cells easily Genes go directly to target cells	$

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

A diversified portfolio allows to utilize advantages across technologies

CEPI COVID-19 vaccine portfolio currently consists of 9 projects

	DNA / mRNA			Viral vector			Protein		
COVID-19	**Inovio**	**Moderna**	**CureVac**	**Merck / Themis**	**AstraZeneca / Univ. Oxford**	**University of Hong Kong**	**Novavax**	**Clover BioPharma**	**University of Queensland / CSL**
Location	USA	USA	Germany	USA / Austria	UK	China	USA	China	Australia
Platform	DNA	mRNA	mRNA	Viral Vector	Viral Vector	Viral Vector	Protein	Protein	Protein
Antigen / Adjuvant	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Receptor Binding Domain / AS03	Full-length S protein / saponin-based Matrix-M	Full-length S protein/AS03 or CPG1018	Full-length S protein / MF59 or AS03 or CPG1018
Current phase	Phase I	Phase II a	Phase I	Preclinical	Phase III	Preclinical	Phase I	Phase I	Phase I

Speed

Scale

Access

An Active Portfolio Management is supporting COVAX ambition to deliver 2 B doses by end of 2021

HIGHLY PRELIMINARY – FOR REVIEW

Active Portfolio Management

Diverse Portfolio

Candidates across 4 technology platforms

Investments in R&D and manufacturing to accelerate production of doses

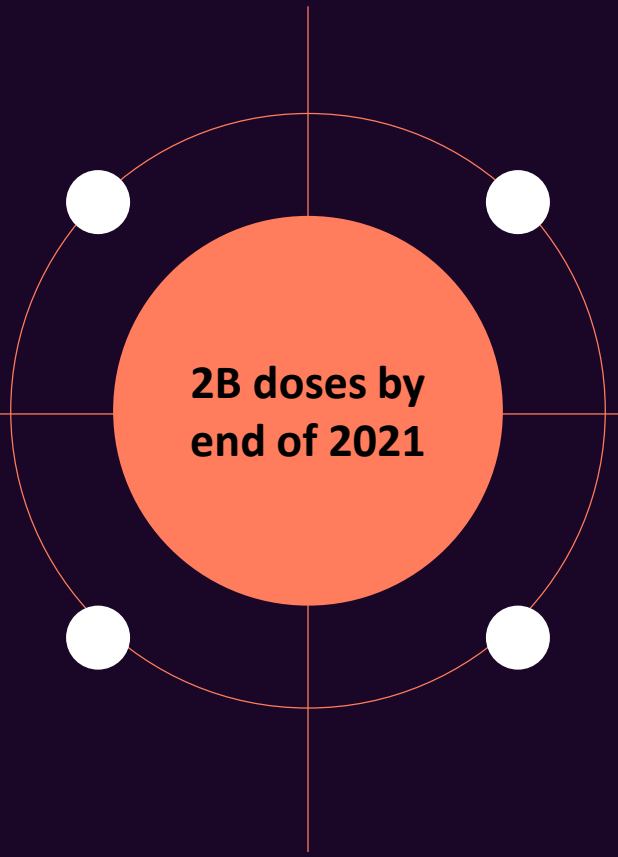
Portfolio spanning various Geographies

Expert and Industry support

150+ developers plans reviewed by experts

Best in class view of external landscape

Industry is fully engaged and supportive



Flexibility to put resources…

… behind the most promising vaccine candidates out of the 100+ in development

Discussions to include BMGF portfolio within COVAX to leverage 2nd wave/ generation of vaccine candidates

Ongoing negotiations with major vaccine manufacturers to optimize use of resources

Continuous assessment of opportunities…

…to expand portfolio e.g., single dose vaccine, new antigens, continued geographical spread, special populations

Advanced discussions with all assets in the clinic on manufacturing e.g., capacity planning

Deals with manufacturers

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

Manufacturer support for Facility and perspective on the approach

Thomas Cueni

Director General, International Federation of Pharmaceutical Manufacturers

Sai Prasad

President, Developing Countries Vaccine Manufacturers Network

IFPMA

dcvmn
Developing Countries Vaccine Manufacturers Network

Participant Discussion

Questions for input

- Does the COVAC Facility address the needs of your country? What would make the value proposition more compelling?

- Are there additional “investment” principles that the Facility should consider adopting?

Allocation, policy, regulatory, safety & monitoring

Three components inform how countries formulate their in-country 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)

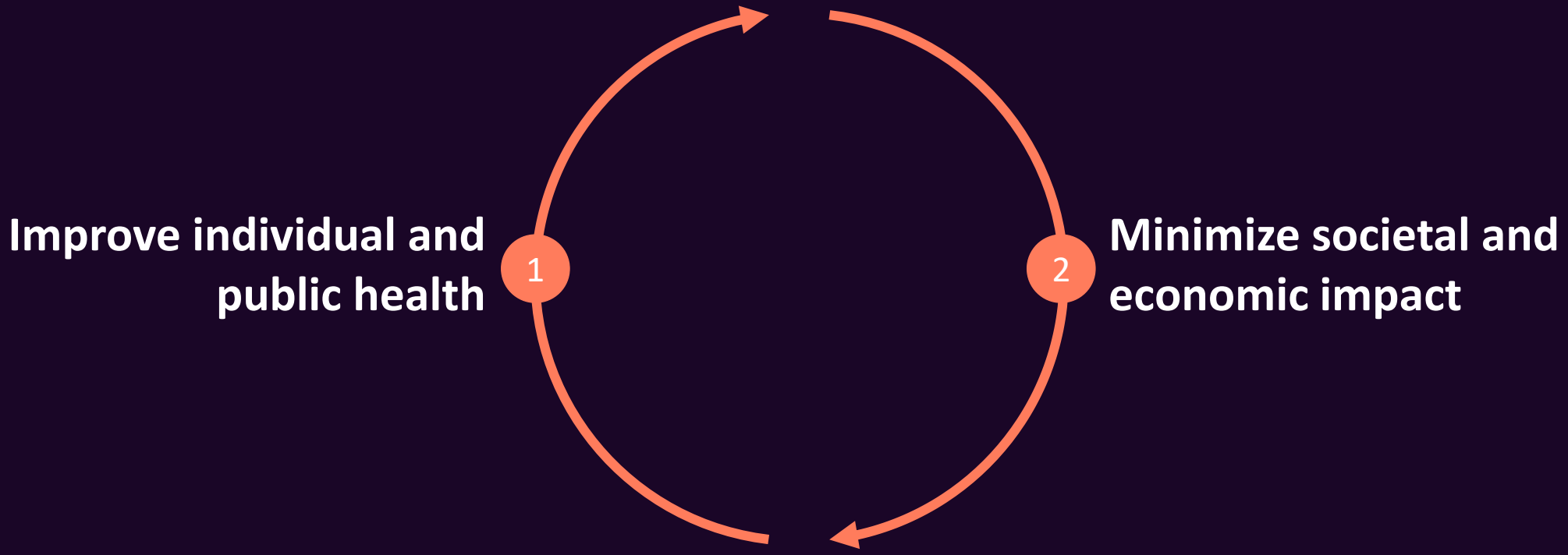
3: Regulatory, Safety & Monitoring

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

Countries

Responsible for final decision on in-country policy, allocation and vaccination strategy

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

1: The global allocation framework secures fair, equitable and necessary access

Initial view for Vaccine Allocation Mechanism

Goals	**Reducing COVID-19 mortality & protecting health systems** will significantly improve the well-being of populations and reduce the impact on societies and economies
Priorities	The goal above in the context of **scarce supply** leads to **prioritization of specific population groups** for vaccination These could include **health and social care workers, older adults, and others with high risk conditions.** Specific policy recommendations from SAGE once performance of specific products is known
Timing	Given the ubiquitous nature of COVID-19, **all countries should receive an initial allocation** as products become available **Eventually,** timing for countries would be **based on a risk assessment of countries**' vulnerability and COVID-19 threat

1: We have continued to develop the draft Allocation Framework and Allocation Mechanism for Vaccines based on your feedback

Goals

Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

Priorities

Health and social care workers	High-risk adults	Further priority groups
All countries receive doses to cover 3% of their population. This would be enough to cover all workers involved in health and social care work.	**All countries receive additional doses beyond the 3% to total 20% of their population (in tranches).** This could include the elderly, adults with comorbities or others depending on locally relevant risk factors	**Countries receive doses to cover more than 20% of their population.** This would cover additional priority populations.

Timing

*Countries receive doses proportionally to their total population**

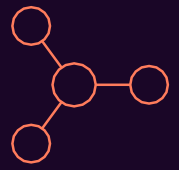
Timing is based on country need, vulnerability and COVID-19 threat

A buffer will also be set aside for emergency deployment based on immediate needs

Note: The fundamental principle applies that all countries receive doses at the same rate to the extent possible, notwithstanding likely practical limitations to be further worked out (e.g. minimum delivery volumes)

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

Different technologies …



Protein

Nucleic Acid

Viral vector

… with different characteristics

Vaccine characteristics and study settings (e.g. trial population or country 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 country 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** • **Need to manage massive workloads** before and after regulatory approval processes • **Need for simultaneous regulatory approval in high number of countries** with different regulatory contexts	• **High number of novel platforms** in the race (e.g. mRNA) • **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

Participant Discussion


CEPI
Gavi
The Vaccine Alliance
World Health
Organization