COVAX

CEPI Gavi The Vaccine Alliance unicef World Health Organization

Welcome

Participant Briefing & Q&A will start at 12:30pm CET

COVAX

CEPI Gavi The Vaccine Alliance unicef World Health Organization

COVAX Vaccine Outlook for 2022, with informational session on Nuvaxovid and Covovax

13 January 2022

Agenda

Topic	Presenter
Welcome, agenda, housekeeping	**Santiago Cornejo**
COVAX Vaccine Outlook for 2022	Derrick Sim / Kristina Lorenson
Spotlight: Nuvaxovid / Covovax	Joachim Hombach
2022 Country-level Demand Planning	Benjamin Schreiber / Benedict Millinchip
Q&A	Moderator – Santiago Cornejo

Housekeeping

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

ENGLISH: Translations are available in French and Spanish, by clicking "Interpretations" at the bottom of the screen

FRANÇAIS: Des traductions sont disponibles en français et en espagnol, en cliquant sur l'icône "Interprétations" en bas de l'écran.

ESPAÑOL: Hay traducciones disponibles en francés y español, haga un clic en "Interpretaciones" en la parte inferior de la pantalla

- **Please stay on mute with video off** to preserve the livestream quality

- If you wish to submit a question, **please use the "Q&A" function** in Zoom
  - Please **write your name and organization** before sharing your question

- Q&A will also be available at the end of the presentations
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  - When you are invited to intervene please unmute your microphone.
  - Please **state your name and organization** before sharing a comment or question
  - When you have completed your **time bound intervention** please use the term 'over' and mute your microphone
  - After speaking, please lower your hand by clicking on the "Lower Hand"

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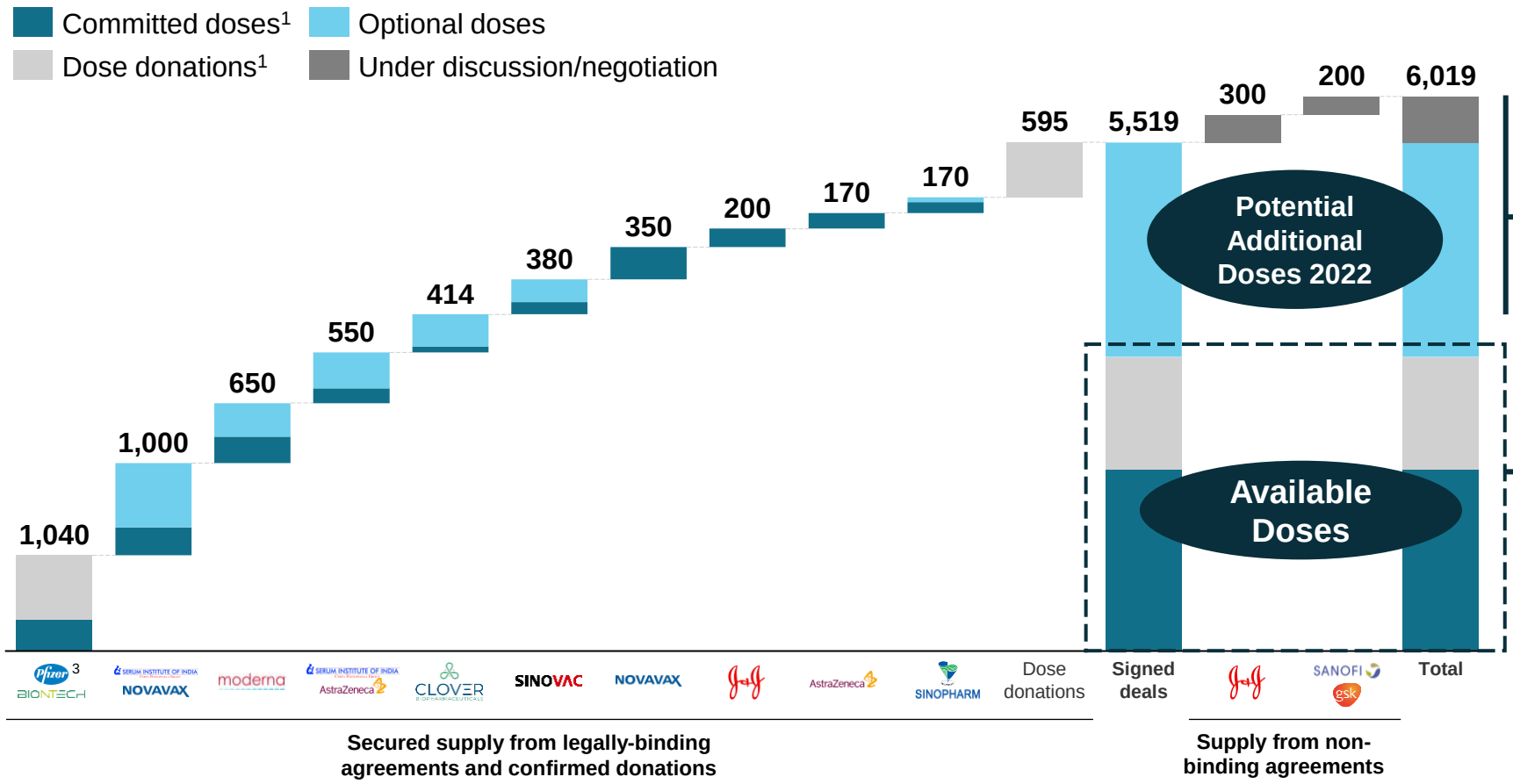
COVAX Portfolio – potentially 6 billion doses of 11 vaccines[4] available

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

Total COVAX portfolio by vaccine, M doses

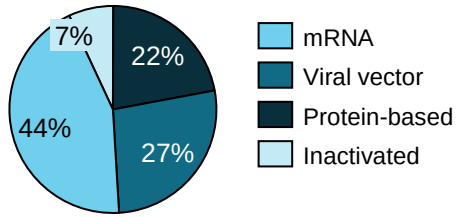


COVAX has **access to 3bn+ extra doses** across several vaccines through its options and other agreements

Currently fundraising for **at least 600mn doses** to create the Pandemic Vaccine Pool for AMC countries to mitigate demand and supply risks in 2022

Currently COVAX has available **~2.8bn doses (funded & donations) by mid-2022**

COVAX portfolio composition, by tech platform



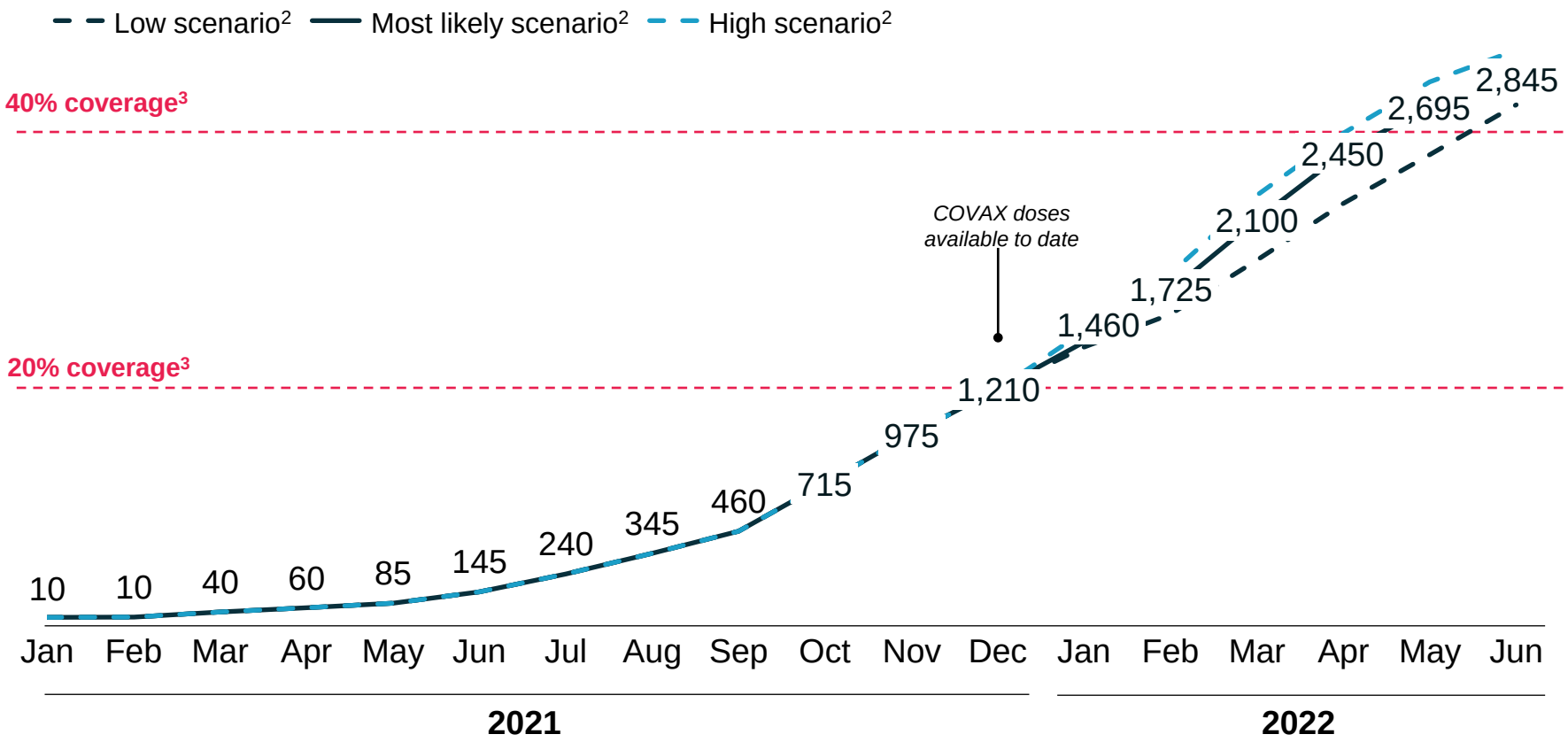
1 "Committed doses" are doses that the COVAX Facility is required to procure. "Optional doses" are doses that the COVAX Facility has the option to procure in the future, but is not required to purchase. Once optional doses are exercised, they become committed doses.
2 "Dose donations" estimated based upon donor commitments to share new doses bilaterally with COVAX. The transfer of COVAX allocations from SFPs to AMC Participants are already included in the volumes secured by COVAX from legally-binding agreements.
3 US support has allowed COVAX to secure one billion doses from Pfizer/BioNTech. Reflecting US funding above its original pledge, 700M of these are recorded as a donation.
4 Subject to signing legally binding contracts, vaccine regulatory approval

COVAX Portfolio ~2.8bn doses available by mid-2022
- additional volumes available in 2022 if need and demand arises

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Forecasted Available Supply for all Participants,

Cumulative, Committed and donated doses only, M doses, 2021 and 2022[1]



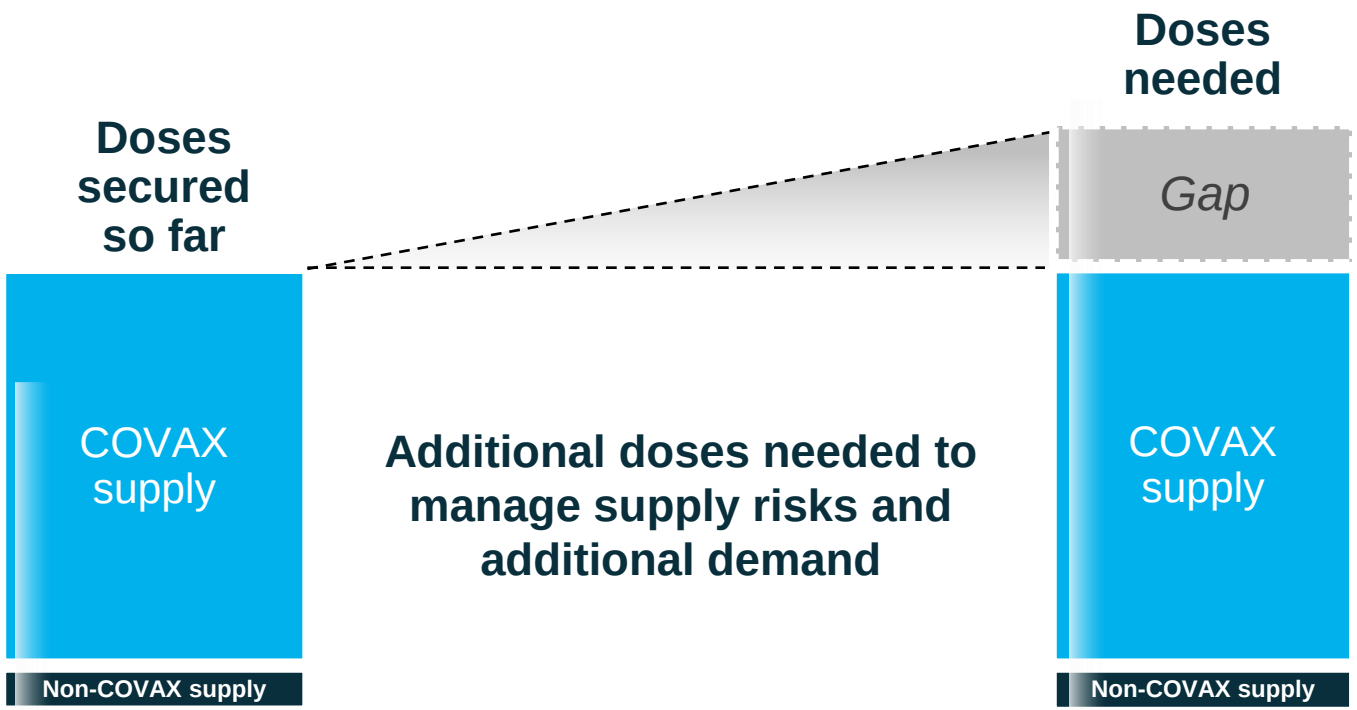
In 2022, COVAX expects regular, predictable, large volumes of vaccines to be available to Participants

- In final months of 2021, COVAX supply increased substantially, with >600 million doses delivered in Q4 2021
- In 2022, we expect this trend to continue – over the first six months, an average of 250-300 million doses will become available for supply each month
- By mid-2022, COVAX expects to have enough supply available for each AMC Participant to achieve approx. 45% full vaccination coverage.
- Note: volume forecast subject to vaccines' regulatory approvals, export authorisation, manufacturing assumptions

1 Forecasts only include committed doses and confirmed dose donations; optional doses and doses under negotiation are not included. Timing of available supply is based on anticipated date of release by manufacturer, at which point doses become available for delivery. Volumes have been rounded to nearest 5M.
2 Scenarios are based on best available information from manufacturers and analysis from Gavi and UNICEF on the impact and likelihood of potential mitigation efforts.
3 Coverage refers to proportion of total population in AMC91 Participants that could be fully vaccinated with available volumes, assuming India receives 20% of AMC-funded volumes.

The COVAX Portfolio's Pandemic Vaccine Pool in 2022

- ongoing fund raising for this Pool will enable response to Participants' incremental needs (eg higher coverage) and mitigate potential risks (eg variant-adapted vaccines)



The Pandemic Vaccine Pool could be used for…

- Increasing primary series coverage to AMC country targets
- Additional doses of J&J and inactivated virus vaccines, and for immunocompromised people, to complete primary series coverage
- Boosters (if recommended) for at-risk populations*
- New variant-adapted vaccines (if recommended) in case of emergency of immunity-escaping variants
- Mitigating potential supply risks

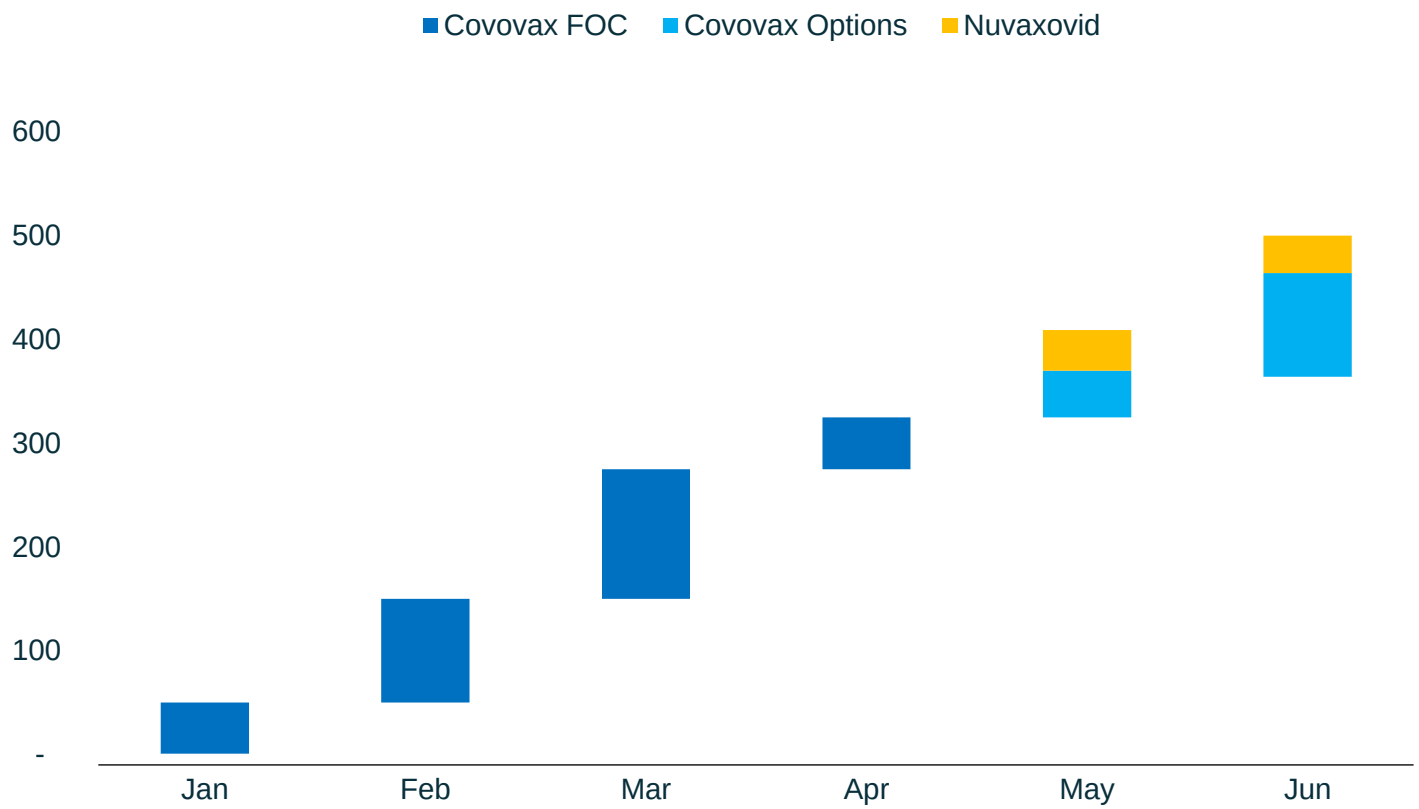
NOTE: There is no current recommendation for use of booster vaccination.

This illustrates a scenario that the Portfolio intends to be able to meet if such vaccination strategies will be recommended by WHO.

COVAX Covovax and Nuvaxovid Estimated Supply 1H 2022
- more volumes available in 2H 2022 if need and demand arises

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Covovax and Nuvaxovid Forecasted Available Supply for all Participants,
Cumulative, Firm Order Commitment (FOC) and Options, M doses, 1H 2022[1,2]



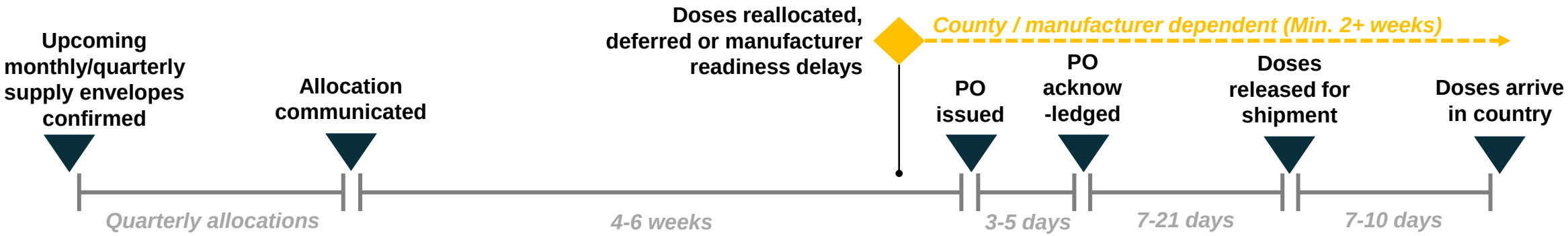
1 Forecasts only include committed doses and confirmed dose donations; optional doses and doses under negotiation are not included. Timing of available supply is based on anticipated date of release by manufacturer, at which point doses become available for delivery. Volumes have been rounded to nearest 5M.
2 Scenarios are based on best available information from manufacturers and analysis from Gavi and UNICEF on the impact and likelihood of potential mitigation efforts.

COVAX Firm Commitment and Options

- A total of 300M doses of Covovax and 350M doses of Nuvaxovid are under firm order commitment (FOC)
- COVAX has the option to purchase another 700M doses of Covovax in 2022
- First quarter forecasts are based on manufacturer input
- Nuvaxovid COVAX doses require EUL of specific supply nodes prior to confirming forecasts

COVAX Facility shipment timeline explainer

ILLUSTRATIVE



COVAX allocation

Allocation rounds conducted prior to the quarter/ month[1] in which the monthly supply envelopes are available

Timing dependent on advanced confirmation of supply envelope from manufacturers, which can be delayed if supply nodes / shelf life is not confirmed in a timely manner

Country preparedness and manufacturer readiness

In order for a PO to be placed, countries must:

- *Sign manufacturer-specific I&L agreement*
- *Grant national regulatory approval*
- *Issue import permit*
- *Complete additional readiness requirements, dependent on manufacturer*

Allocations must be accepted or refused within 4 weeks however preparedness steps may take longer. If doses refused or timelines not met, doses are reallocated, adding ~4+ weeks

Shipment deferral may be requested by country based on absorption capacity constraints, adding min ~3 weeks, but up to ~3 months

Manufacturers may experience additional readiness delays due to scale up or logistical challenges, which can add additional time

PO issuing to arrival in country

Procurement agency places PO and manufacturer acknowledges PO once availability of doses is confirmed

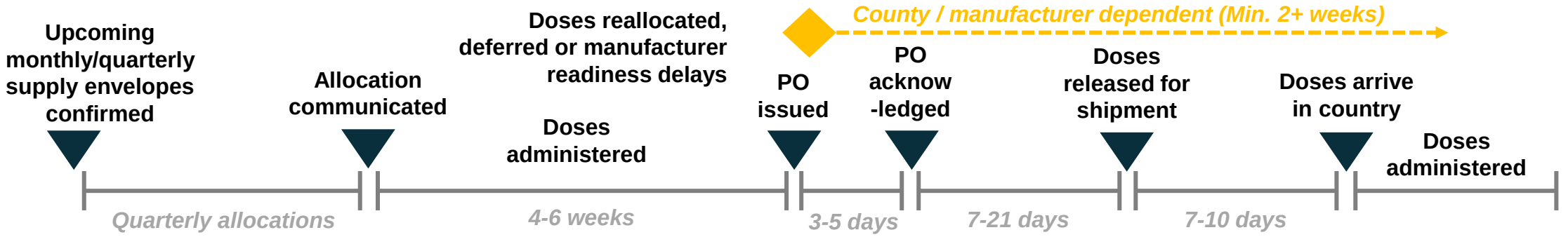
Notification of goods readiness, or confirmation of batch release timelines dependent on administrative processing at manufacturer

Arrival in country dependent on timing of packaging and labeling, and shipment logistics, including flight scheduling

[1] COVAX conducts allocations on a quarterly basis, or triggered when a new product achieves EUL, with exceptional allocation rounds conducted in between as needed; [2] Additional readiness requirements may include tripartite readiness calls, UCC capacity confirmation, and additional financial obligations

COVAX Facility shipment timeline explainer

ILLUSTRATIVE



	Drug Substance/Drug Product	Min Shelf-life at Time of Arrival
Pfizer/BioNTech USG	BioNTech/Pfizer, Wyeth/Pharmacia	6 mo
AstraZeneca	SK Bio, Wuxi, Catalent BWI/ SK Bio, Catalent IT, Chemo	3 mo
SII-AstraZeneca	SII/SII	6 mo
Sinopharm	Sinopharm/Sinopharm	6 mo
Sinovac	Sinovac/Sinovac	12 mo
J&J	Janssen/Aspen, Catalent Emergent/Catalent, Merck, GRAM	6 mo
Moderna	Lonza, Moderna/Catalent, Rovi, Baxter	5 mo
Covavax	SII/SII	**6 mo**
Nuvaxovid	SK Bio, Novavax CZ, BioFabri/ Baxter, Siegried, SII	**6 mo**

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Product Spotlight:

NVX-CoV2373 COVID-19 vaccine

(Novavax/Covovax)

COVAX Participant Briefing and Q&A

Joachim Hombach

13 January 2022

World Health Organization | IVB

Outline

1. Novavax/Covovax vaccine platform
2. Evidence review
    - Performance, safety profiles, boosters, interchangeability (mix and match)
3. Performance against variants
4. SAGE recommendations
5. Programmatic characteristics

COVID-19 Vaccine platforms in the COVAX Portfolio

Vaccine platform	Description	COVID-19 Vaccines
Messenger Ribonucleic Acid (mRNA)	• mRNA vaccines provide the instructions to human cells to make part of the Covid virus spike protein. • This spike protein triggers the recipient's immune system to develop a protective response which defends against future exposure to the covid virus	**COMIRNATY** ® (Pfizer BioNTech) **SPIKEVAX** ® (Moderna)
Recombinant Viral Vector	• A modified virus (the viral vector), other than the virus causing covid, is used to deliver the instructions to human cells to make part of the Covid virus spike protein. • This spike protein triggers the recipient's immune system to develop a protective response which defends against future exposure to the covid virus.	**COVISHIELD** ® (Serum Institute of India) * **VAXZEVRIA** ® (AstraZeneca) * **Ad26.COV 2-S** ® (Janssen–Cilag Int.) * **Ad26.COV 2-S** ® (Janssen Biotech Inc.) *
Inactivated Virus	• An inactivated vaccine (or killed vaccine) consists of killed covid virus or particles that are recognized by the immune system to elicit an immune response (examples of other vaccines in the routine program in this platform are **IPV and most influenza vaccines**)	**Inactivated SARS-CoV-2 vaccine** ® (BIBP/Sinopharm) **CORONAVAC** ® (Sinovac Life Sciences) **COVAXIN** ® (Bharat Biotech)
Recombinant spike protein nanoparticle	• Subunit vaccines contain specific fragments of the covid spike protein, which have been carefully selected to produce combinations of these molecules likely to produce a strong and effective immune response (examples of other vaccines in the routine program in this platform are **pertussis, HPV and HepB**)	**COVOVAX** ® (Serum Institute of India) **NUVAXOVID** ® (Novavax, Inc.) **SCB-2019** ® (Clover Biopharmaceuticals Ltd.)

Novavax Vaccine platform

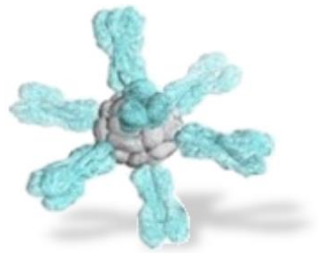
Recombinant protein nanoparticles formulated with Matrix-M

Safety database includes >12,500 with exposure to nanoparticle vaccine

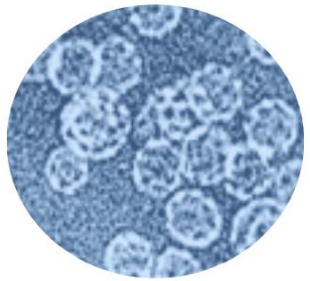
Long-term safety in >2,500 with nanoparticle vaccine formulated with Matrix-M

- Ebola
- Respiratory Syncytical Virus (RSV)
- Trivalent influenza
- Quadrivalent influenza

Additionally >30,000 participants in ongoing COVID-19 studies



Recombinant protein nanoparticle



Matrix-M

Novavax Vaccine Platform

Manufactured by Novavax and Serum Institute India

- NVX-CoV2373 will be marketed as **Nuvaxovid (Novavax)** and **Covovax (Serum Institute of India)**.
- Both products received EUL in December 2021 based on the Novavax core non-clinical and clinical data for regulatory evaluation.

Product	EUL date	NRA of record
Nuvaxovid (Novavax)	Dec 20	European Medicines Agency
COVOVAX (SII)	Dec 17	Central Drugs Standard Control Organization

- **Nuvaxovid and Covovax are considered fully equivalent,** although they are produced at different manufacturing sites and assigned different product names.
- **WHO evidence review and policy recommendations are the same for both products.**

NVX- COV2373 Clinical development program

Phase 3 **US & Mexico**	*N= 29,960*	Licensure- enabling safety in US population. Licensure- enabling efficacy in US populations
Phase 3 **United Kingdom** Health et al. NEJM 30 June 2021 Tobak et al. Lancet ID in Press	*N= 29,960*	Licensure- enabling safety data Licensure- enabling efficacy data Safety of co- administration with influenza vaccine
Phase 2b **South Africa** Shinde et al. NEJM 20 May 2021	*N=4,422*	Evaluated preliminary efficacy Defined safety profile HIV+ subgroup
Phase 1/2 **US & Australia** Keech et al. NEJM 02 September 2020 Formica et al. PLoS Medicine Oct 2021	*N=131 Phase 1* *N=1,288 Phase 2*	Established dose level in younger and older adults. Confirmed need for adjuvant and 2 dose schedule. Defined immunologic phenotype. Described preliminary safety profile.

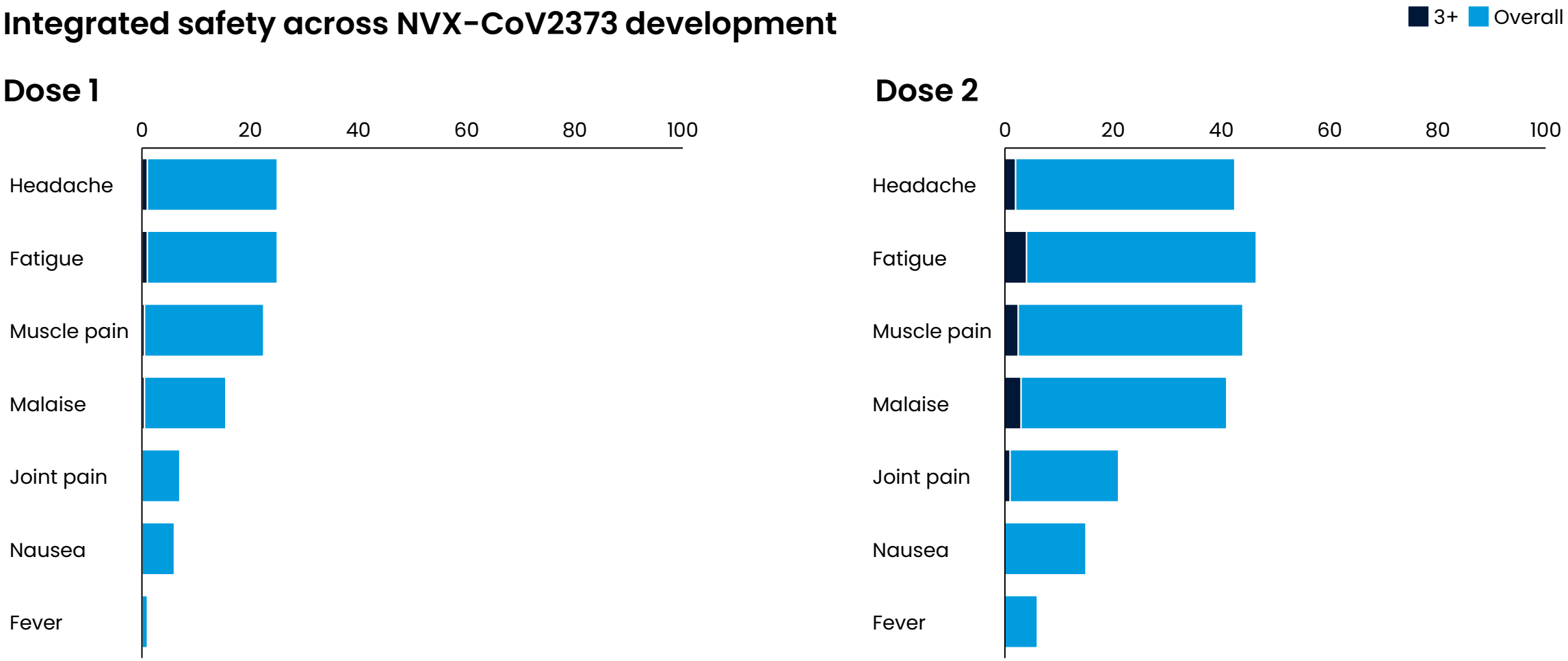
Consistent Efficacy across Phase 3 studies

	UK	US and Mexico
Overall Efficacy	**89.7%** (95% CI 80-95)	**90.4%** (95% CI 83-95)
Efficacy against non-VOC isolates	**96.4%** Prototype	**100%** (95% CI 86 - 100)
Efficacy against VoC / VoI	**86.3%** Alpha (B.1.1.7)	**93.6%** (95% CI 83 – 97) (51% alpha)
Efficacy against moderate and severe disease	**87%** (95%CI 74-94)	**100%** (95% CI 87-100)
Median follow up:	**56 days after 2nd dose**	**64 days after 2nd dose**

Safety and reactogenicity

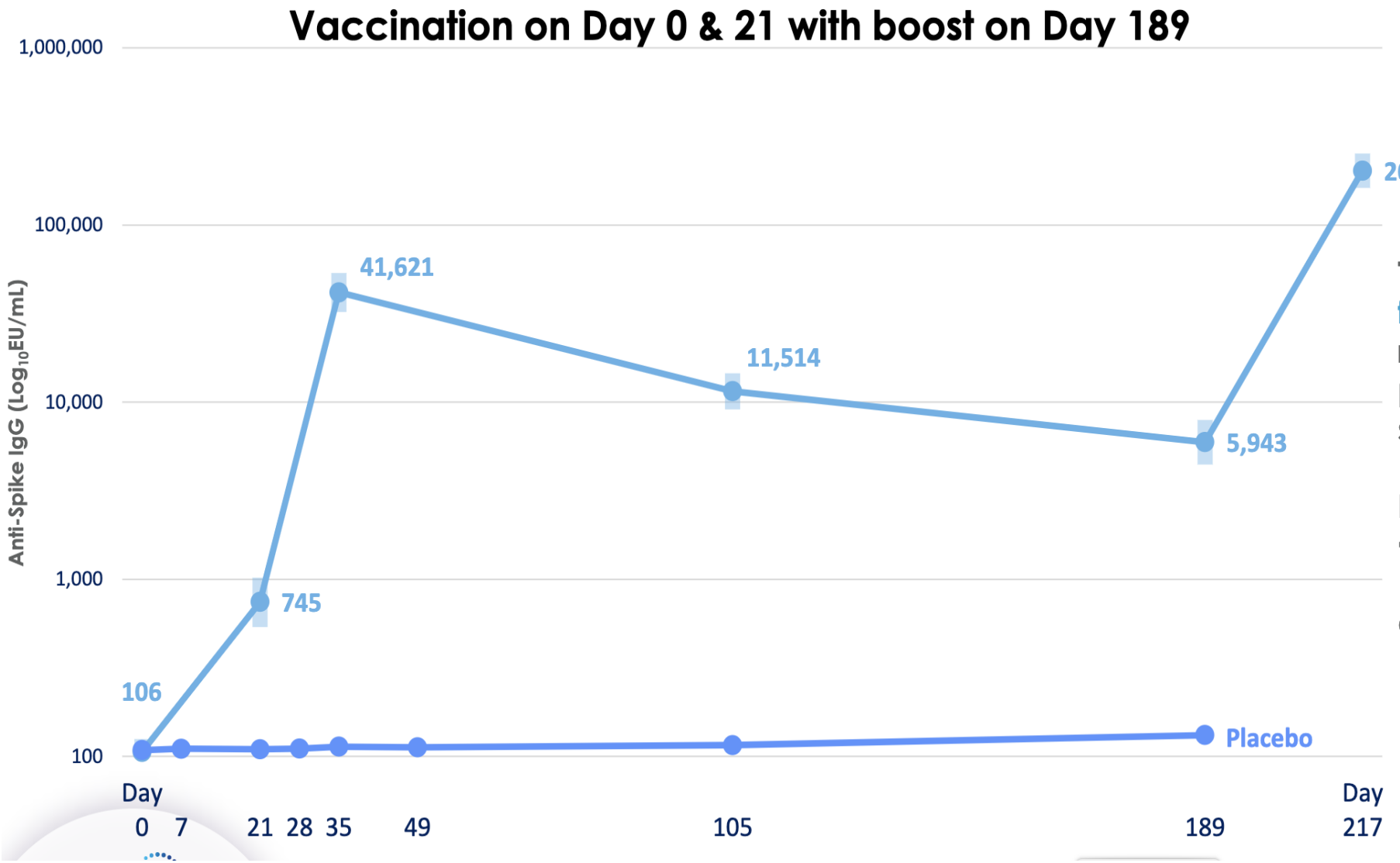
Systemic: Majority “None” or “Mild”

Integrated safety across NVX-CoV2373 development



Boosters were evaluated for immunogenicity

Antibody response increased ~ 4.6 fold over peak response seen after 2 doses



Titers increased ~4.6-fold compared to peak response seen after primary vaccination series.

IgG titers increased ~3.9-fold in adults aged 18-59 & ~5.4-fold in adults aged 60-84.

Interchangeability

The available evidence on NVX-CoV2373 in the context of heterologous usage is currently limited to two studies.

Heterologous primary series – Com-COV2

Overview

Study	Stuart et al; Lancet
Country	UK
Study type	Single-blind RCT
Population	Adults ≥50y

Groups (ranked by increasing post-D2 GMC)

Dose 1	Dose 2	N	Day 28 NAb GMC (95% CI), NT_{50}
AZ	AZ	171	109 (70–168)
AZ	NVX	167	432 (301–618)
BNT	NVX	172	1109 (805–1529)
BNT	BNT	167	1501 (1188–1896)
AZ	MOD	167	1684 (1313–2162)
BNT	MOD	164	1883 (1546–2294)

+9.5w

Conclusions

- Antibody response: AZ-NVX > AZ-AZ but BNT-NVX < BNT-BNT
- Across all groups, cellular response was strongest for AZ-NVX but weakest for BNT-NVX
- NVX as second dose had equivalent or lower reactogenicity compared with homologous doses

Heterologous boosters – COV-BOOST

Overview

Study	Munro et al; Lancet
Country	UK
Study type	Blinded RCT
Population	Adults ≥30y

Groups (ranked by increasing post-boost GMC)

Primary	Boost	N	Day 28 NAb GMC (95% CI), pseudo-NT_{50}
2 x AZ	AZ	98	193 (161–231)
2 x AZ	JNJ	95	563 (454–698)
2 x AZ	NVX	87	727 (598–883)
2 x BNT	NVX	94	766 (624–939)
2 x BNT	AZ	98	950 (802–1126)
2 x BNT	JNJ	75	1441 (1188–1749)
2 x AZ	BNT	93	1621 (1314–1998)
2 x BNT	BNT	95	1789 (1520–2107)
2 x BNT	MOD	91	2019 (1621–2513)
2 x AZ	MOD	97	2368 (2054–2730)

>10w

Conclusions

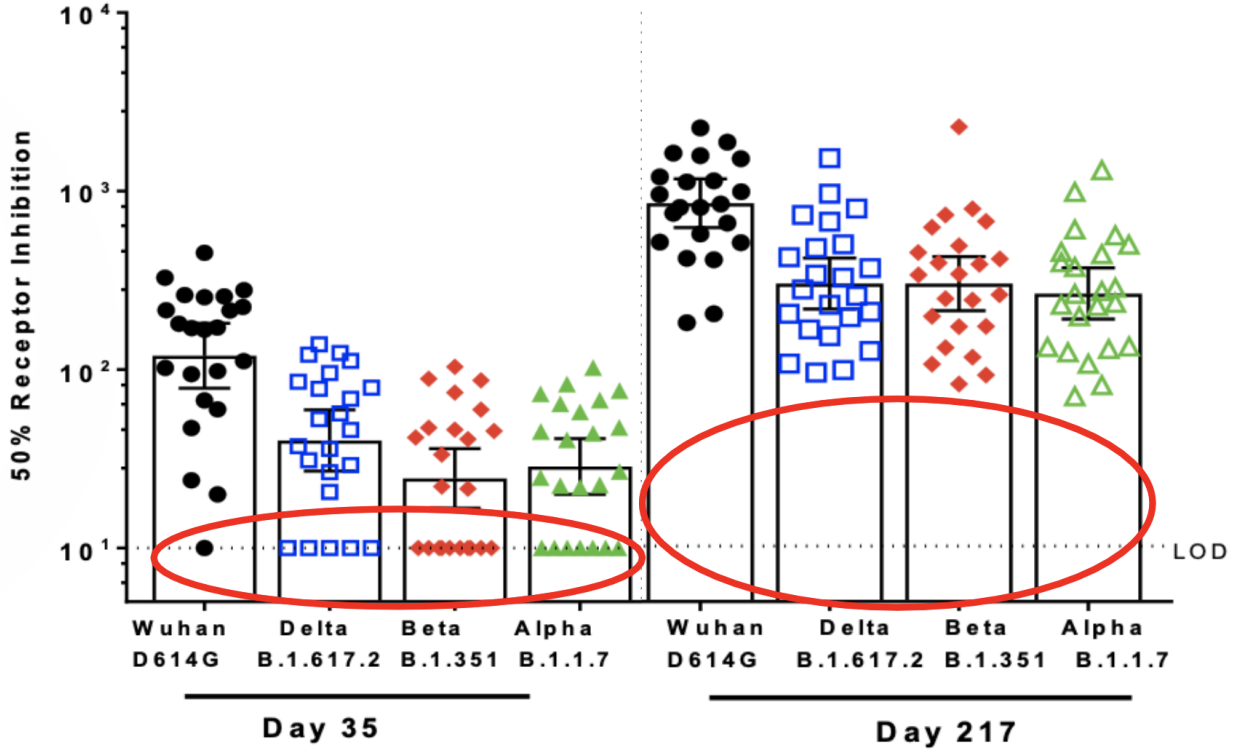
- All WHO EUL vaccines boosted antibodies relative to MenACWY control
- Antibody response: AZ-AZ-NVX > AZ-AZ-AZ but BNT-BNT-NVX < BNT-BNT-BNT
- After AZ-AZ, NVX boosted cellular response more than AZ
- After BNT-BNT, NVX boosted cellular response less than BNT
- NVX had equivalent or lower reactogenicity compared with homologous booster doses

Performance against variants

Limited data against Omicron

Antibodies (after boosting) were assessed for performance against variants, including Delta

All participants developed high levels of functional hACE2 responses against all variants



Note: No assessment against Omicron in this study

Fold Reductions in Neutralizing Antibodies, by Vaccine Platform

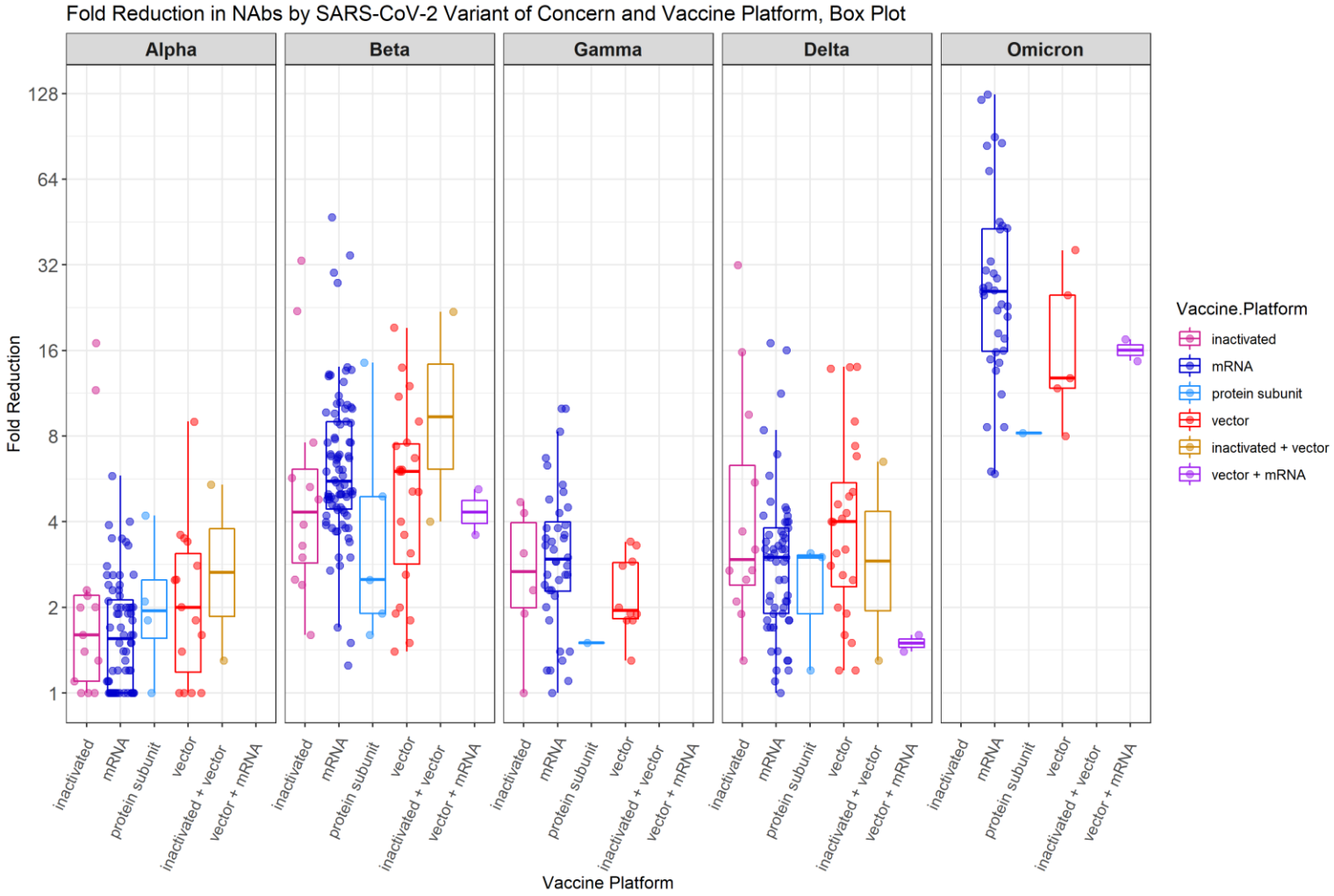
Primary Series (excludes boosters)

Inclusion criteria:

- Reference strain is ancestral strain (non-VOC)
- samples collected within 6 months of complete vaccination
- Fold-reductions reported, or raw data provided for calculations

Omicron Results:

Vaccine	Fold-Reduction (IQR across all studies)	# Studies
Pfizer BioNTech - Comirnaty	17-45	20
Moderna-mRNA-1273	6-86	12
AstraZeneca-Vaxzevria	12-36	3
Gamaleya – Sputnik V	12	1
Janssen-Ad26.COV2.S	8	1
Novavax - Covavax	8	1
Not plotted (all or most samples below LOD)		
Janssen-Ad26.COV2.S		4
AstraZeneca-Vaxzevria		3
Pfizer BioNTech - Comirnaty		4
Sinopharm		3
Gamaleya-Sputnik V		1
Sinovac-CoronaVac		3



Fold Reductions in Neutralizing Antibodies, by Vaccine Platform

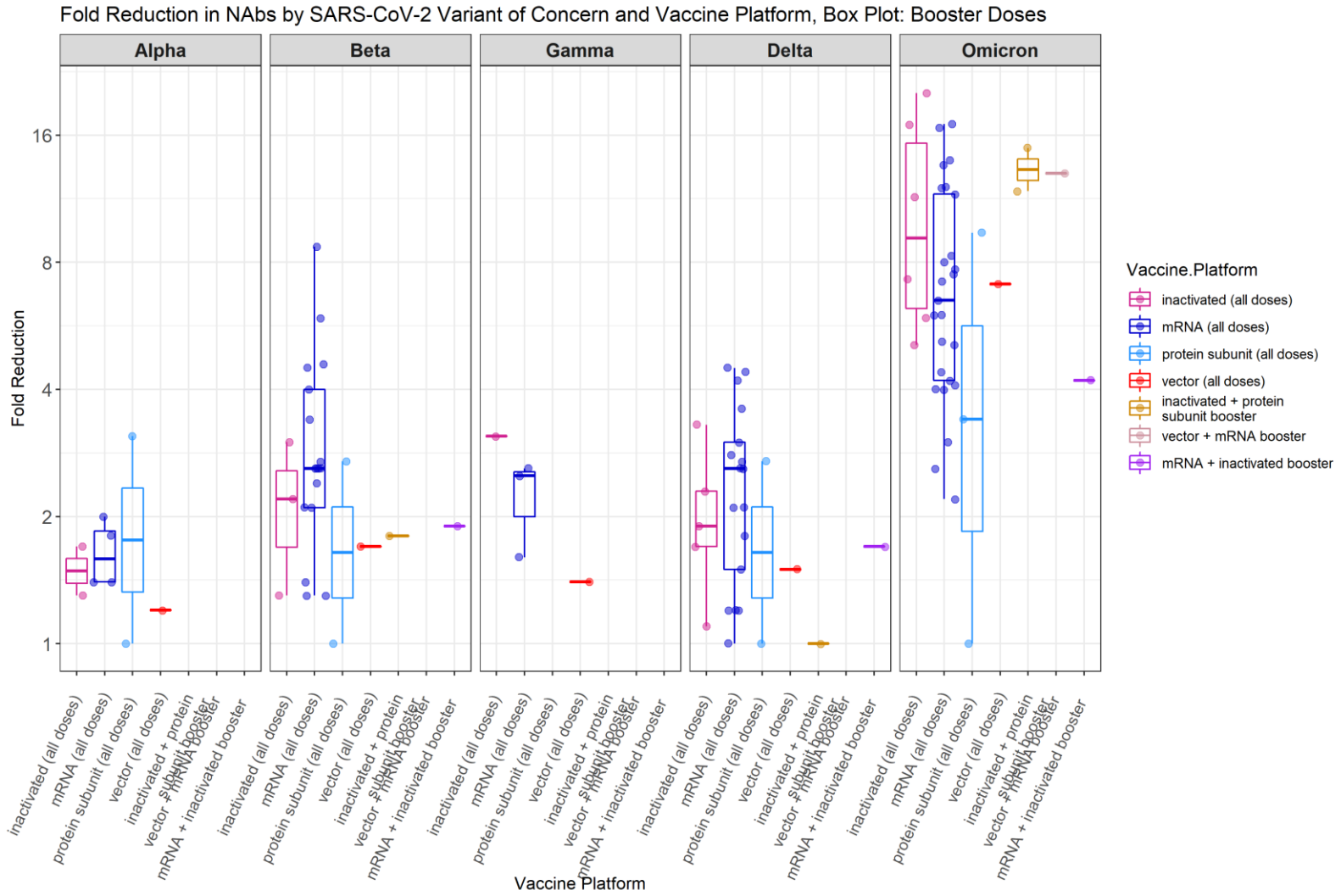
Booster Doses

Inclusion criteria:

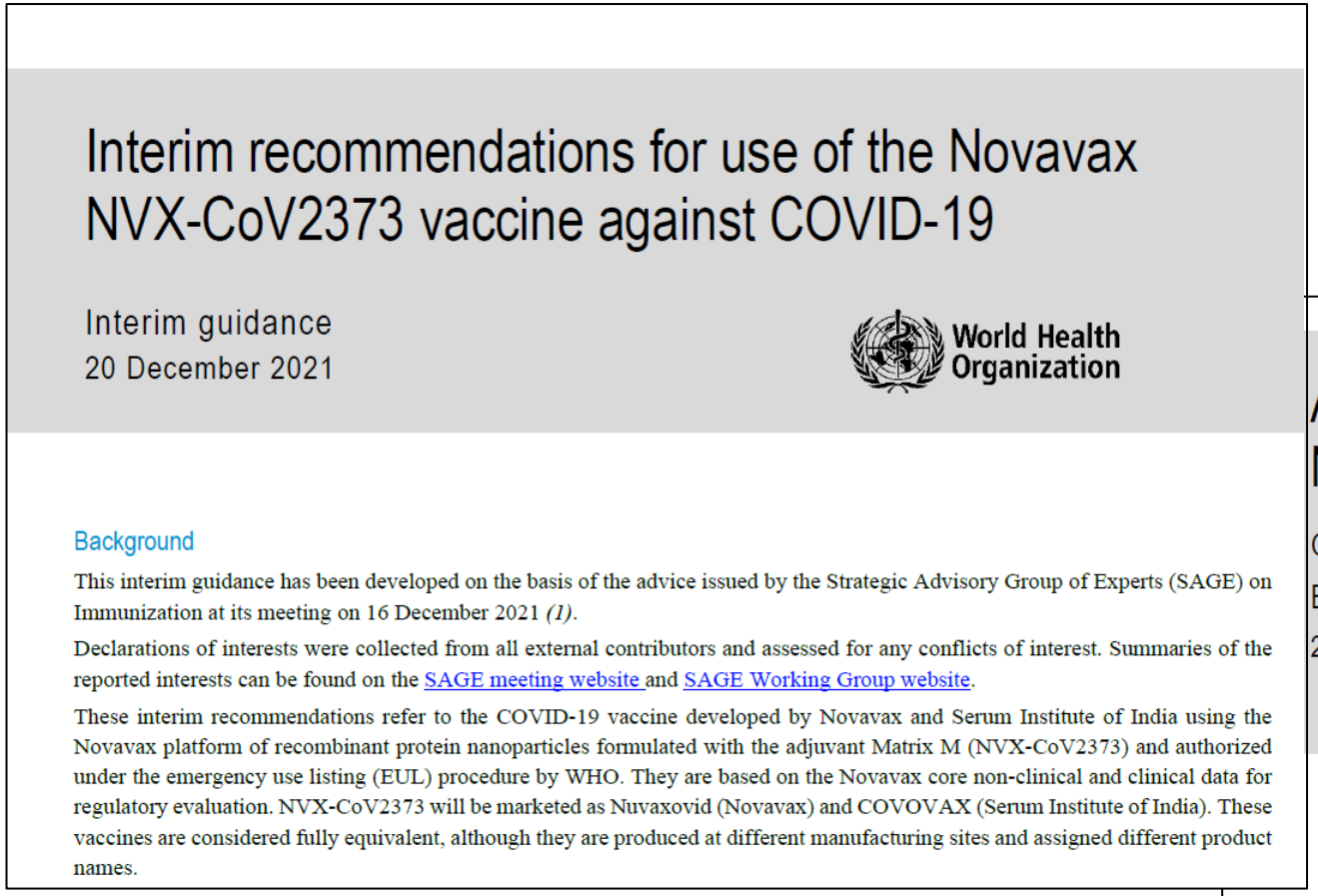
- Reference strain is ancestral strain (non-VOC)
- samples collected within 6 months of complete vaccination
- Fold-reductions reported, or raw data provided for calculations

Omicron Results:

Vaccine	Fold-Reduction (IQR all studies)	# Studies
Pfizer BioNTech-Comirnaty (3 doses)	4-12	15
Moderna-mRNA-1273 (3 doses)	4-14	6
Beijing CNBG-BBIBP-CorV (3 doses)	6-20	3
Anhui ZL–Recombinant (3 doses)	0.3-9	2
Novavax-Covavax (3 doses)	3.4	1
Sinovac-Coronavac (3 doses)	7-17	2
Janssen-Ad26.COV2.S + Moderna-mRNA-1273 booster	13	1
Beijing CNBG-BBIBP-CorV + Anhui ZL – Recombinant booster	12-15	2
Gamaleya-Sputnik V + Gamaleya-Sputnik Light booster	7	1
Pfizer BioNTech-Comirnaty + Janssen-Ad26.COV2.S booster	4.2	1



Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19



Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19

Interim guidance
20 December 2021

World Health Organization

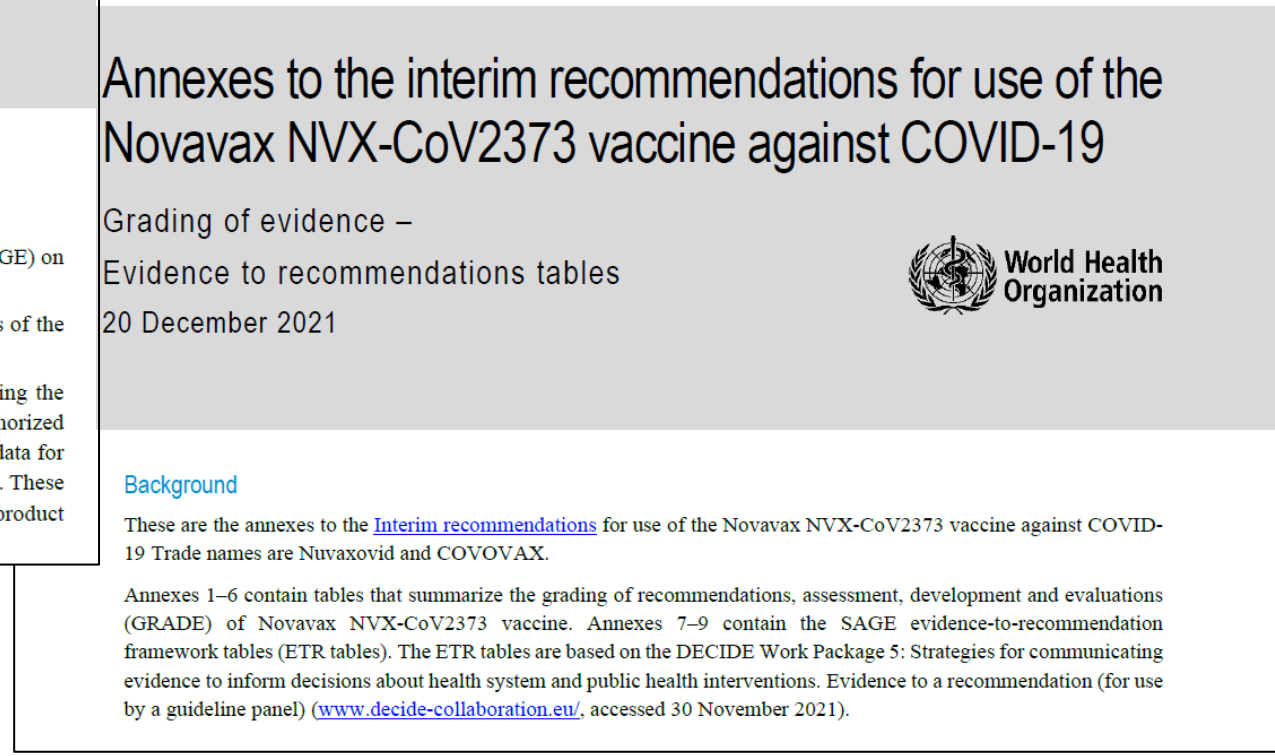
Background

This interim guidance has been developed on the basis of the advice issued by the Strategic Advisory Group of Experts (SAGE) on Immunization at its meeting on 16 December 2021 *(1)*.

Declarations of interests were collected from all external contributors and assessed for any conflicts of interest. Summaries of the reported interests can be found on the SAGE meeting website and SAGE Working Group website.

These interim recommendations refer to the COVID-19 vaccine developed by Novavax and Serum Institute of India using the Novavax platform of recombinant protein nanoparticles formulated with the adjuvant Matrix M (NVX-CoV2373) and authorized under the emergency use listing (EUL) procedure by WHO. They are based on the Novavax core non-clinical and clinical data for regulatory evaluation. NVX-CoV2373 will be marketed as Nuvaxovid (Novavax) and COVOVAX (Serum Institute of India). These vaccines are considered fully equivalent, although they are produced at different manufacturing sites and assigned different product names.

NVX-CoV2373 will be marketed as Nuvaxovid (Novavax) and COVOVAX (Serum Institute of India).



Annexes to the interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19

Grading of evidence –
Evidence to recommendations tables
20 December 2021

World Health Organization

Background

These are the annexes to the Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19 Trade names are Nuvaxovid and COVOVAX.

Annexes 1–6 contain tables that summarize the grading of recommendations, assessment, development and evaluations (GRADE) of Novavax NVX-CoV2373 vaccine. Annexes 7–9 contain the SAGE evidence-to-recommendation framework tables (ETR tables). The ETR tables are based on the DECIDE Work Package 5: Strategies for communicating evidence to inform decisions about health system and public health interventions. Evidence to a recommendation (for use by a guideline panel) (www.decide-collaboration.eu/, accessed 30 November 2021).

https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-novavax-nvx-cov2373

Recommendations (general use)

- **Intended use**: Persons aged 18 years and above.
- **Administration:** Two doses (0.5 ml) given intramuscularly with an interval of 3-4 weeks.
- **Logistics**: The vaccine is provided as a refrigerated liquid formulation stored at 2–8 °C in a multidose vial containing 10 doses (0.5 ml each). The vials should be protected from light.
- **Interchangeability**: The available evidence on NVX-CoV2373 in the context of heterologous usage is currently limited to two studies.
- **Additional dose:** Additional doses of a vaccine may be needed as part of an extended primary vaccination series for target populations where the immune response following the standard primary series is likely to be insufficient.
- **Booster**: No booster dose currently recommended.

Recommendations (general use, continued)

- **Co-administration**: There should be a minimum interval of 14 days between administration of this vaccine and any other vaccine against other conditions. Can be co-administrated with inactivated influenza vaccine.
- **Contraindication**: A history of anaphylaxis to any component of this vaccine is a contraindication to its use (none reported in trials)
- **Precautions**: As for all COVID-19 vaccines, the COVID-19 NVX-CoV2373 vaccine should be given under health care supervision, with the appropriate medical treatment available in case of allergic reactions. (No serious allergic reactions have been reported in trials)

Recommendations (special populations)

- **Older people**: Vaccination is recommended for older persons without an upper age limit.
- **Persons with comorbidities**: Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19.
- **Children and adolescent under 18 years**: Until safety and immunogenicity data are available, routine vaccination of individuals in this age group is not recommended.
- **Pregnant women**: Developmental and reproductive toxicology (DART) studies have not shown harmful effects of NVX-CoV2373 in pregnant animals and their offspring. Available data on vaccination of pregnant women with NVX-CoV2373 vaccine are insufficient to assess vaccine safety or efficacy in pregnancy. **WHO recommends the use of the COVID-19 NVX-CoV2373 in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks. E.g., if there is elevated community transmission and no other WHO EUL COVID-19 vaccine with a more established safety record in pregnancy is locally available**
- **Lactating women**: WHO recommends the use of the COVID-19 NVX-CoV2373 vaccine in lactating women as in other adults. WHO does not recommend discontinuing breastfeeding because of vaccination.

Recommendations (special populations, continued)

- **Moderately and severely immunocompromised** (including HIV with CD4 count<200 cells/µl): WHO recommends an extended primary series including an additional (third) dose for immunocompromised persons, given between 1–3 months after dose 2.
- **Persons living with HIV who are stable on Antiretroviral Therapy:** HIV-positive persons who are well controlled on highly active antiretroviral therapy and are part of a group recommended for vaccination can be vaccinated.
- **Persons with previous SARS-Cov-2 infection**: Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serological testing for prior infection is not recommended for the purpose of decision-making about vaccination.
- **Persons with acute COVID-19**:Persons with acute PCR-confirmed COVID-19 should not be vaccinated until after they have recovered from acute illness and the criteria for discontinuation of isolation have been met.

Recommendations (special populations, continued)

- **Persons who previously received passive antibody therapy for COVID-19**: As a precautionary measure, vaccination should be deferred for at least 90 days to avoid interference of the antibody treatment with vaccine-induced immune responses.
- **Special settings**: Persons in settings with high population densities, such as refugee and detention camps, prisons and slums, where physical distancing is not implementable, should be prioritized for vaccination as outlined in the WHO Prioritization Roadmap.

Programmatic considerations

- **Presentation:** Ready-to-use liquid adjuvanted formulation in vials containing 10 doses
- **Injection supplies:** Auto-disable (AD) syringe 0.5 mL
  Needle for intramuscular injection 23G × 1″ (0.60 × 25 mm)
- **Multi Dose Vial Policy:** Discard opened vials **6 hours** after first puncture or at end of immunization session, whichever comes first
- **Vaccine Vial Monitor (VVM):** None
- **Storage temperature:** Unopened vials in a refrigerator +2 to +8 °C. Do not freeze.
- **Shelf life:** 9 months or until expiry date
- **Secondary packed volume/dose**

COVOVAX® Single-dose vials: Carton 50 vials/50 doses: 15.8 cm^3
10 dose presentation: Carton 50 vials/500 doses: 2.1 cm^3

NUVAXOVID® Carton 10 vials/100 doses: 2.05 cm^3

Back up

Summary – Policy

	***COVOVAX*® (Serum Institute of India)** ***NUVAXOVID*® (Novavax, Inc.)**
Platform	**Recombinant Spike Protein Nanoparticle Platform**
Efficacy	**90% (95% CI: 80–95)** against mild, moderate, or severe SARS-CoV-2 infection
Dosing/ Schedule	**Two doses (0.5mL each),** intramuscular in deltoid muscle, recommended **interval of 3-4 weeks between doses** Minimum interval 14 days between administering this vaccine and all other vaccines, except inactivated influenza vaccine (can be co-administered)
Intended use	**18 years and above**
Special indications	**Booster doses:** WHO recommends countries should consider booster doses only when high coverage with 2 doses has been achieved in high priority groups as identified in the WHO Prioritization Roadmap **Schedules**: WHO supports flexible approach to homologous vs. heterologous schedules and considers two heterologous doses of any EUL COVID-19 vaccine to be a complete primary series. Heterologous vaccination should be implemented carefully considering vaccine supply, supply projections, and other access considerations, alongside potential benefits and risks of the specific products used. Depending on product availability, countries implementing: • WHO EUL inactivated vaccines for initial doses may consider using WHO EUL vectored or mRNA vaccines for subsequent doses • WHO EUL vectored vaccines for initial doses may consider using WHO EUL mRNA vaccines for subsequent doses • WHO EUL mRNA vaccines for initial doses may consider using WHO EUL vectored vaccines for subsequent doses **Pregnancy**: WHO recommends use of this vaccine in pregnant women if benefits of vaccination to pregnant woman outweigh potential risks. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination **Breastfeeding**: WHO recommends use of this vaccine in breastfeeding women as in non-breastfeeding. WHO does not

Summary – Programmatic considerations

	***COVOVAX*® (Serum Institute of India)** ***NUVAXOVID*® (Novavax, Inc.)**
Presentation	Ready-to-use liquid adjuvanted formulation in vials containing 10 dose
Syringe	Auto-disable (AD) syringe 0.5 mL Needle for intramuscular injection 23G × 1" (0.60 × 25 mm)
Multi Dose Vial Policy (MDVP)	Discard opened vials 6 hours after first puncture or at end of immunization session, whichever comes first
Vaccine Vial Monitor (VVM)	None
Secondary packed volume/dose	**COVOVAX®** **Single-dose vials:** Carton 50 vials/50 doses: 15.8 cm^3 **10 dose presentation:** Carton 50 vials/500 doses: 2.1 cm^3 **NUVAXOVID®** Carton 10 vials/100 doses: 2.05 cm^3
Storage temperature and shelf life	Unopened vials in a refrigerator **+2 to +8 °C:** **9 months or until expiry date**
Handling considerations	Do not freeze

Agenda

Topic	Presenter
Welcome, agenda, housekeeping	**Santiago Cornejo**
COVAX Vaccine Outlook for 2022	Derrick Sim / Kristina Lorenson
Spotlight: Nuvaxovid / Covovax	Joachim Hombach
2022 Country-level Demand Planning	**Benjamin Schreiber / Benedict Millinchip**
Q&A	Moderator – Santiago Cornejo

CONTEXT:

COVAX is moving from being supply constrained to having much more supply and visibility – focus is now to ensure countries can achieve their vaccination targets

COVAX Allocations will become more demand-driven in early 2022

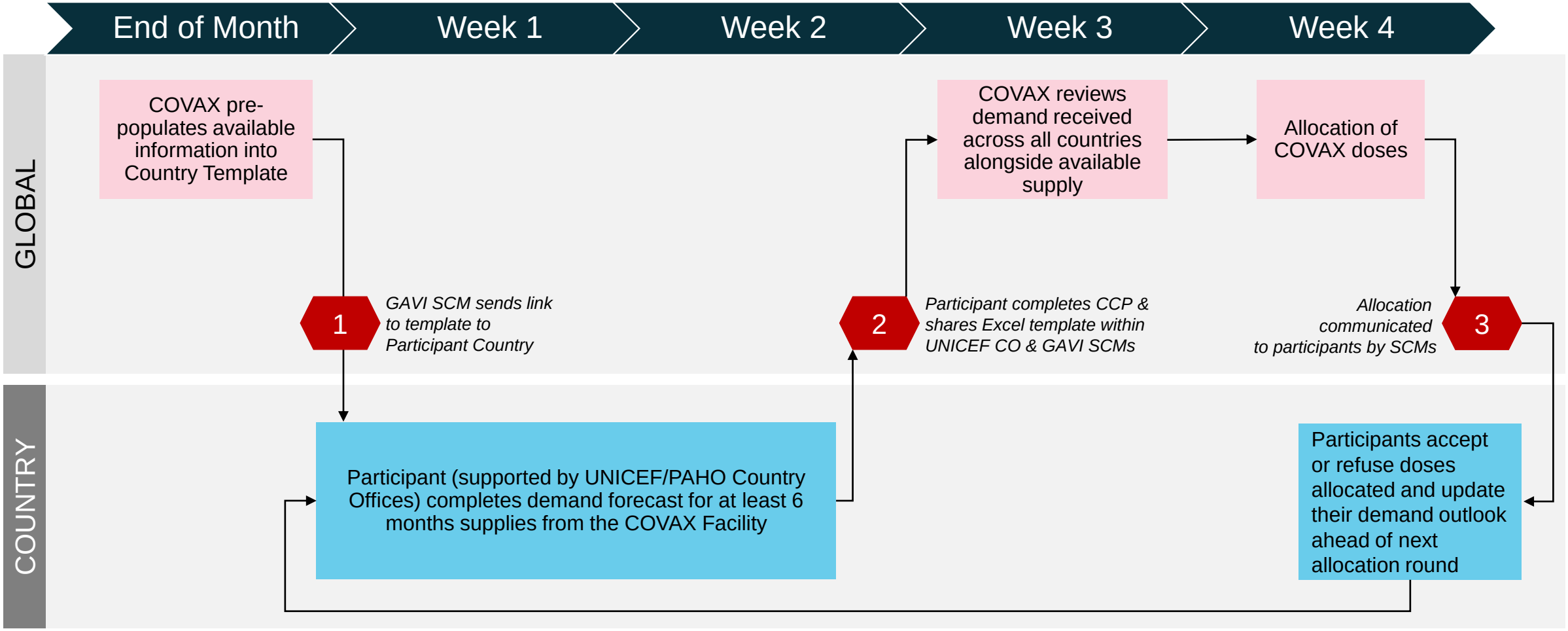
OBJECTIVE:

Provide countries the **right product**, with the **right number of doses** and **with more visibility**

How COVAX will support the in-country planning process

Regular and aligned process	• A monthly process that is simpler to follow and communicate • An aligned forecasting and allocation process
Standardized information	• Providing a consistent Excel template for all participants to complete with COVAX teams' support. *(in due course we will migrate the Excel into the CCP platform)*
Training and support	• Provision of videos and guides and distance support to fill-in required data

Overview of the monthly, rolling demand forecasting process



Key

Work done by COVAX | Work done by Participant | Milestones

Agenda

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COVAX

CEPI Gavi The Vaccine Alliance unicef World Health Organization

Feedback and Q&A

COVAX

CEPI

Gavi
The Vaccine Alliance

unicef

World Health Organization

Thank you