COVAX Facility
Consultation with the self-financing group – 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 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 Consultations – ~3 h

Topic	Presenter
Welcome & Objectives of the consultation	Andrew Witty
Agenda & housekeeping	Andrew Witty
Scene-setting, benefits of the COVAX approach	Richard Hatchett (CEPI) / Seth Berkley (Gavi) / Soumya Swaminathan (WHO)
Deep dive 1: Value proposition and what those participating can expect to receive	
1. Facility overview and benefits of pooled procurement	Seth Berkley (Gavi)
2. COVAX candidates and the actively managed portfolio	Richard Hatchett (CEPI)
3. Deals with manufacturers	Mel Saville (CEPI) / Derrick Sim (Gavi)
4. Manufacturer support for Facility and perspective on the approach	Thomas Cueni (IFPMA) and Sai Prasad (DCVMN)
Participant Discussion	
5. Allocation, policy, regulatory, safety & monitoring	Kate O'Brien / Mariangela Simao / Emer Cooke (WHO)
Participant Discussion	

Meeting preparation – Day 2

Agenda for 17 July Consultations – ~3 h

Topic	Presenter
Welcome and recap from Day 1	Andrew Witty w/ Seth, Richard, and Soumya
Participant discussion/ overflow questions from Day 1	
Deep dive 2: Terms of participation - agreements with Facility	
1. Overview of the different agreements	Aurélia Nguyen (Gavi) / Anthony Brown (Gavi)
2. Financial commitments	Marie-Ange Saraka-Yao (Gavi)
3. Non-financial commitments	Aurélia Nguyen (Gavi) / Dick Wilder (CEPI)
Participant discussion	
Deep dive 3: COVAX Facility governance	
Governance	Aurélia Nguyen (Gavi) / Anthony Brown (Gavi)
Participant discussion	
Timelines and next steps	
1. What to expect – between now and 31 Aug	Richard Hatchett (CEPI) / Seth Berkley (Gavi) / Soumya Swaminathan (WHO)
2. General questions for wrap-up of the consultation	Richard Hatchett (CEPI) / Seth Berkley (Gavi) / Soumya Swaminathan (WHO)

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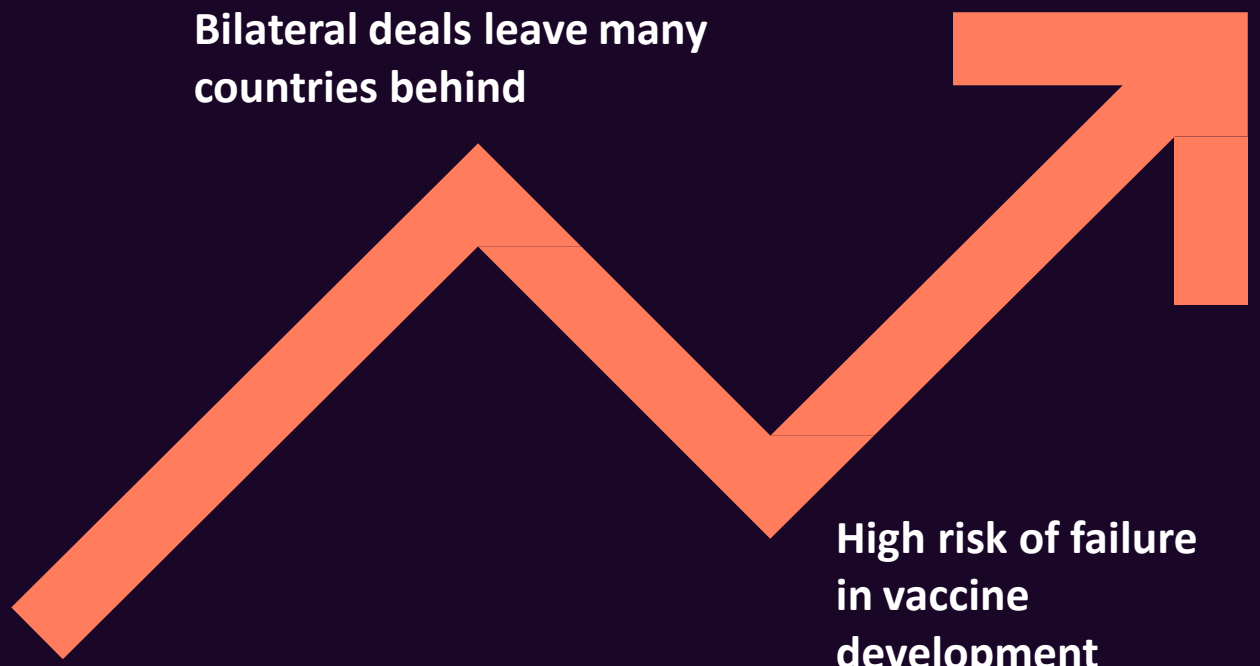
- **Share any further input offline to covax@gavi.org**

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 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

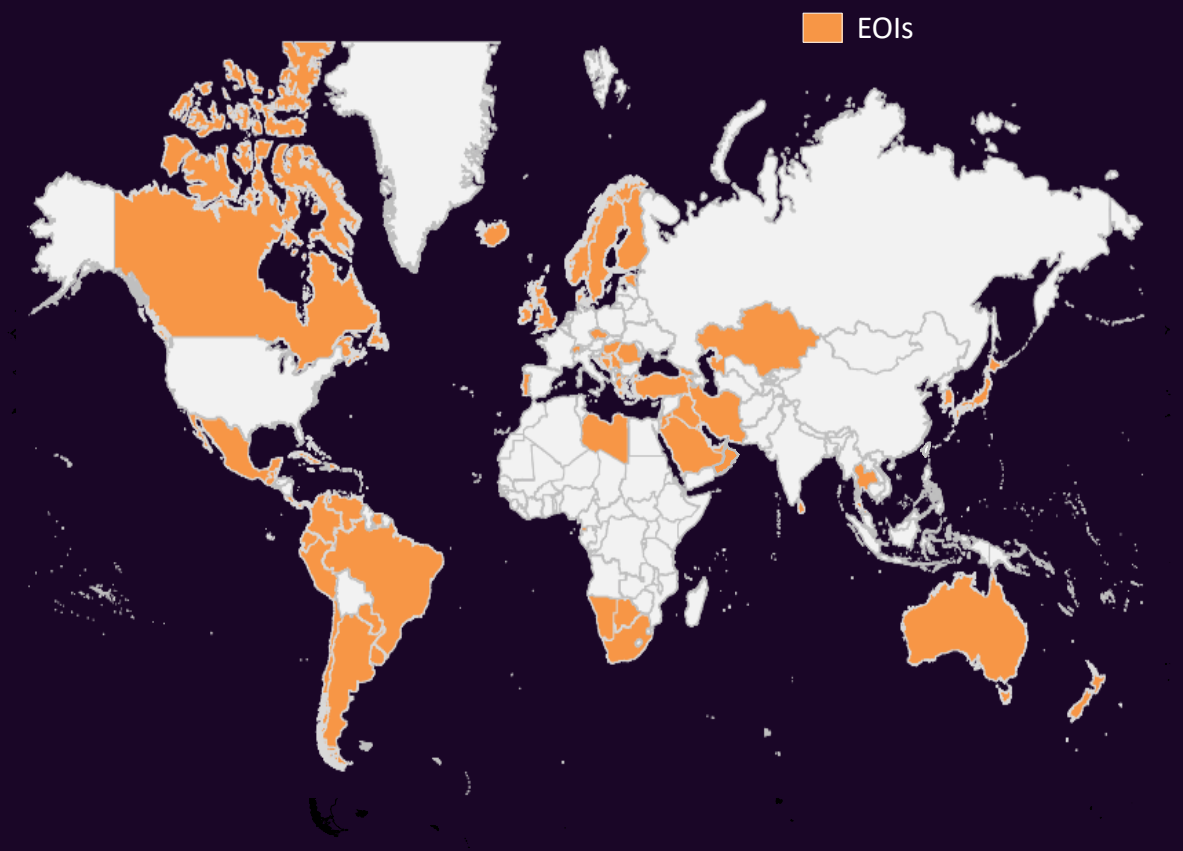
One world, protected.

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

One world, protected.

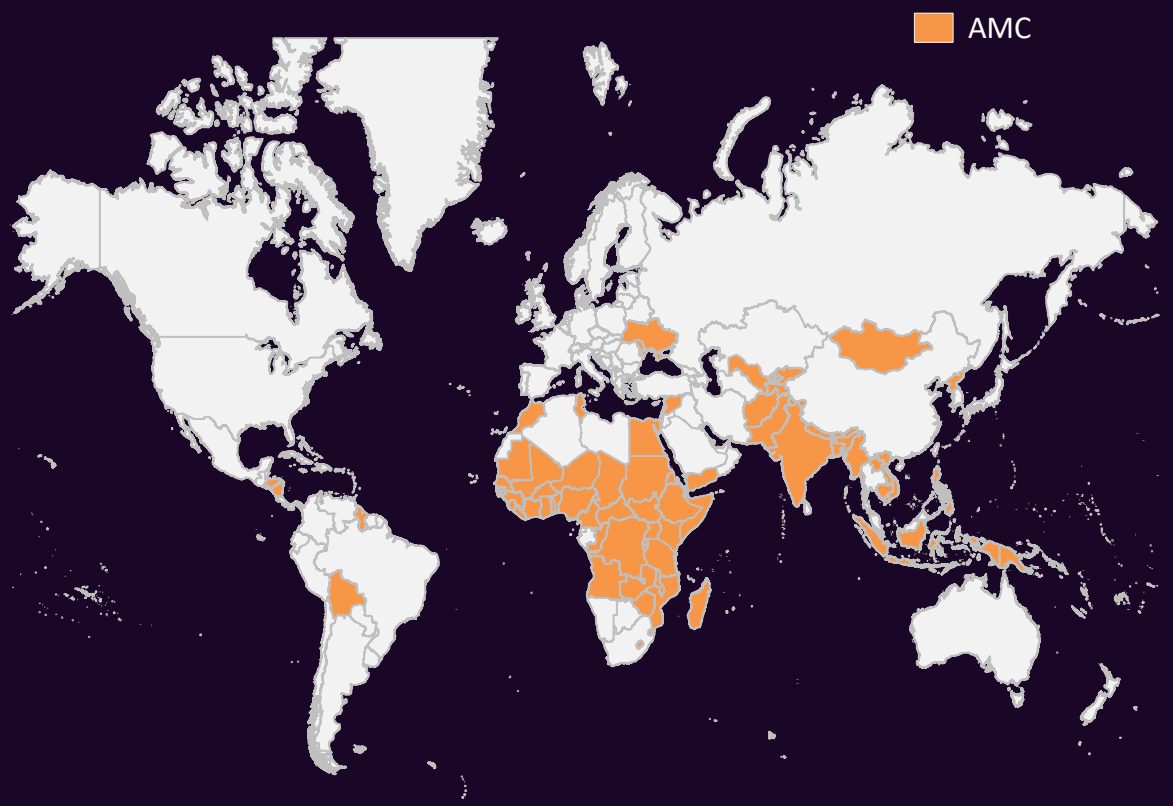
77 EOIs received *(to date)*



HIC: 40 EOIs, 0.5+ B people

UMIC: 37 EOIs, 1.0+ B people

COVAX AMC with ODA donor-support



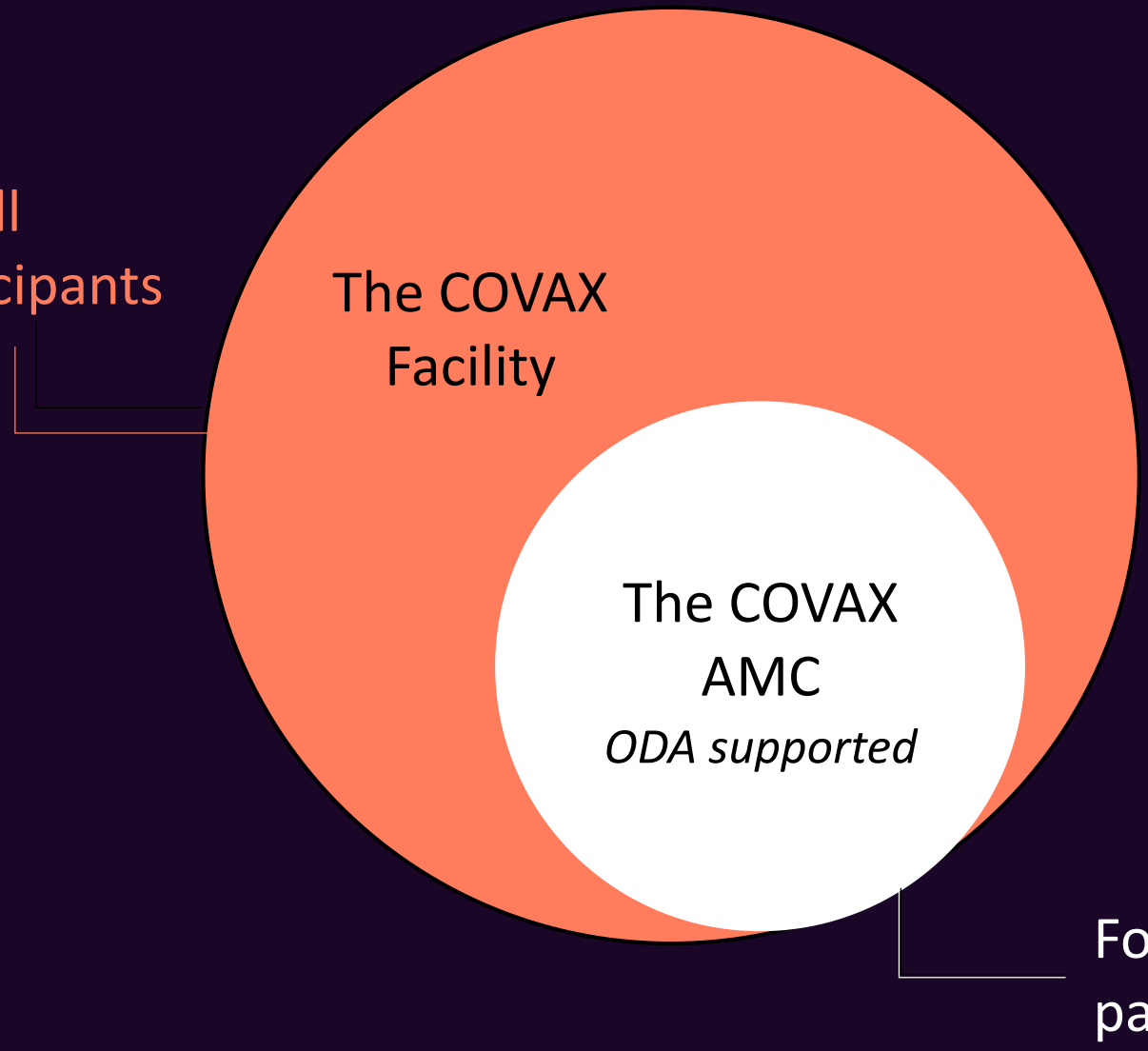
90 potential participants, 3.8+ B people

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

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 …

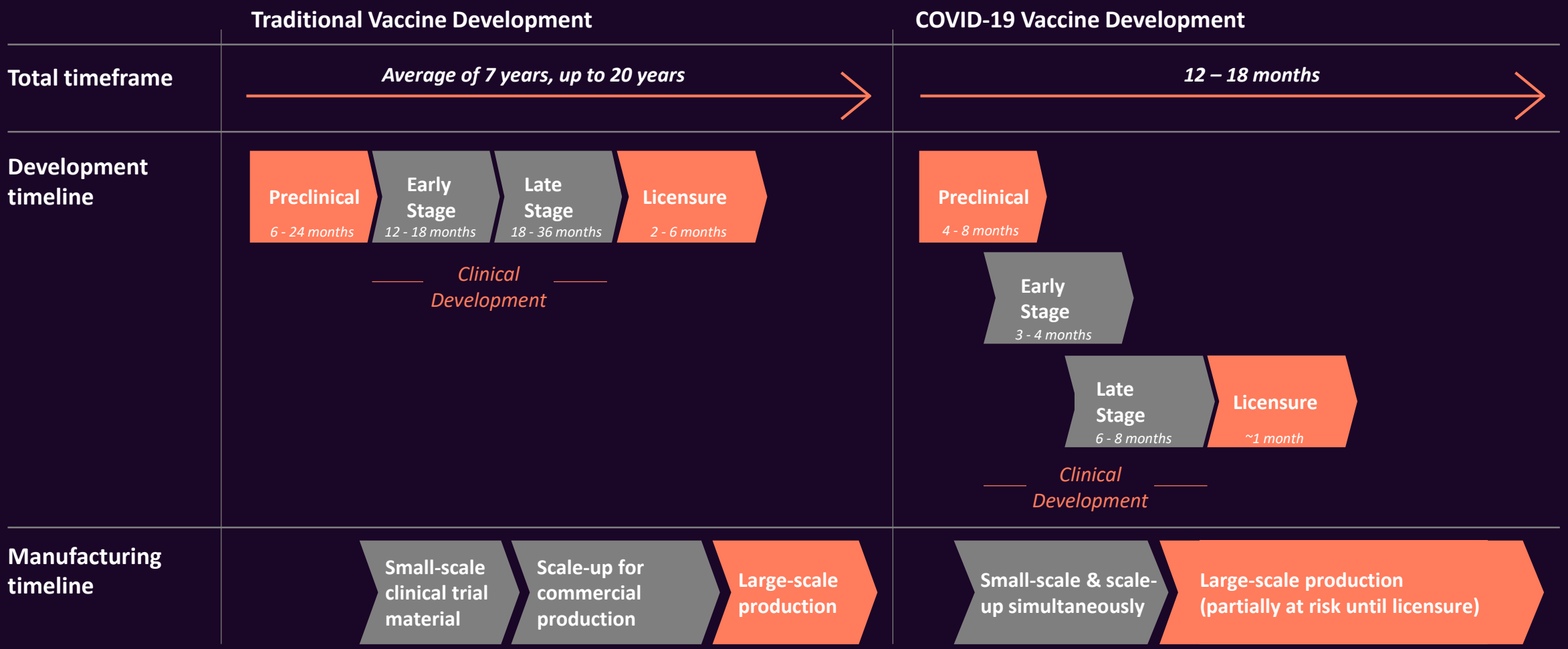
- 60% of the world's birth cohort
- > 822 million children vaccinated
- Manufacturer base grown from 5 to 17
- 5 bn doses procured ($9 bn) since 2012

Text

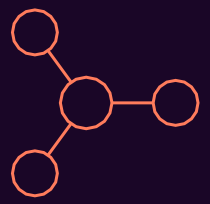
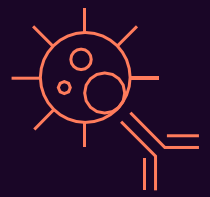
COVAX candidates and the actively managed portfolio

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

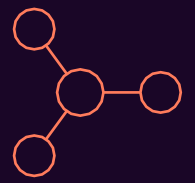
HIGHLY ILLUSTRATIVE



Different vaccine technologies are under development

Technology		Description	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 **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 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	$
	**Inactivated**	Vaccine technology is widely used Less risk of adverse effects 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

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

Current BMGF portfolio being evaluated for inclusion in COVAX

	Protein						Viral vector	saRNA	Inactivated
COVID-19	**Candidate #1**	**Candidate #2**	**Candidate #3**	**Candidate #4**	**Candidate #5**	**Candidate #6**	**Candidate #7**	**Candidate #8**	**Candidate #9**
Location	South Korea	China	India	India	USA	China	USA	UK	Global (multi-manufacturer partnership)
Platform	Protein (CHO + E.coli)	Protein (Pichia)	Protein (Pichia)	Protein (Pichia)	Protein (CHO + E.coli)	Protein (CHO)	Viral vector / DNA (HEK)	saRNA	Inactivated (Eggs)
Antigen / Adjuvant	RBD-NP	RBD	RBD	RBD-VLP	RBD-NP	RBD-dimer	Full length S protein	Full length S protein	Full length S protein
Current phase	Tech Transfer	Late discovery	Discovery	Late discovery	Tech transfer	Phase I	Late discovery	Phase I	Late discovery

BMGF "Wave 2" portfolio selected based on potential for combination of attributes relative to leading SARS-CoV2 vaccine candidates:

Higher Potency

Existing Manufacturing Capacity

Lower Cost of Goods

Novel Approach

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

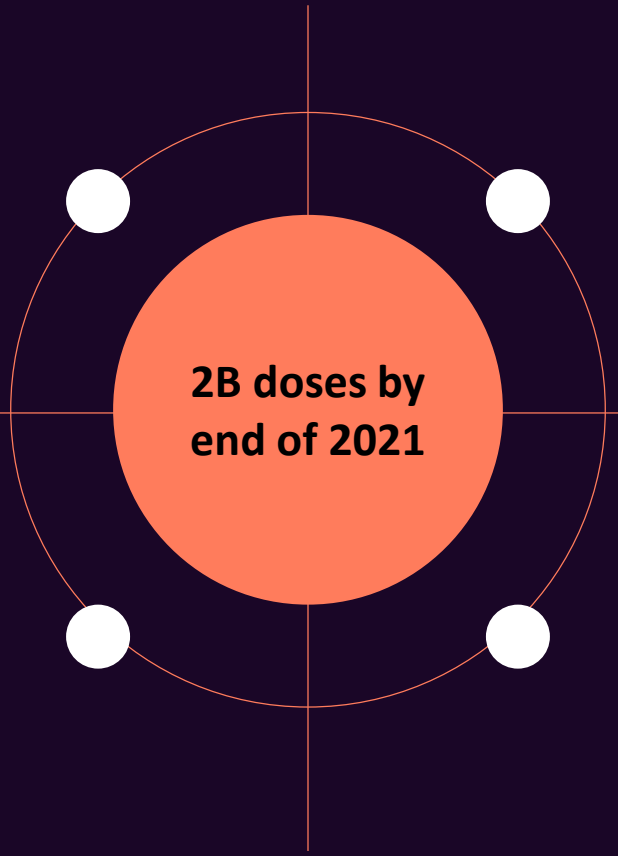
Portfolio spanning various Geographies

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

Vaccines Portfolio and Funding

Overview of funding forecast for candidates in R&D and manufacturing, in $M

HIGHLY PRELIMINARY

NUMBERS ROUNDED TO NEAREST 50 $M

	Number of candidates	R&D	Tech transfer & At-risk manufacturing	Total
Protein	3	750	1,250	2.0 B
Nucleic acid	3	200	1,100	1.3 B
Viral vector	3	200	450	0.7 B
Additional candidates/ investment	Up to 4	900	4,000	4.9 B
Additional items		400 (e.g. enabling science)	E.g., bags, glass: 150	0.5 B
Total	Up to 13	2.4 B	7.0 B	9.4 B

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 or territory? 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 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

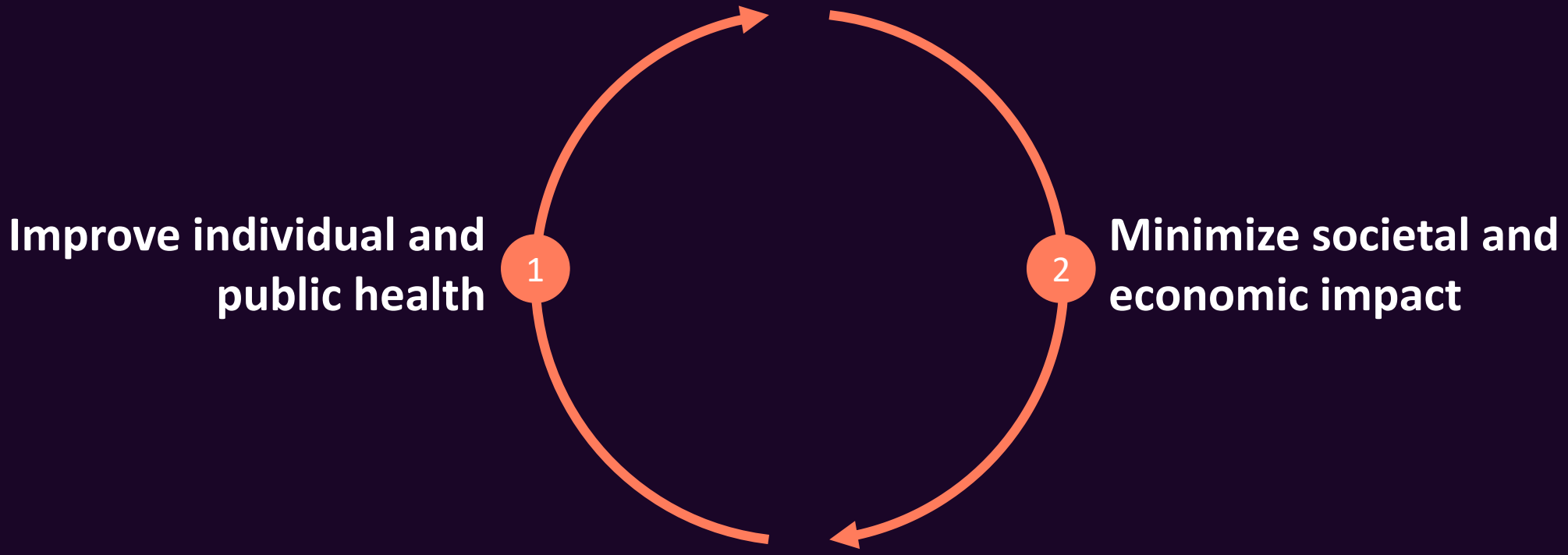
1: Allocation Framework

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

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	Those goals, 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. High risk settings** are also a consideration. Specific **policy recommendations from SAGE, based on** product performance and safety evidence and with evolving data on transmission and disease will be made
Timing	Given the ubiquitous nature of COVID-19, **an initial allocation should be received by all** as products become available **Eventually,** timing would be **based on a risk assessment of participants**' 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 participants receive doses to cover 3% of their population. This would be enough to cover all workers involved in health and social care work.	**All participants receive additional doses beyond the 3% to total 20% of their population (in tranches).** This could include the elderly, adults with comorbidities or others depending on locally relevant risk factors	**Participants receive doses to cover more than 20% of their population.** This would cover additional priority populations.

Timing

*Participants receive doses proportionally to their total population**

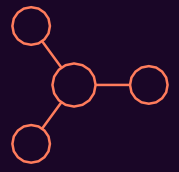
Timing is based on participants' need, vulnerability and COVID-19 threat

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

Note: The fundamental principle applies that all participants 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

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** • **Need to manage massive workloads** before and after regulatory approval processes • **Need for simultaneous regulatory approval in high number of juristictions** 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

Questions for input

- Are the priorities for the first allocation of vaccine across all countries and territories clear and aligned with your views?

- Is the principle to allocate enough vaccine to immunize up to 20% of each participants' total population an acceptable approach? Are there suggestions how to strengthen this?


CEPI


Gavi
The Vaccine Alliance


World Health
Organization

COVAX Facility
Consultation with the self-financing group – Day 2

July 17, 2020

DAY 2
Welcome and recap from Day 1

Meeting preparation – Day 2

Agenda for 17 July Country Consultations – ~3 h

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- **Share any further input offline to covax@gavi.org**

Participant discussion/ overflow questions from Day 1

Questions for input

After reflecting on the discussion from Day 1, do you have any new questions you would like to ask?

Deep dive 2:
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 • 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 • 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 • 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 • Manufacturers requested to disclose third party funding for R&D or manufacturing, which will be considered in contractual conditions • Vaccines from any manufacturer considered including those not in the CEPI/BMGF portfolio

Overview of the different agreements

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.

DRAFT Key terms of the agreement (1/3)

Term	Proposal
Parties	• Gavi, the Vaccine Alliance (on behalf of the COVAX Facility). • The relevant participant, acting through its appropriate ministry of state.
Role of Gavi as administrator of the Facility	• Enter into legally binding commitment agreements with Self-Financing participants • Convene the Independent Product Group • Negotiate and enter into volume guarantees with a range of vaccine manufacturers • Monitor the performance of the COVAX Facility • Convene the Shareholders Council and providing regular reporting to the participants • Day-to-day management of the Facility

DRAFT Key terms of the agreement (2/3)

Term	Proposal	
Expectations of participants	• Financial commitment to purchase a pre-defined number of doses – Upfront payment – Speed premium • Non-financial commitments	**Details follow**
Financing of commitment	• Participant's commitments will need to be legally binding • Based on the participant's credit rating profile and its ability to provide financial commitments both as an up-front down payment and over time, the commitment may require a security, for example an additional financial guarantee from a strongly rated commercial financial institution or development finance institutions	

DRAFT Key terms of the agreement (3/3)

Term	Proposal
Facility Term	• The term of the Facility will be defined to include a first phase ending by an agreed date or a date at which doses sufficient to cover 20% of the population have been offered for procurement • The parties will reassess whether to continue at the end of the first phase
Pharmaceutical Manufacturers	• The Facility will enter into advance Vaccine Purchase Commitment Agreements with Pharmaceutical Manufacturers, based on applicable terms and conditions and payment mechanisms that may include up-front payments, deferred payments and such instruments to enable the delivery of the vaccines as structured by the Facility. • Key terms around the commitments made by vaccine manufacturers include: – Use all payment advances towards the COVID-19 vaccine program – Keep the Facility informed of progress in its COVID-19 vaccine program – Deliver its production of its COVID-19 vaccine program to participants on agreed terms and conditions – Requirements to inform the Facility of public funding

Financial commitments

COVAX implements a risk-sharing approach that ensures vaccine supply by offering shares into multiple vaccines and sharing of manufacturing risk

The COVAX risk-sharing approach:

Buying into a portfolio of multiple vaccine candidates allows countries to insure themselves against failure of individual vaccines and secure cost-effective access to successful vaccines, sufficient to cover at least 20% of population

Sharing risk of development, guaranteeing volumes and building manufacturing capacity now means accessing vaccines quickly once proven successful

Active portfolio management by experts from Gavi, CEPI, WHO and others ensures maximum return on investment and efficient use of assets as insights in individual assets and portfolio evolves

COVID-19 vaccine development differs from “traditional” vaccine market

“Traditional” vaccine market

- Countries and health systems purchase licensed vaccines from individual companies
- Individual companies invest in R&D, spreading risk across their entire vaccine portfolio (incl. non-vaccines and/or financial investor risk)
- Individual companies invest in manufacturing only
  after vaccines have been demonstrated to be effective in clinical trials
- Process typically takes average of 7 years, up to 20 years

COVID-19 vaccine development

- COVID-19 is global and affects everyone – this requires equitable access to vaccines at the same time to stop the acute phase of pandemic
- World needs large numbers of doses urgently with multiple countries vying for allocation of volume.
- 160+ candidates exist from numerous companies, with 20+ (and counting) in clinic, but none so far has been demonstrated to be effective in clinical trials

- Manufacturing investments in capacity and raw materials needs to happen now alongside R&D to accelerate vaccine availability, compressing the development timeline to 12-18 months
- **This is only possible if**
  - **Risk is shared across a diverse portfolio with candidates from multiple companies**
  - **Manufacturers commit to an exceptional approach and minimal returns pricing**

Traditional market – existing vaccines cost $20-50 for HICs, with prices typically tiered for UMIC and L(M)ICs

Price per dose for vaccines (US $)

Vaccine	HIC	UMIC	L(M)IC
PCV	$48.2	$19.9	$5.4
Rotavirus	$20.8	$9.4	$3.6
HPV	$50.9	$11.6	$4.6

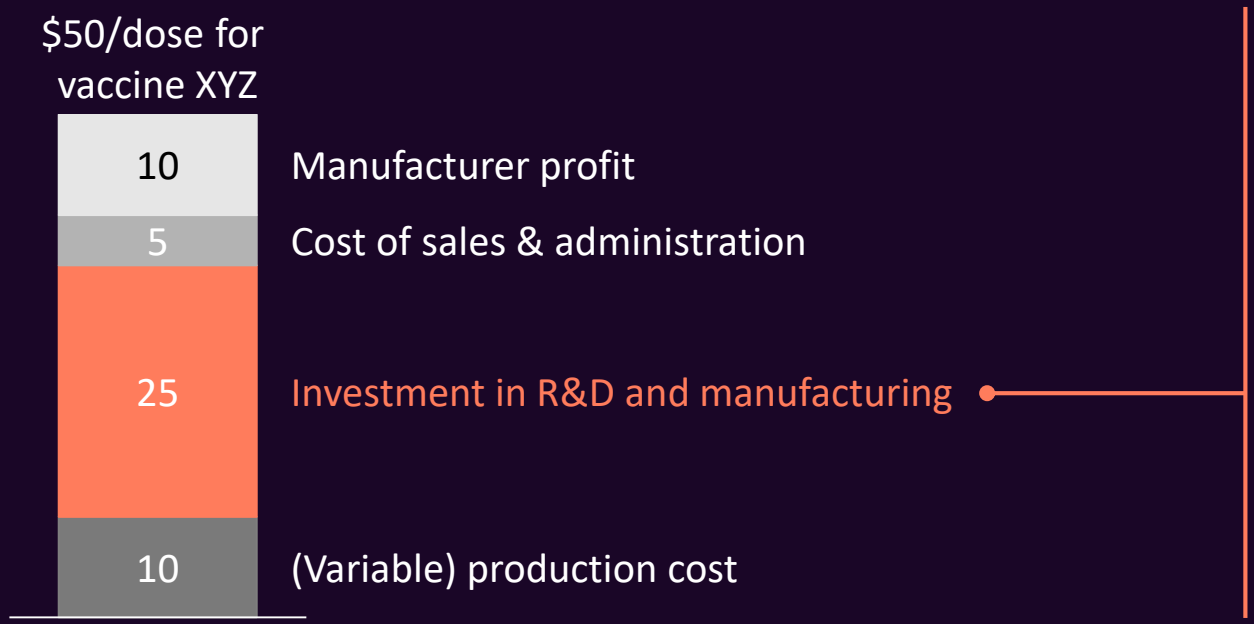
Other vaccines are priced at $20-50 for HICs – the final price for COVAX vaccines will also be dependent on factors such as the product and technology involved

Pricing is also often tiered for UMICs and L(M)ICs, and a 1 : 2 : 5 tiering for L(M)IC : UMIC : HIC has been assumed for the current analysis

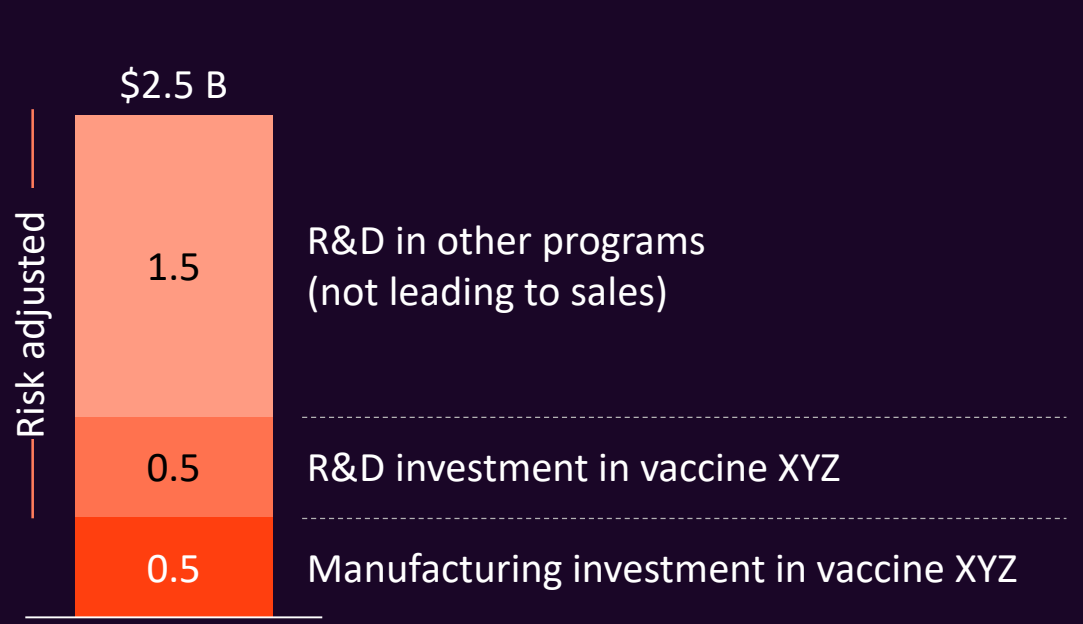
Source: WHO Market Information for Access to Vaccines (MI4A) Vaccine Purchase Data

Traditional market – commercial prices for vaccines cover production cost as well as a “charge” for past investments in R&D & manufacturing

ILLUSTRATIVE breakdown of commercial price (US $) for “traditional” vaccine market



R&D and manufacturing investment amortised over 100 M doses



- **Upfront investments in R&D and manufacturing are borne by developers/manufacturers, “at risk”**
- **Developers/manufacturers expect to recover their investment (including profit and cost of capital) through pricing of commercially available vaccines**

COVAX Facility offers access to a diverse portfolio, with candidates from multiple companies, accelerating availability at lowest possible cost

The final price per dose will depend on a number of factors

- Technology platform of a successful vaccine – which affects manufacturing costs
- Level of participation – which spreads fixed costs over more or fewer participants
- Negotiations with manufacturers

COVAX Facility will negotiate with manufacturers to achieve lowest possible price for all participants. Participants will have visibility and transparency on costs incurred

The following shows cost breakdown in the scenario where prices are tiered by income level (TBC)

For the first 2 B doses (accounting for all upfront cost & lack of optimization of the manufacturing process), possible all-inclusive initial prices for participants are:

- **HICs: $25 - 40 per dose**
- **UMICs: $10 - 16 per dose**
- **L(M)ICs: $5 - 8 per dose**

Note: these are indicative prices. Final price may be lower

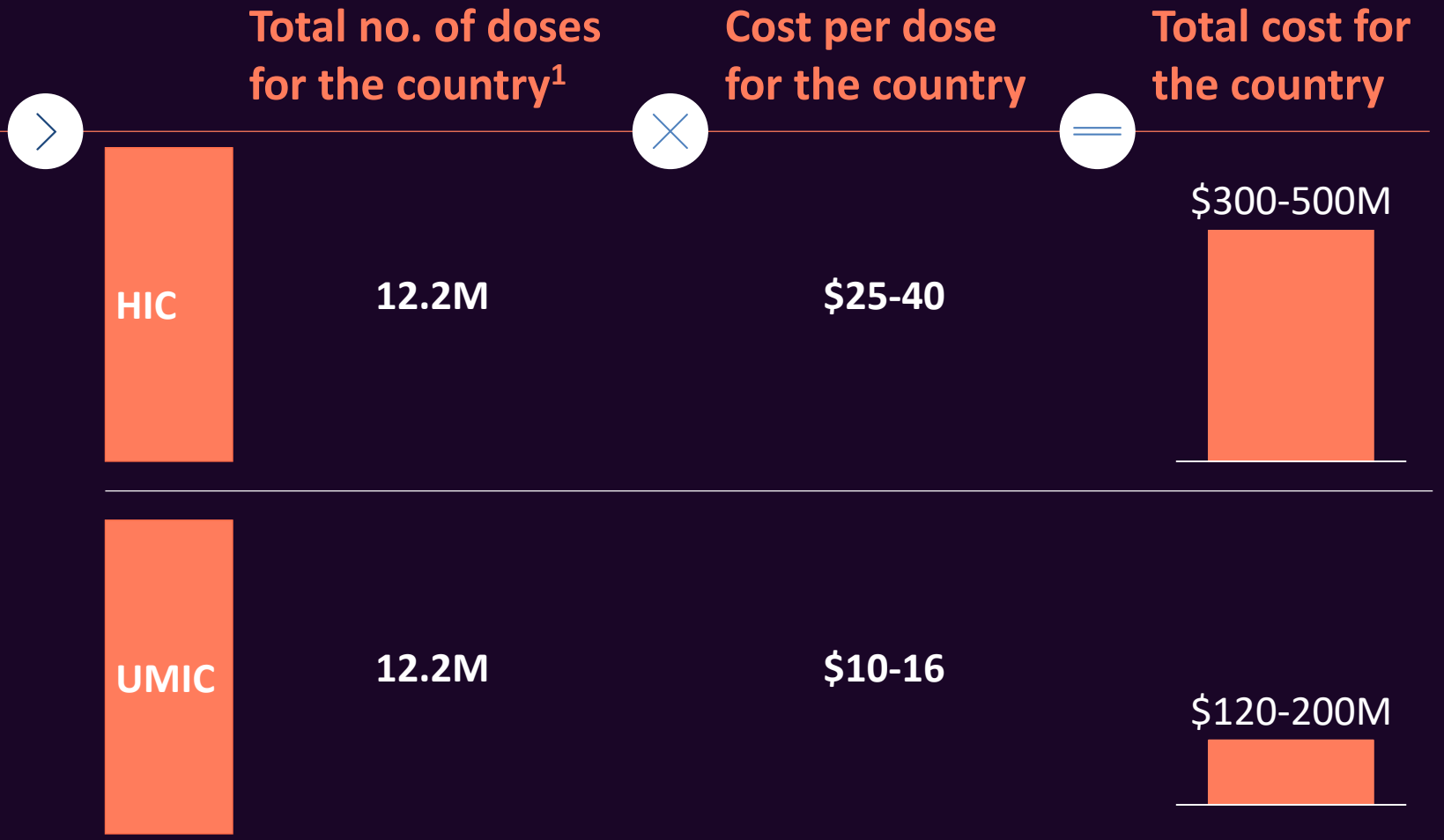
Country example – Country with population of 50M participating in global facility

Allocation framework

- Up to 20% population coverage, doses are allocated proportional to population of all participants

COVAX aspiration: global participation

- A total population of 7.8B in all participants
- Therefore, a participant with 50M population out of the 7.8B in total population corresponds to 12.2M[1] of first 2B doses



1. Accounting for 100M dose emergency buffer out of first 2B, i.e. 12.2M = 50M/7.8B * (2 B -100 M)

Upfront payments will be needed for COVAX to continue to strengthen the portfolio and accelerate manufacturing and access to vaccines

Timeline of payments required

~15% of the total cost of procurement will be required to be paid immediately

Review with participants what else may be needed

All procurement costs thereafter are “pay-as-you-go” i.e., once countries have approved the vaccine and are ready to receive it

Payments for an example country with a population of 50m

			Total
HIC *(based on assumption of $30 per dose[1])*	~$50m	~$300m	~$350m
UMIC *(based on assumption $12 per dose[1])*	~$20m	~$130m	~$150m

1. We have assumed a range for cost per dose of $25-40 for HICs and $10-16 for UMICs. We use assumptions for a point estimate of $30 per dose for HICs and $12 per dose for UMICs purely for demonstrative purposes

There are a number of possible sources of financing, including options to spread cost over a number of years

Potential sources of financing – *not exhaustive*

- National budgets
- Regional and multi-lateral development bank instruments
- Debt instruments
- …

Lower levels of participation give participating countries more of the first 2 B doses, but require higher upfront payments

	COVAX aspiration: Global participation With 950M doses allocated among participating HIC/UMICs		Lower level of participation With 950M doses allocated among participating HIC/UMICs	
HICs	Total participating population: 1.3B	A HIC with 50M population will receive 12.2M doses, and pays: ~$50M upfront[1] by Sep 2020	Total participating population: 0.5B	A HIC with 50M population will receive 32M doses, and pays: ~$140M upfront[1] by Sep 2020
UMICs	Total participating population: 2.6B	A UMIC with 50M population will receive 12.2M doses, and pays: ~$20M upfront[1] by Sep 2020	Total participating population: 1.0B	A UMIC with 50M population will receive 32M doses, and pays: ~$50M upfront[1] by Sep 2020
	$2.6B upfront payments[1] from HIC/UMICs		**$2.6B upfront payments[1] from HIC/UMICs**	

1. Upfront payments needed for COVAX to continue to strengthen the portfolio and accelerate manufacturing

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.

Questions for input

Based on your experience, how should issues of liability risk (including through national legislation) and compensation in the context of the deployment of vaccines, including recently licensed vaccines, be addressed?

We invite you to share with us your solutions and experiences to address these issues

Please email covax@gavi.org with input

Deep dive 3:
Proposed COVAX Facility governance[1]

1. Pending Gavi board approval

Guiding principles to enable the design of the Facility's Governance

PROPOSAL

Structural considerations

- **Build on existing governance structures** and not recreate or unnecessarily expand existing mechanisms (principle of ACT-Accelerator)
- **Ensure an accountable and representative governance framework** to all stakeholders
- Be in place for the **entire lifespan of the Facility**

Objectives

- Enable the Facility to enter into **time and commercially sensitive transactions with varying terms**, accounting for different manufacturer profiles and needs
- **Anticipate potential needs to adapt and adjust the use of funds**, given uncertainties (e.g., disease epidemiology)
- **Ensure representation of all participants** and provide sufficient visibility

Self-financing participants form a ‘Shareholders Council’

PROPOSAL

Members/ composition	• Representatives of self-financing participants
Meeting cadence	• Monthly - TBC
Role & Responsibility	• Provide strategic guidance to COVAX management on areas related to the status of vaccines under development • Share information with the Secretariat and each other and receive access to regular updates from Secretariat • Appoint members to MSDC • Additional responsibilities being defined

Existing governance/advisory bodies of the COVAX Facility

PROPOSAL

	Gavi board	MSDC Market Sensitive Decisions Committee	SAGE Strategic Advisory Group of Experts	RDMIC R&D and Manufacturing Investment Committee
	Gavi The Vaccine Alliance	Gavi The Vaccine Alliance	World Health Organization	CEPI
Portfolio		✓	✓	✓
Allocation			✓	
Financing	✓	✓		✓
Operations	✓			

Newly proposed governance/advisory bodies of the COVAX Facility

PROPOSAL

	Shareholders council	Dose Allocation body	Independent product group
Portfolio	✓		✓
Allocation	✓	✓	
Financing	✓		
Operations	✓		

Role and composition of proposed governance bodies (1/2)

PROPOSAL

		Affiliation	Composition	Role
Gavi Board		Gavi The Vaccine Alliance	• Gavi, WB, BMGF, UNICEF, WHO, Governments of developing countries (5), Governments of donor countries (5), CSO, IFPMA, DCVMN, independents, research institutes	• Oversee role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to Gavi including full oversight of the Gavi COVAX AMC
MSDC	Market sensitive decisions committee	Gavi The Vaccine Alliance *Expanded	• Board (Vice) Chair, AFC Chair, PPC Chair, UNICEF, WB, Gavi, BMGF, Governments of developing countries (2), Governments of donor countries (3), CSO • TBC - Self-financing participants (3), COVAX AMC participant	• Review the business terms of the proposed COVAX volume guarantee agreements that the Facility would enter into with manufacturers

Role and composition of proposed governance bodies (2/2)

PROPOSAL

		Affiliation	Composition	Role
Shareholders Council		*NEW	• Self-financing participant representatives	• Provide strategic guidance to COVAX management on areas related to the status of vaccines under development • Share information with the Secretariat and each other and receive access to regular updates from Secretariat • Appoint [3] members of the Shareholders Council to the MSDC
RDMIC	Research & development & manufacturing investment committee	CEPI	• CEPI, Gavi, BMGF, (ex) industry R&D and manufacturing experts, public health expert	• Drive CEPI portfolio strategy & investment decisions aligned with overall COVAX strategic objectives • Decide CEPI investment allocation and requirements across the portfolio • Make project selection and investment decisions

Role and composition of proposed advisory bodies

PROPOSAL

		Affiliation	Composition	Role
IPG	Independent product group	*NEW	• 5-7 independent experts, selected by panel from Gavi, WHO, CEPI, IFPMA and DCVMN	• Provide independent advice to e.g., COVAX Facility members, Gavi, the MSDC and inform selection of vaccine candidates for Facility • Assess whether candidates have met criteria for eventual purchase • Review overall portfolio, consider updates in clinical development, manufacturing and supply
SAGE	Strategic Advisory Group of Experts	World Health Organization	• 15 experts in the fields of epidemiology, public health, vaccinology, infectious diseases, drug regulation, immunization delivery, safety, etc.	• Advise WHO on overall global policies and strategies, incl. vaccines, research and development, delivery of immunization and its linkages with other health interventions
tbd	Dose allocation body (tbd)	*NEW	• To be defined – independent technical experts	• Review and analyze data/ documentation, provide technical input • Make allocation recommendations in accordance with final technical design, approved by Member States, of the WHO Allocation Framework

Participant discussion

Questions for input

What is the appropriate composition of the Shareholders Council? How do we make it a working body (representative body)?

Would there be an interest in an executive body of the Shareholders Council?

Do we need a forum to bring together the three groups of participants into the same body (self-financing, AMC-supported, AMC donors)?

What information is critical to be shared in regular updates?

Closing:
Timelines and next steps

What to expect – between now and 31 Aug

COVAX Facility engagement plan for the self-financing group

Date	Key activity	Description
Week of July 20	Consultation follow-ups *AMC consultations*[1]	Including written responses to outstanding questions
Week of July 27	Term sheet consultations	Regional consultations on the term sheet
Week of Aug. 3	Individual term sheets	Individual term sheet sent to all interested parties
Week of Aug. 10	Term sheet and governance consultation	Consultations to address remaining questions about the term sheet and governance
Aug. 17-31	Additional consultations	Pending

1. For the COVAX AMC eligible group

What to expect – between now and 31 August

Week of 3rd August

Draft **term sheets** sent to all that have expressed interest

Week of 10th August

Participate in further **consultations on the term sheet and governance of the Facility**

31st August

Deadline to make **binding commitments** to become a Facility Participant

General questions for wrap-up of the consultation

Questions for input

What questions do you still have?

What else do you need in order to get to the final commitment? And how can we best meet that need?


CEPI


Gavi
The Vaccine Alliance


World Health
Organization

Appendix

Meeting presenters Day 1 & 2 (1/2)

Presenter	Title	Organization
Andrew Witty	Co-lead, WHO COVID-19 Vaccine Programme	WHO
Richard Hatchett	CEO	CEPI
Seth Berkley	CEO	GAVI
Soumya Swaminathan	Chief Scientist	WHO
Mel Saville	Director of Vaccine Development	CEPI
Derrick Sim	Director of Vaccine Demand & Supply	GAVI
Thomas Cueni	Director General	International Federation of Pharmaceutical Manufacturers
Sai Prasad	President	Developing Countries Vaccine Manufacturers Network

Meeting presenters Day 1 & 2 (2/2)

Presenter	Title	Organization
Kate O'Brien	Director, Department of Immunization, Vaccines and Biologicals	WHO
Emer Cooke	Director, Regulation of Medicines and other Health Technologies	WHO
Aurélia Nguyen	Managing Director, Vaccines & Sustainability Department	GAVI
Anthony Brown	Senior Legal Counsel	GAVI
Marie-Ange Saraka-Yao	Managing Director, Resource mobilisation, Private Sector Partnerships & Innovative Finance Department	GAVI
Dick Wilder	General Counsel and Director of Business Development	CEPI