COVAX Facility ‘Principles of Participation’: Consultation with the self-financing group

August 11, 2020

Welcome & objectives of the consultation

Objectives

1. Provide an update on the vaccine candidate pipeline

2. Provide an opportunity to discuss, clarify, and come to a common understanding on the “Principles of Participation”, in particular on financial terms, allocation and governance

3. Consider an alternative option and align on appetite for adjusting the approach

4. Share next steps to join the COVAX Facility

Agenda & housekeeping

Meeting preparation

Agenda for 11 August Consultation – 3h

Topic	Presenter
Welcome and objectives of the consultation	Seth Berkley (Gavi), Richard Hatchett (CEPI), Soumya Swaminathan (WHO)
Agenda & housekeeping	Andrew Witty
COVID-19 & Vaccine candidate update	Richard Hatchett (CEPI)
Deep dive 1: Financial terms and allocation, with alternative option	Santiago Cornejo (Gavi), Mariangela Simao/Kate O'Brien (WHO)
Deep dive 2: Governance	Brenda Killen (Gavi)
Open Q&A	Andrew Witty
Timeline and next steps	Seth Berkley (Gavi)
Closing	Andrew Witty

Housekeeping

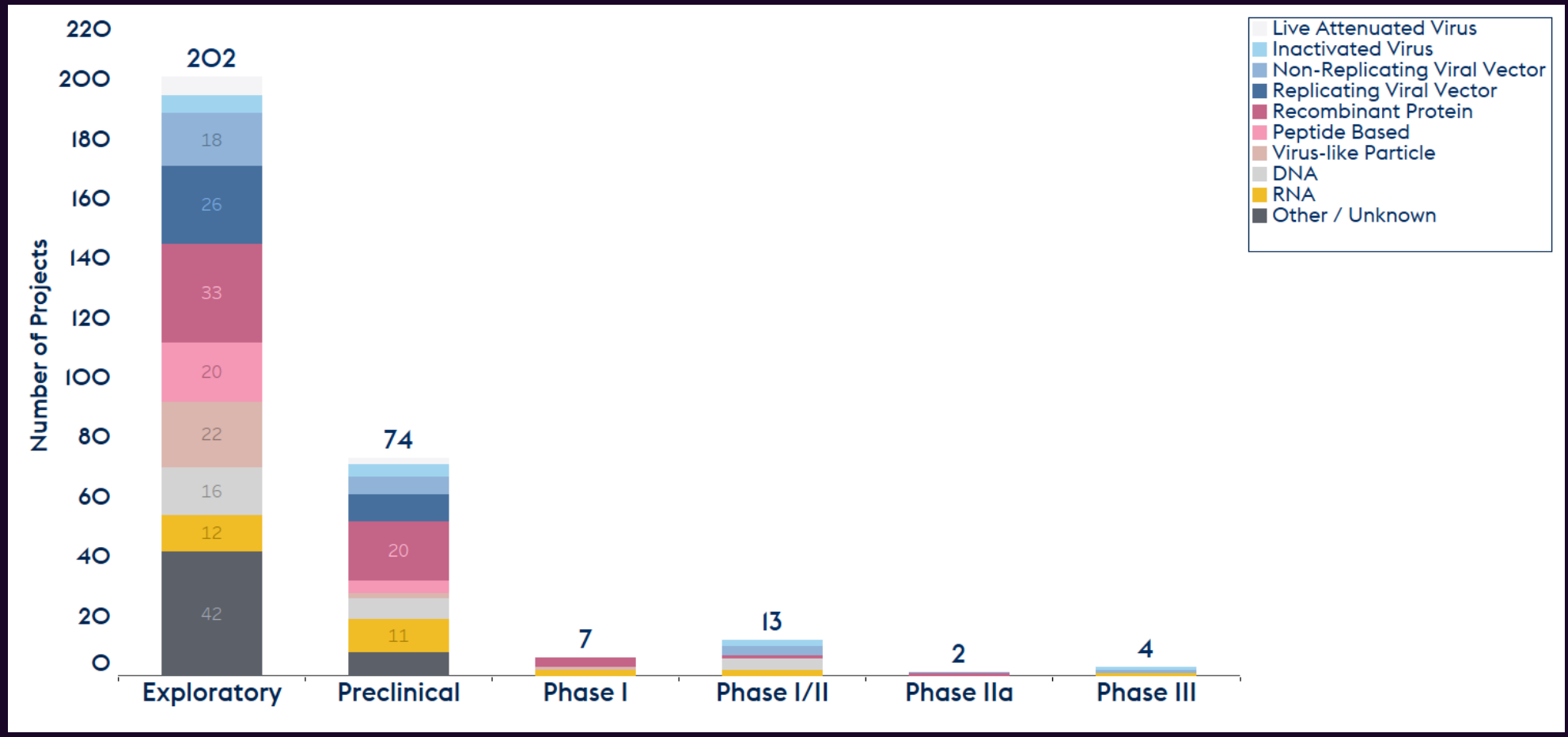
We **have a full house today, so we kindly ask you to…**

- **Please stay on mute with video off** while not speaking to preserve the livestream quality
- We will have time for Q&A after each deep-dive and during the open Q&A. **Please click the 'raise your hand' button** if you would like to speak and we will call on you, or **ask your question directly in the chat**
- **Please state your name and where you are from before sharing a comment or question**
- Please make **time bound interventions.** Given the time constraints, we will proceed directly to the content and not have opening statements
- You are invited to use **informal forms of address**
- **Share any further input offline to covax@gavi.org**

Text

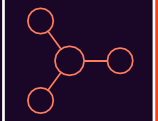
COVID-19 & vaccine candidate update

CEPI is tracking 302 active COVID-19 vaccine candidates



- **Exploratory:** project has not started with in-vivo testing
- **Preclinical:** project started to test in-vivo / manufacture CTM but not yet started with testing on human
- **Phase I:** safety and immunogenicity; **Phase IIa:** Safety and efficacy and dose schedule; **Phase I/II:** combine of Phase I and IIa**. Start is defined as first subject dosed**
- **Unconfirmed:** the development status cannot be confirmed using available internal and publicly available information

26 candidates are in the clinic, with 4 currently in Phase IIb/III

		Phase I	Phase I/II	Phase IIa	Phase IIb / III and III	Registration / introduction
	Viral vectors	Shenzhen GIMI aAPC	Shenzhen GIMI LV-SMENP-DC Janssen Ad26.COV2-S Gamaleya rAd5, rAd26	Cansino Ad5	AstraZeneca AZD1222	
	RNA	CureVac CVnCoV Walvax Biotech mRNA	Pfizer / BioNTech mRNA-BNT162 Imperial saRNA		Moderna mRNA-1273	
	DNA		Genexine GX-19 Osaka /AnGes AG0301 Inovio INO-4800 Cadila 2019-nCov vaccine			
	Protein sub-unit	Medicago VLP Queensland UQ-1-SARS-CoV-2-Sclamp Vaxine Covax-19 Clover SCB-2019	Novavax NVX-CoV2373	Anhui Zhifei Recombinant		
	Inactivated		Bharat Biotech BBV 152 Beijing Institute of Biotechnology Institute of Medical Biology, CAMS		Wuhan Institute of Biological Products Sinovac Biotech	

CEPI COVID-19 vaccine portfolio currently consists of 9 projects, 7 in the clinic

	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/II	Phase III	Phase I	Preclinical	Phase III	Preclinical	Phase I/II	Phase I	Phase I

Speed

Scale

Access

An Active Portfolio Management is supporting COVAX ambition to deliver 2B 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

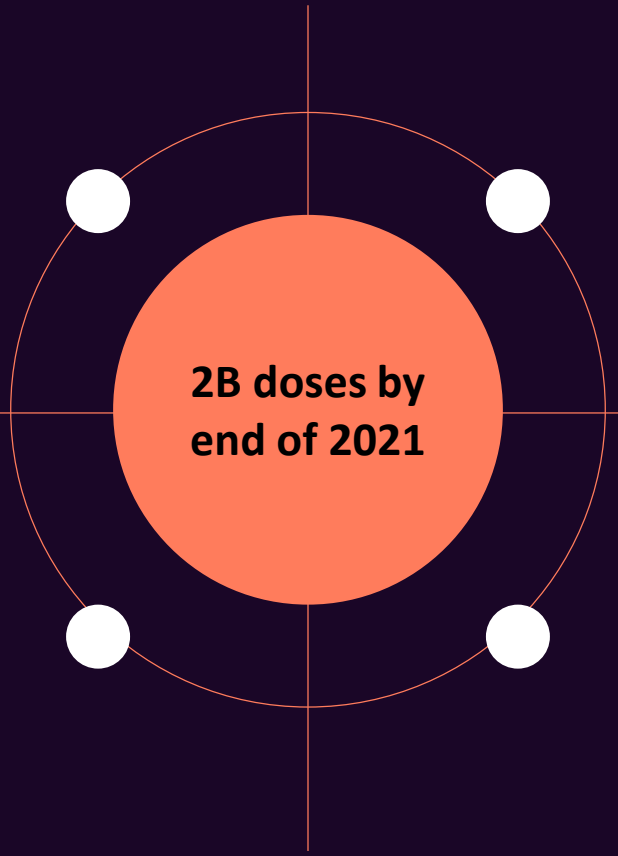
Portfolio spanning various Geographies

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

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

Overview of clinical trials from data

	Oxford/AZ	CanSino	Moderna	Pfizer/ BioNTech1	Pfizer/ BioNTech2
Site	UK	China	USA	USA	Germany
Design	Phase 1/2, single-blind, randomized control trial	Phase 2, double-blind, placebo-controlled, randomised	Phase I, open label, dose escalation	Phase 1/2, observer-blinded, dose escalation randomised	Phase 1/2 , Open-label, Non-randomised
Regimen[1]	**1 or 2 im doses, 5 x 1010 viral particles, 4 weeks apart**	**Single im dose, 5 x 1010 or 1 x 1011 viral particles**	**2 im doses, 25, 100 or 250 mg mRNA in LNP, 4 weeks apart**	**2 im doses, 10, 30 or 100 mg mRNA in LNP, 3 weeks apart**	**a single im dose 60 mg or 2 im doses, 1, 10, 30, 50 mg mRNA in LNP, 3 weeks apart**
Age range	18-55	18-83[2]	18-45	18-55	18-55

1. so far, all vaccine regimens are intramuscular2. so far, CanSino is the only study to include the elderly in trials

Early clinical data

Immune response

- Binding and neutralizing antibody induced with all candidates
- Cellular immune responses induced
- Level of response cannot be directly compared as different methodology used between vaccines

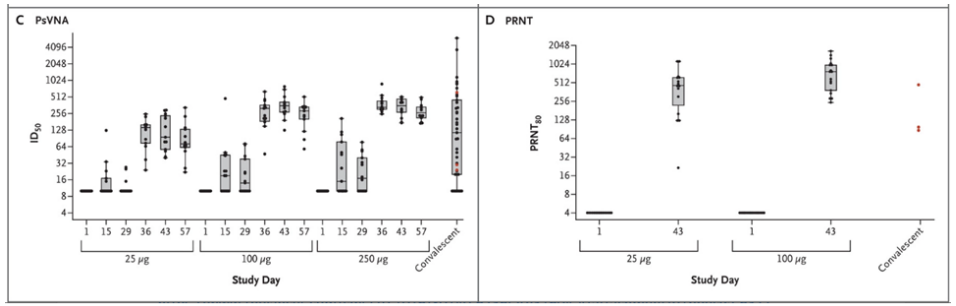
Safety profile

- Generally well tolerated
- Some vaccines have more reactions after the second dose

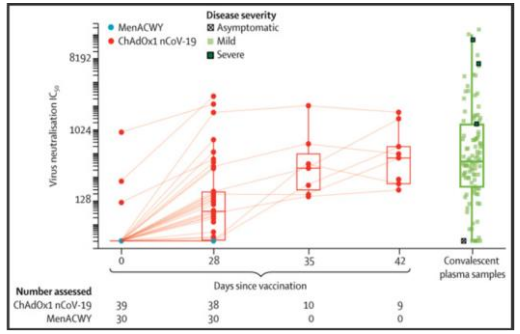
Conclusions

- Early data promising
- Efficacy trials needed to see if they protect from COVID-19

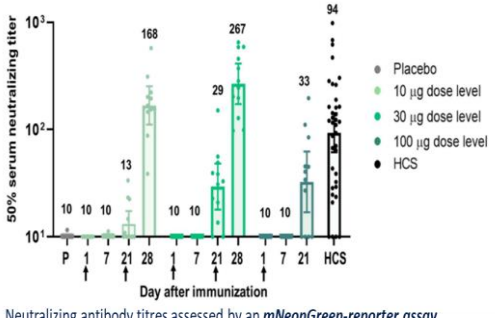
Jackson et al NEJM 2020 (Moderna)



Folegatti et al Lancet 2020. U. Oxford/AZ



From Mulligan et al medRxiv 2020. Pfizer/BioNtech



Zhu et al Lancet 2020 Cansino

	Day 14				Day 28			
	Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)	p value	Low dose group (n=36)	Middle dose group (n=36)	High dose group (n=36)	p value
ELISA antibodies to the receptor binding domain								
GMT	76·5 (44·3-132·0)	91·2 (55·9-148·7)	132·6 (80·7-218·0)	0·29	615·8 (405·4-935·5)	806·0 (528·2-1229·9)	1445·8 (935·5-2234·5)	0·016
≥4-fold increase	16 (44%)	18 (50%)	22 (61%)	0·35	35 (97%)	34 (94%)	36 (100%)	0·77
Neutralising antibodies to live SARS-CoV-2								
GMT	8·2 (5·8-11·5)	9·6 (6·6-14·1)	12·7 (8·5-19·0)	0·24	14·5 (9·6-21·8)	16·2 (10·4-25·2)	34·0 (22·6-50·1)	0·0082
≥4-fold increase	10 (28%)	11 (31%)	15 (42%)	0·42	18 (50%)	18 (50%)	27 (75%)	0·046

Data are mean (95% CI) or n (%). The p values are the result of comparison across the three dose groups. If the difference was significant across the three groups, the differences between groups were estimated with 95% CIs. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. GMT=geometric mean titre.

Table 3: **Specific antibody responses to the receptor binding domain, and neutralising antibodies to live SARS-CoV-2**

Deep dive 1: Financial terms and allocation, with alternative option

1

What is the investment?

2

What does it cost the Facility to make this investment?

3

What does it cost for participants?

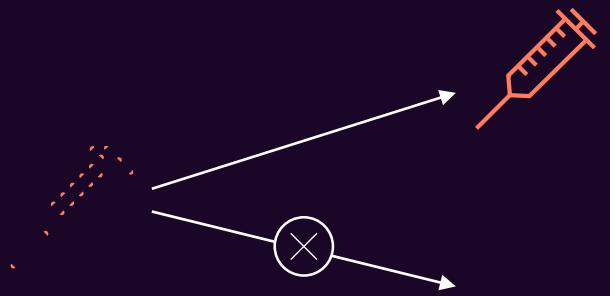
4

What is the payment and dose allocation schedule?

1: No single vaccine is guaranteed to succeed or has enough capacity …

For planning purposes, the Facility is targeting to 2 B doses by end of 2021

- Many vaccines in development – none guaranteed to succeed
- No single manufacturer has the capacity to supply the global volume required

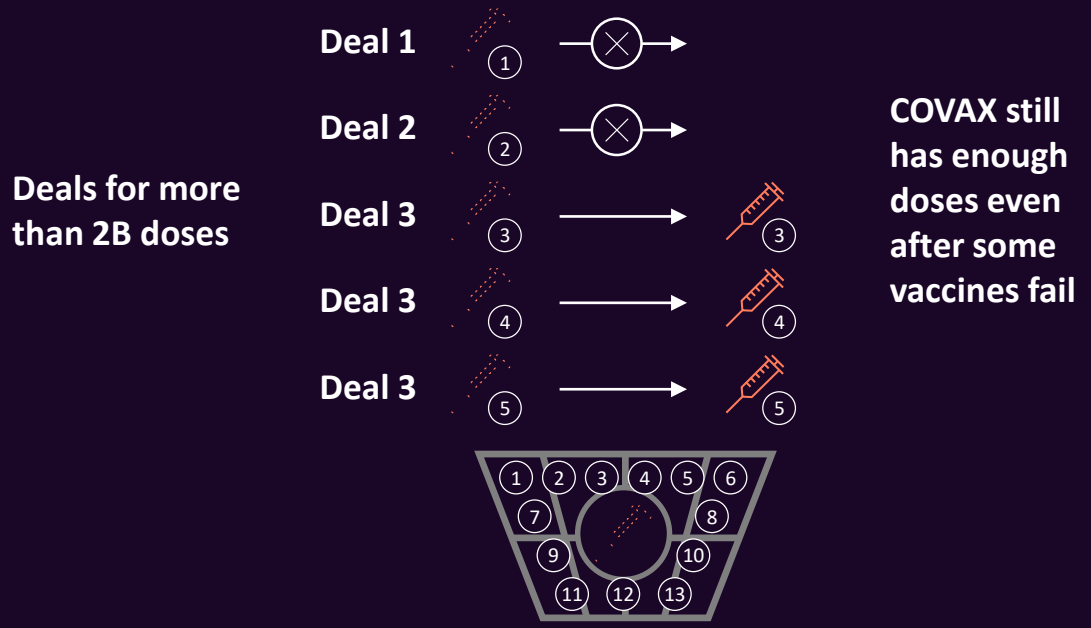


Single deals might fail

A diversified portfolio is needed to diversify risk and create capacity to scale

… COVAX thus selected a basket of vaccines to mitigate these risks

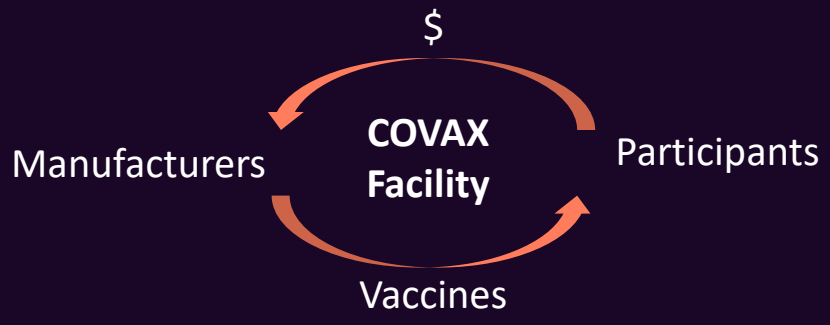
- A **basket of deals is needed** to increase the chances of delivering 2B doses by end of 2021
- **Deals for more than 2 B doses are needed** to account for the risk of unsuccessful development



COVAX is creating a basket of 10-15 vaccines

2. The overall financial structure of the Facility

The COVAX Facility cost principles



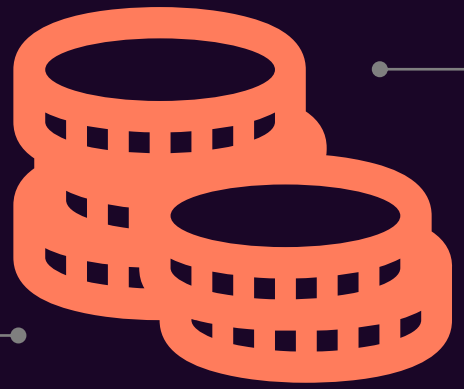
- **Negotiate to achieve minimal returns pricing**
- **Costs passed through to participants "as-is"**
- **Full transparency**
- **Participants involvement in Facility governance**

Three COVAX Facility cost categories

Speed / access premium
Payments made to manufacturers:

- To accelerate investments manufacturers would otherwise delay (e.g., technology transfer)
- As down payments for Advance Purchase Agreements

Ex-factory cost
Variable cost to manufacturers of producing the doses



Facility operating costs

- Cost of limiting risk exposure and reducing upfront payment requirements (e.g., insurance and interest associated with debt financing)
- Management fees (e.g., headcount, lights-on)

2. The most important cost driver is ex-factory costs: our modelling reflects all available data, public and non-public

Manufacturer and vaccine	Country/ Organisation	Size of deal[1]	Cost per dose[1]	Date announced	Stage of developmt	Details of deal
moderna	BARDA	$0.48 B	N/A	16 Apr	Phase II	• Deal is to fund late-stage clinical trials and scale up manufacturing for the vaccine, with no volume commitment
AstraZeneca / University of Oxford	*Operation Warp Speed*	$1.2 B, 300m doses	$4/dose	21 May	Phase II/III	• Includes funding to speed up development and manufacturing of the vaccine
AstraZeneca / University of Oxford		$0.84 B, 300m doses	$2.8/dose	13 Jun	Phase II/III	• AstraZeneca has pledged to provide doses for no profit
SANOFI / gsk		$0.63 B, 60m doses	$10/dose	Reported to be close to a deal on 6 Jul	Phase I/II planned in Dec	• Will likely involve an option to buy the vaccine should it work in human trials
NOVAVAX	*Operation Warp Speed*	$1.6 B, 100m doses	$16/dose	7 Jul	Phase I/II	• Deal funds Phase 3 clinical trial, scale-up of manufacturing, and delivery of doses
Pfizer	*Operation Warp Speed*	$1.95 B, 100m doses	$19.5/dose	22 Jul	Phase I/II	• Deal does not cover R&D costs, only the cost of dose procurement and distribution

1. Full cost structure TBC as to fully-loaded price per dose

There is an urgent need to conclude deals for the facility as vaccine volumes are being reserved in other multilateral and bilateral deals

Reported deal sizes may not reflect “fully loaded costs” or contain the same elements as COVAX deals

Nevertheless these deals form an empirical base which will help to revise our costing estimates

2. The Facility is assembling a robust portfolio of ~10-15 candidates…

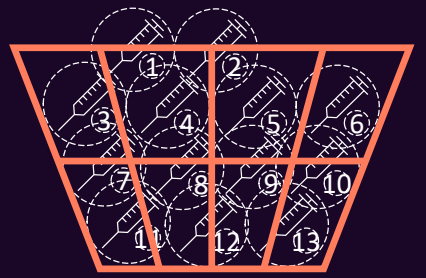
Vaccines prioritised for COVAX deal

Partial landscape of vaccine candidates

Candidate	Phase	Technology
Selected candidate 1		
Selected candidate 2		
Other candidate		
Selected candidate 3		
Other candidate		
Selected candidate 4		
Other candidate		
Selected candidate 5		
Selected candidate 6		
Selected candidate 7		
Selected candidate 8		
Other candidate		
Other candidate		
Selected candidate 9		
Other candidate		
Selected candidate 10		
Other candidate		
Selected candidate 11		
Other candidate		
Other candidate		
Other candidate		
Selected candidate 12		
Other candidate		
Other candidate		
Other candidate		
Other candidate		
Selected candidate 13		
…	…	

- Confidential -

COVAX DEALS



Participants have access to a diversified basket of vaccines

The portfolio is actively managed – successful candidates are added and unsuccessful ones removed

The portfolio and assumptions (e.g. price, dose and attrition assumptions) used are for illustrative purposes only and do not suggest an intention of the management team.)

All deals will have to go through full review by the relevant scientific and governance bodies. This document is for discussion purposes only.

2. …and have modelled the costs associated with this portfolio as precisely as possible

This is a weighted average for vaccines with tiered prices

Illustrative portfolio

Candidate	Estimated ex-factory cost, $/dose	Estimated # of doses by end 2021, M doses	Total ex-factory cost by end 2021, $ M
Selected candidate 1			
Selected candidate 2			
Selected candidate 3			
Selected candidate 4			
Selected candidate 5			
Selected candidate 6			
Selected candidate 7			
Selected candidate 8			
Selected candidate 9			
Selected candidate 10			
Selected candidate 11			
Selected candidate 12			
Selected candidate 13			
TOTAL	*Weighted average* **8.70**	**4,141**	**36,031**

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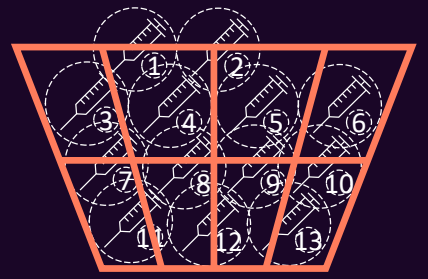
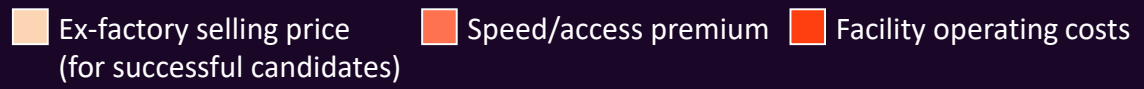


The vaccines in the portfolio have **different prices** given the different technology platforms and manufacturing locations

To reach 2 B by end of 2021, the Facility is planning **for deals up to 4 B doses to account for a 50% attrition rate**

The total **ex-factory cost are estimated at ~$20 B** due to an expected ~50% attrition rate

2. How is the COVAX price per dose calculated and what does it include?



Estimated COVAX Facility cost for 2 B doses, in $B

Payments to manufacturers

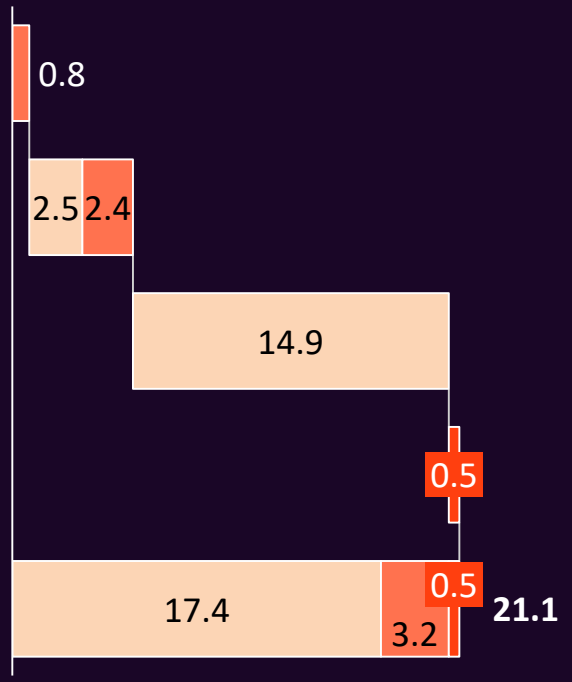
PRE-APPROVAL fixed costs (tech transfer, scale-up/-out)

PRE-APPROVAL variable costs (reservation fees, APC down payments)

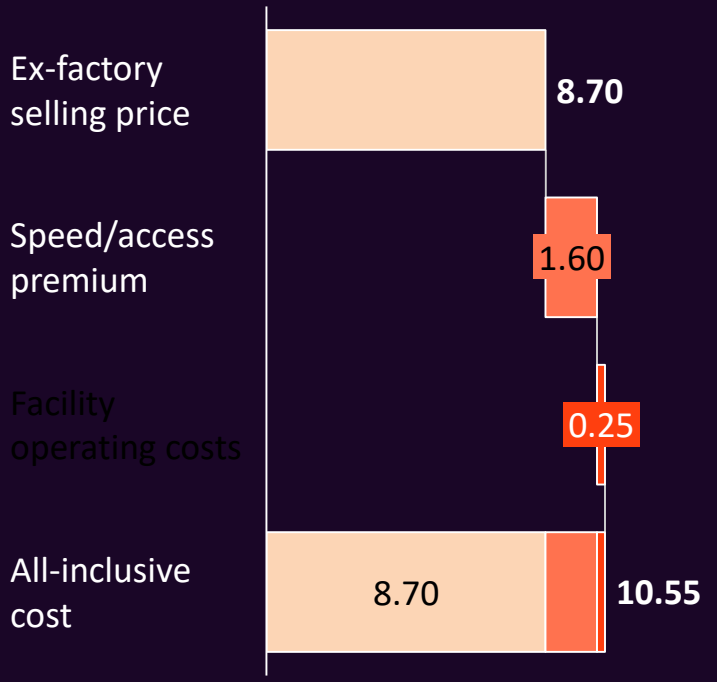
POST-APPROVAL costs (regular purchases, net of any pre-approval variable costs)

Facility operating costs, (incl. financing and insurance)

Total all-inclusive cost



Estimated all-inclusive cost, in $/dose



$21.1B all-inclusive cost for 2B doses at $10.55/dose including:

- **$8.70/dose ex-factory selling price**
- **$3.2B speed/access premium amortized as $1.60/dose**

3. Participants will pay the actual Facility negotiated price for vaccine

The Facility strives for best possible prices

The COVAX Facility will use its significant buying power to negotiate best possible price for participants, striving for flat, minimal returns pricing

All-inclusive price per dose for participants includes ex-factory selling price from manufacturer

Participants pay less/ more for individual vaccines with lower / higher ex-factory selling prices

Participants pay according to income level if manufacturers tier prices

Manufacturers have indicated a variety of pricing models for the COVID-19 pandemic

Some manufacturers have publicly committed to flat prices during pandemic

Responding to UNICEF/Gavi call for expression of interest, ~70% of manufacturers expect to tier prices, maybe to a lesser extent than historical industry practice, e.g. 1 : 1.5 : 2

Historically, manufacturers have tiered prices based on income

Price per dose, USD *(LMIC multiple)*

	L(M)IC	UMIC	HIC
PCV	$5.4	$19.9 *(x 3.7)*	$48.2 *(x 8.9)*
HPV	$4.6	$11.6 *(x 2.5)*	$50.9 *(x 11.1)*
Rota	$3.6	$9.4 *(x 2.6)*	$20.8 *(x 5.8)*

Typical ratio ~ 1 : 4 : 7

3. Some manufacturers in the portfolio have indicated their intention to tier prices

Ex-factory cost per dose for modelled portfolio before attrition, cost per dose USD

Without price tiering	If manufacturers tier prices with an average ratio of 1:1.5:2[1]		If manufacturers tier prices with an average ratio of 1:2:3[2]	
	HIC	$12.55	HIC	$14.00
$8.70	UMIC	$9.70	UMIC	$9.70
	LIC/LMIC	$6.90	LIC/LMIC	$5.50

- Level of tiering from manufacturers not yet determined, but Facility will negotiate for minimal returns pricing
- The Facility anticipates tiering of speed/access premium in line with manufacturer imposed tiering of ex-factory costs

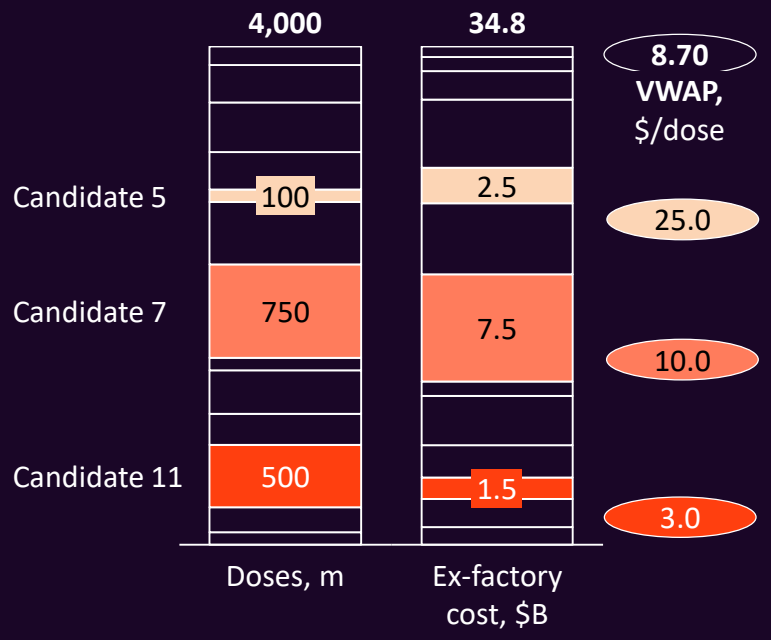
1. Actual prices will differ. Ratio of indicative prices does not perfectly match the 1:1.5:2 ratio as some candidates in the portfolio are expected to have one price for all participants.
2. Actual prices will differ. Ratio of indicative prices does not perfectly match the 1:2:3 ratio as some candidates in the portfolio are expected to have one price for all participants

3. Average price will depend on which candidates succeed

ILLUSTRATIVE

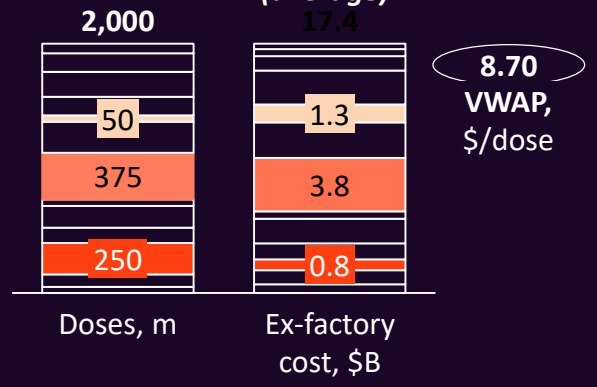
- Expecting half of candidates to fail, we need to strike deals worth 4Bn doses to ensure 2Bn doses can be distributed
- Robust, diversified portfolio with 10-15 deals includes candidates with different ex-factory price per dose (cf. different technologies, yields)
- Expected ex-factory selling price $8.70 / dose is VWAP[1] across portfolio before attrition
- Actual cost will reflect portfolio composition after attrition

Portfolio before attrition



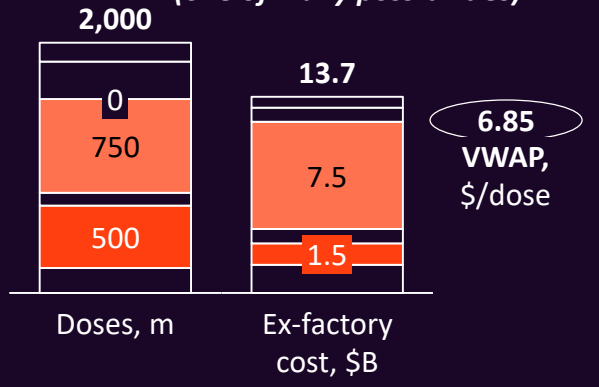
Portfolio after attrition, 50% attrition assumed

Modelled portfolio *(average)*



Assumed portfolio for modelling purposes: average based on 50% volume for all candidates

Actual portfolio *(one of many possibilities)*



Actual portfolio: individual candidates either succeed (100% volume) or fail (0%)

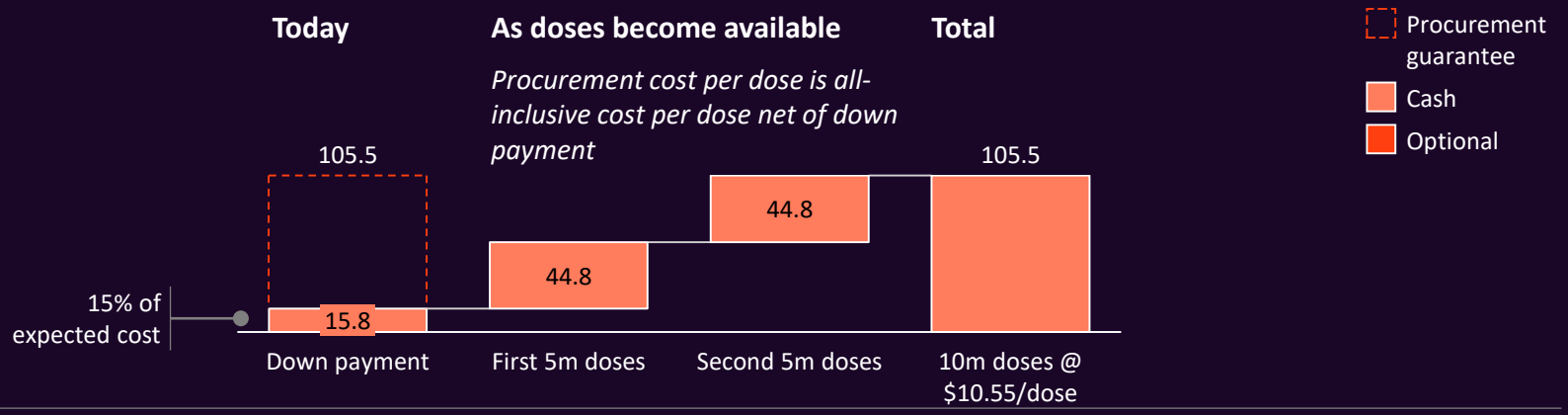
1. Volume-weighted average price

3. Participants will pay the actual price per dose which may be lower or higher than current estimates

ILLUSTRATIVE FOR PARTICIPANT PURCHASING 10M DOSES (2-DOSE REGIMEN FOR 20% COVERAGE OF 25M POPULATION)

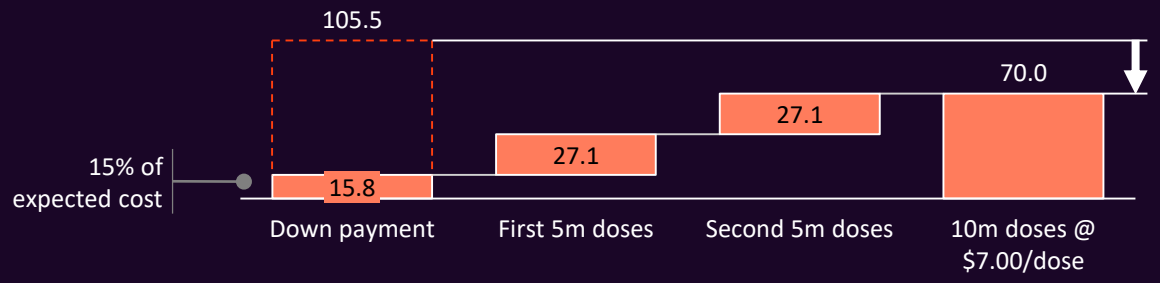
Current best estimate (used for the purpose of calculating upfront payments financial commitment)

Actual price per dose equal to expected price per dose, i.e. **$10.55 / dose**



If price per dose is lower, e.g. **$7.00 / dose**

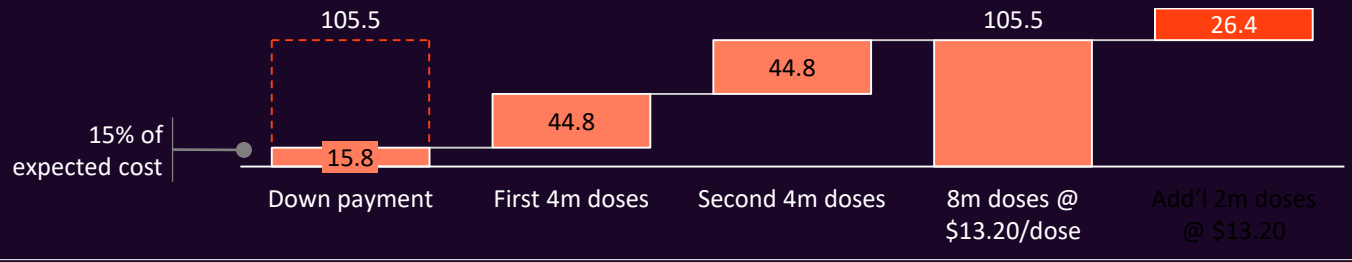
- Facility strikes better deals with manufacturers
- Inexpensive technologies lead to successful vaccines



Unused amount could be used to purchase additional doses if available

If price per dose is higher, e.g. **$13.20 / dose**

- Inexpensive technologies all fail or prices higher than expected due to low yields
- Facility has access to other (more expensive) technologies



Participant receives **only 8m doses** but can choose to purchase additional doses if available

4: Participants make a binding financial commitment upon joining

All-inclusive estimated cost per dose

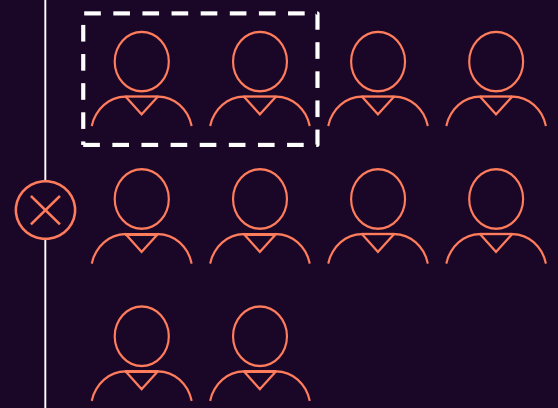
$10-11

Per dose

Expected # of doses per regimen

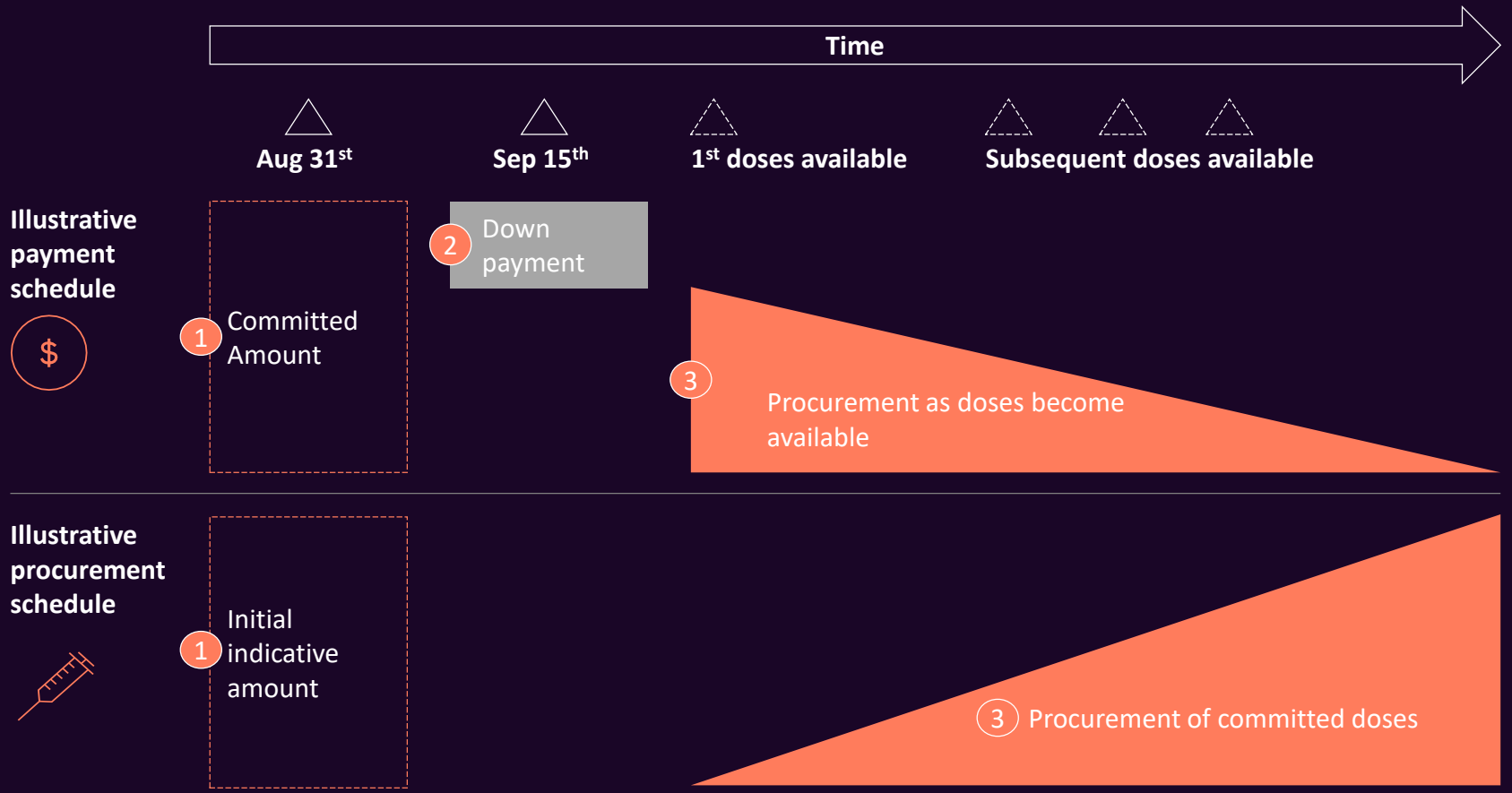
2

Agreed percentage of participants' population



The Committed Amount represents the **total binding financial commitmen**t that Self Financing participants make

4. Participants sign up for the Committed Amount by Aug. 31st and subsequently provide a 15% Down Payment



1. **A Participant makes a binding financial commitment** (the Committed Amount) in exchange for a certain number of doses

2. 15% of the Committed Amount is **paid upfront as a Down Payment**

3. As vaccines become available, the **Participant procures doses, drawing down their Committed Amount**

4. Allocation framework: key features

Proportional Distribution

2B doses allocated proportionally to population to Funded and Self Financing participants[1], keeping a buffer of 5% for humanitarian emergencies and acute outbreaks

Gradual allocation

Vaccines rolled out as they are produced until participants reach their indicative target amount[2]

Adapting to country context

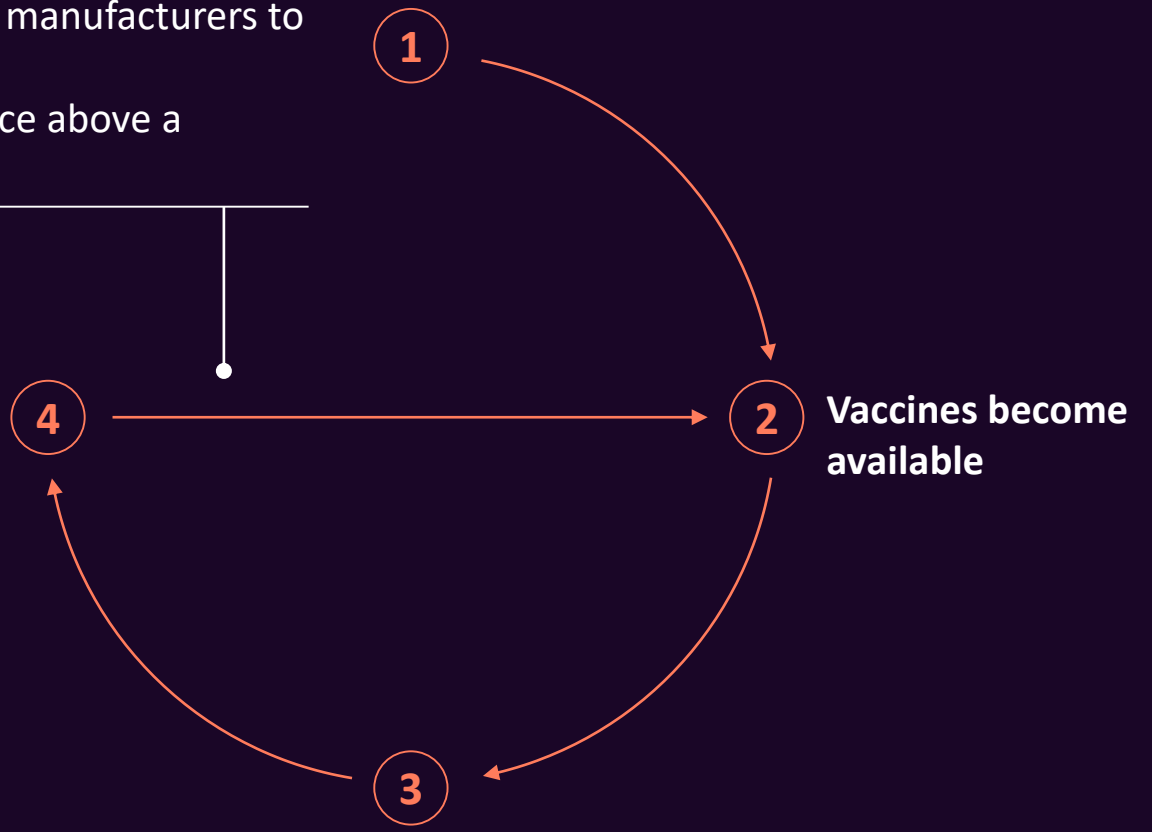
Country policies will guide national priorities for vaccine use. WHO will provide recommendations based on SAGE advice which will support country deliberations

1. Allocation of doses for a participant's indicative target amount. The first phase of the allocation framework is in effect up to 20% population coverage. Funding or participant readiness constraints would not delay the distribution of vaccines to other participants.
2. Notwithstanding logistical and operational considerations, for example shipment size.

4. First phase of Allocation framework: Coverage of 20% of Participant population[1]

Risk mitigation actions:

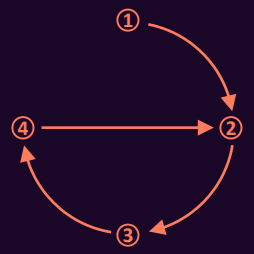
- Options in contracts with manufacturers to meet preferences
- Opt-out in case actual price above a certain threshold



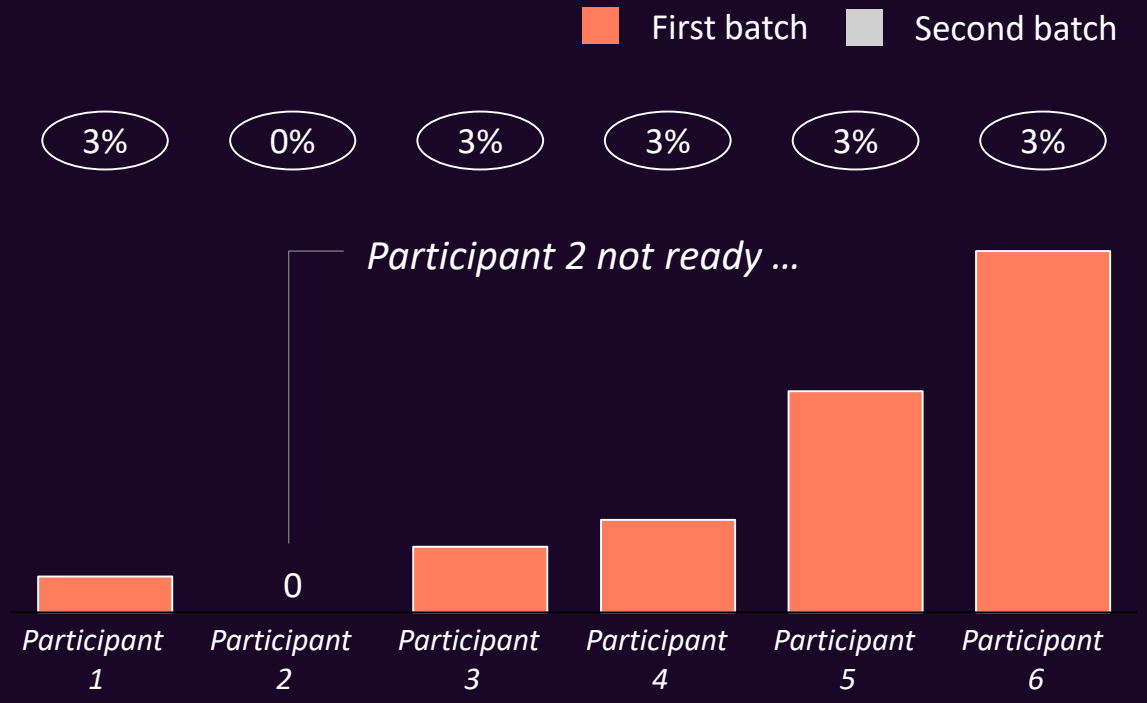
1. Lack of funding or readiness by a Participant or set of Participants would not delay the distribution of vaccines to other Participants in alignment with the WHO Allocation Framework
2. Vaccines will be allocated such that all Participants receive a fair and balanced allocation of Approved Vaccines across characteristics (e.g., minimising the number of distinct vaccines allocated to each country, considering price, immunisation schedule), acknowledging operational considerations

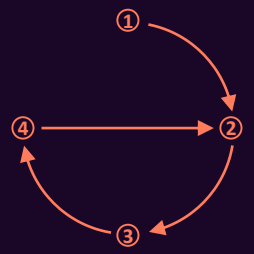
X% Received doses relative to participant's population

Example:
6 participants are allocated doses from 2 vaccine batches

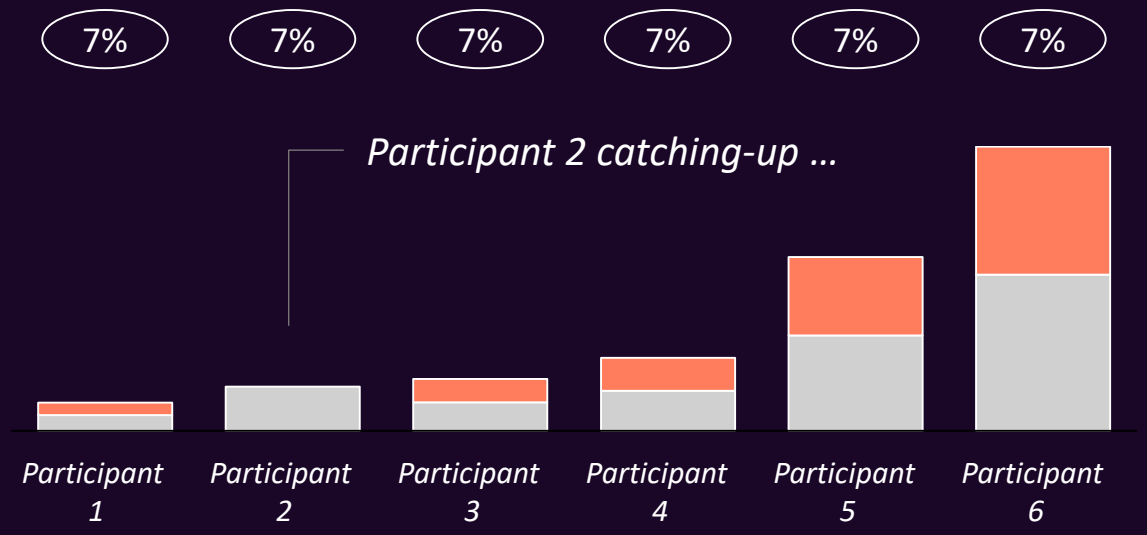


Month 1





Month 2



Alternative option: Shareholder financing model

Aim is to strengthen proposal particularly by:

- simplifying financial obligations on participating countries;
- increasing focus on mobilising upfront investment to increase global production capacity;
- enabling countries to buy vaccine in accordance with approval of their national regulators, vaccination strategy and national regulations;
- countries (rather than the facility) to choose which vaccines they buy (if more than one is available);
- create an exchange/clearing house to manage any oversupply of vaccines;
- generate funding through the Gavi AMC mechanism to support 92 lower and lower-middle income economies.

Shareholder model: simple overview

COVAX puts forward a proposal for investment in agreements to support and secure vaccine production.

Countries share cost of this investment based on the size of adult population they would like to vaccinate (within range 10-30%) and receive entitlement to buy shares of available vaccine. Donors fund investment for Gavi countries.

COVAX negotiates deals with vaccine manufacturers, making up-front investments and payments in return for commitments to provide vaccine at specific volume, price and delivery schedule.

If vaccine successful, countries exercise entitlement to buy their share from manufacturers. If more than one vaccine successful COVAX manages an exchange/clearing house enabling countries to exchange rights to buy different vaccines.

Alternative proposal: example

- *Countries with total population of 5bn sign up for COVAX seeking doses for an average of 20% of population (1bn people). Self-funding Country X with population of 50m signs up to COVAX and decides it wants to invest on the basis of vaccinating 20% of its population (10m people). This is 1% of the total population to be vaccinated through COVAX.*
- *COVAX puts forward a proposal for a $3b investment tranche*
- *Country X pays $30m contribution to COVAX (1% of the investment needed; which is equivalent to $3/person)*
- *Donors make contributions to Gavi to enable it to make contributions to the COVAX fund for the eligible countries.*
- *A vaccine is successful. The regulator in Country X approves use of the vaccine. Country X exercises its right to buy directly from the manufacturer its 1% share at the $10/dose price and delivery schedule negotiated by COVAX. It does this on the basis of a model contract agreed between COVAX and the company including standard language on liabilities. Vaccine for 600m people becomes available in 2021. Country X receives enough vaccine for 6m people in 2021 . As further vaccine becomes available in 2022 Country X receives vaccine for a further 4m people.*
- *If two vaccines are successful, country X is entitled to a share of both vaccines proportionate to its upfront investment. Country X chooses to exercise its right to buy the successful Vaccine A (an adenovirus vaccine). Country X does not exercise right to buy Vaccine B (an mRNA vaccine). Country X is able to sell or trade its share of Vaccine B. Vaccine B is in high demand from other countries on the basis of the early delivery schedule and low price negotiated by COVAX reflecting upfront at risk investment in manufacturing and vaccine trials.*

Alternative option: Shareholder financing model

While this alternative scenario could be more attractive it still requires additional analysis and exploration to understand its feasibility. Some key elements include:

- **Would countries' up-front payment be substantially higher? Would countries be willing to contribute higher up-front payments for greater choice?**
- **Would all manufacturers agree to provide options to procure future vaccines rather than firm commitments?**
- **Who would be held liable (financially) in the scenario that committed vaccines are not chosen by countries?**

Q&A on
Deep dive 1: Financial terms and allocation, with alternative option

Deep dive 2: Governance

Guiding principles behind the Facility's Governance

Structural considerations

- **Build on Gavi's existing Board and Committees,** with new governance bodies established to ensure appropriate oversight, to avoid unnecessarily expanding 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

The details of the governance arrangements, including terms of engagement with civil society and other non-funded/non-funding participants, are still being refined as the Facility is established

Existing mechanisms will be supplemented to ensure sufficient representation and oversight from Self-Financing Participants

Detailed next

		Portfolio	Allocation	Financing	Operations
Existing Bodies	**Gavi Board**			✓	✓
	MSDC *Market Sensitive Decisions Committee*	✓		✓	
	AFC *Audit and Finance Committee*			✓	
	SAGE *Strategic Advisory Group of Experts*	✓	✓		
	RDMIC *R&D and Manufacturing Investment Committee*	✓		✓	
Newly Proposed Bodies	**Shareholders Council**	✓	✓	✓	✓
	Independent Allocation Body		✓		
	Independent Product Group	✓			
	AMC Stakeholders Group			✓	✓

Self-financing participants form a ‘Shareholders Council’

Members/ composition	• Representatives of all **self-financing participants** • Could additionally include representatives of **AMC Stakeholders Group** and/or for **observers** e.g. CSOs, regional bodies
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 (e.g. overview of the Facility’s processes on dose allocation) • Representatives from Shareholders Council **included on MSDC for review of COVAX-related agreements**

Self-Financing Participants in collaboration with Facility would agree and establish the final terms of reference and operating procedures. Shareholders Council may establish a form of Steering Committee to liaise with the existing governance bodies to take key decisions

Market Sensitive Decisions Committee

Members/ composition	• Gavi Board and key Committee Chairs, UNICEF, WB, Gavi, BMGF, Governments of implementing countries (2), Governments of donor countries (3), CSO
Meeting cadence	• **As needed to review manufacturer agreements**

Role & Responsibility	• Reviews **business terms of proposed agreements** with manufacturers to ensure
	  • reasonableness of terms and acceptable level of reputational risks
	  • availability of resources to back proposed agreements

Connection to other bodies	• Receives **scientific advice from the Independent Product Group**

Will include representatives of Self-Financing Participants from the Shareholders Council for review of COVAX-related agreements with manufacturers

Illustrative process: vaccine candidate decision-making

Not exhaustive - focuses on how Self-Financing Participants engage in process

- Facility Secretariat regularly assesses and updates **Shareholders Council** on pipeline
- **Self-Financing Participants provide strategic guidance** on prioritisation

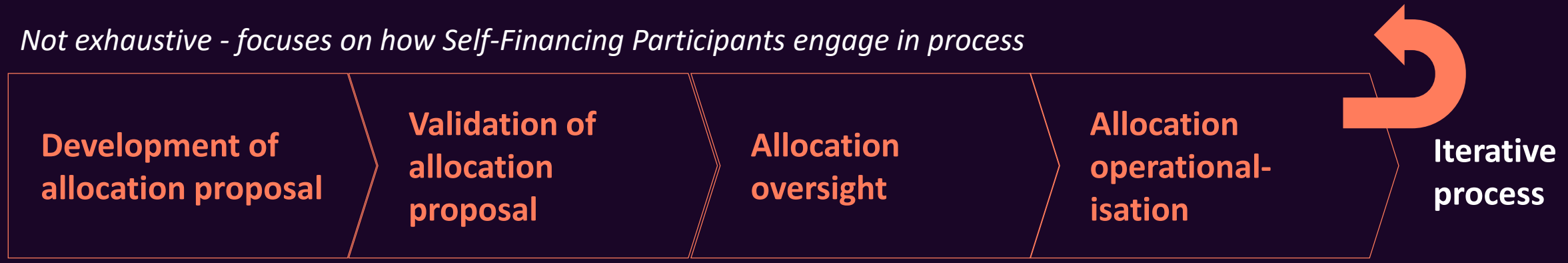
- **Independent Product Group** validates prioritised candidates to pursue deals
- **Self-Financing Participants informed,** express preferences to inform volume commitments/ options

- **MSDC (with Shareholders Council representation)** reviews and approves individual deal terms

- Facility Secretariat regularly assesses and updates **Shareholders Council** on Facility's portfolio
- **Self-Financing Participants provide strategic guidance** to inform prioritisation of additional candidates

Illustrative process: allocation

Not exhaustive - focuses on how Self-Financing Participants engage in process



- **Self-Financing Participants express preferences** for different vaccines
- Allocation proposal developed by **Joint Allocation Taskforce** (w/i COVAX Facility) which applies allocation principles

- **Independent Allocation Body** validates proposal
- Includes **independent experts and observers (incl. observers from self-financing participants[1], etc.)**
- Document decisions for transparency

- **Body within COVAX Governance to be determined** (with Self-Financing Participant representatives) to provide oversight to allocation activities

- Facility Secretariat operationalises **distribution of doses** to Participants through relevant mechanisms
- **Participants validate the allocation** and/or inform the Facility of mutually agreed trades/swaps

1. Process to select representatives under development

Q&A on
Deep dive 2: Governance

Open Q&A

Timelines and next steps

COVAX Facility timeline & next steps for self-financing group

Date	Key activity	Description
August 31	Commitment agreement to be signed	Self-financing group signs legally binding commitment agreements (English version)
September	Financing provided	As needed, self-financing participants have until 15 Sept to secure adequate financing; upfront payments provided to Facility
September 29	Gavi Board meeting	Gavi Board to discuss COVID-19 vaccine programme for AMC-eligible economies
October (tbc)	Shareholders Council meeting	First meeting to establish final terms of reference and operating procedures; receive update on vaccine candidate pipeline and manufacturer deals

Thank you & close


CEPI


Gavi
The Vaccine Alliance


World Health
Organization