Dialogue with civil society:
ACT-A and COVID-19 vaccines

27 October 2020

This working document may be adjusted in the future due to the evolving nature of the pandemic and new information that may impact COVAX modelling and estimates.

Housekeeping

- Please use mute and turn video off while not speaking to preserve livestream quality
- We will have time for Q&A after the initial presentation
- Use zoom chat to indicate your desire to speak – and if called on please state your name and organization in opening

Agenda

1. Update on CSO representation on COVAX	WHO
2. COVAX Facility and related updates	Gavi
3. Updates on the vaccine pipeline	CEPI/Gavi
4. Allocation framework and policy considerations	WHO
5. Q&A/Discussion	All

CSO representation

CSOs are already important contributors in key COVAX bodies –

COVAX called for nominations for 10 CS representatives

Proposed CSO representation in COVAX activities

		Examples of activities	
COVAX Coordination Meeting (CCM)	**Development & manufacturing** Led by CEPI. with industry	Active portfolio management and supporting activities including: enabling science, manufacturing, clinical development and operations	• ***Technical Review Group (TRG)*** • ***Enabling science – sub-team (SWAT)*** • ***Manufacturing – sub-team (SWAT)*** • ***Clinical development and operations – sub-team (SWAT)***
	Policy & allocation Led by WHO	Vaccine strategy and policy, access and allocation, ethical guidelines	• ***Vaccine strategy*** • ***Access and allocation*** • CSOs are already part of SAGE: – Dr Folake Olayinka (JSI) – SAGE member – Dr Chizoba Wonodi (Gavi CSO Board)
	Procurement & delivery at scale Led by Gavi	Procurement (incl. COVAX Facility, AMC), country readiness and delivery, monitoring and learning	• ***Country Readiness and Delivery coordination group*** • ***Country Readiness and Delivery – demand sub-group*** • ***Country Readiness and Delivery – communication, advocacy and training sub-group*** CSO reps already in following groups + Gavi CSO Steering Committee: • 1 CSO rep already on Gavi Board • 1 CSO rep already in the Market Sensitive Decisions Committee • 1 CSO rep already in the Programme and Policy Committee • 3 CSO interim reps already in COVAX HSS-Connector data working group • 1 CSO rep already in Gavi's Evaluation Advisory Committee

https://www.who.int/docs/default-source/act/notes-to-guide-choice-of-cso-reps-vf4332c078381a4415a24b50843ad04f28.pdf?sfvrsn=2b288445_2

Recap on the selection process for CSO representatives in COVAX Pillar

- CSO dialogue on 28 July informed the draft process
- Process agreed with Vaccines Pillar CCM in early August
- Call for nominations disseminated on 14 August with deadline of 25 August
- Deadline extended to 14 September at request of CSOs
  - To date, 160+ nominations received --- with thanks for the interest
  - All nominations were then shared with CSO focal points shortly after the deadline
- Both CSOs and COVAX set up processes to shortlist candidates
- Shortlists were shared in consideration of achieving the best mix of skills and qualifications per group
- CSOs and COVAX Pillar organisations agreed on successful candidates

Final selected candidates

GROUP	NAME	ORGANIZATION	GENDER	COUNTRY/ REGION
CCM	Mesfin Teklu Tessema	IRC	M	AFRO/USA
Access/Allocation	Karrar Karrar	Save the Children	M	Sudanese/UK
Vaccine Strategy (not active for now)	*To be confirmed*			
Country Readiness & Delivery				
CRD Coordination	Kathleen Clark	IFRC	F	Europe
CRD- Communication, Advocacy, Training	Carla Toko	Village Reach	F	AFRO/DRC
CRD- Demand	Robert Kanwagi	World Vision	M	AFRO
TRG/SWAT				
Manufacturing SWAT	Alain Alsalhani	MSF	M	EURO/Syria
Enabling Science SWAT	Sheetal Sharma	Safari Doctors	F	AFRO/Kenya
Clinical Development and Operations SWAT	Farah Kumar	Aga Khan Foundation	F	Asia/Pakistan
Technical Review Group	Rebecca Grais	MSF	F	Europe/USA

COVAX Facility, Gavi Board decisions and related operational considerations

Aurelia Nguyen,

Managing Director,
Office of the COVAX Facility

Gavi, the Vaccine Alliance

184 Participants representing over 85% of the world's population

Participant Engagement

	Number of participants	Total Population, mn	Doses, mn
Fully Self-Financing	63	2,594	461
Team Europe	29	445	90
AMC92	92	3'919	950*
Total	**184**	**6,958**	**1,601**

*The precise number could vary up or down dependent on final variables. There are an additional 100m doses allocated to the Emergency Buffer

Funding

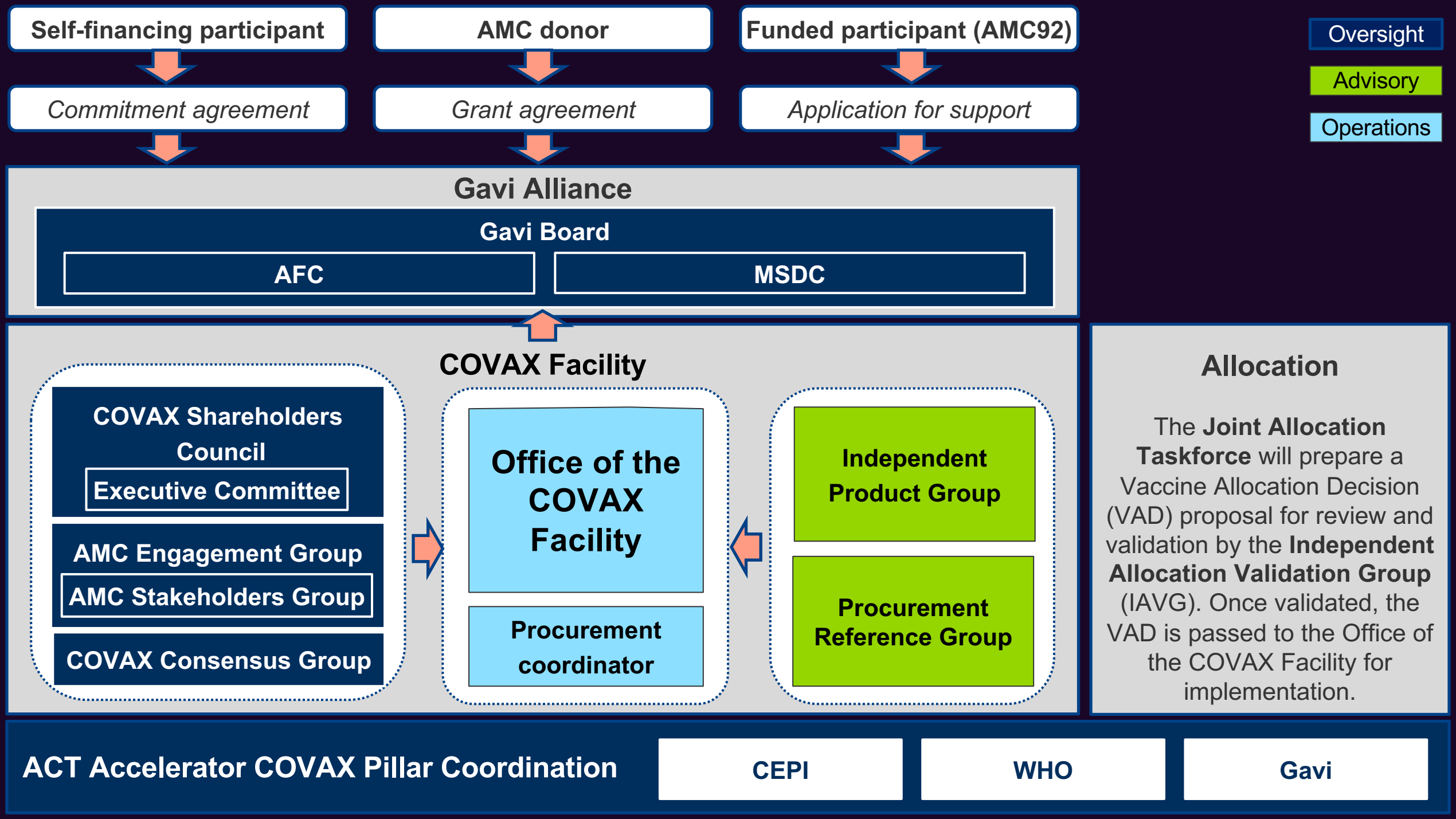
> $1 Billion
received in prepayments
from Self Financing Participants

90%
Pledges received for 2020 AMC
$2 billion fundraising target

At least $5billion additional is sought for 2021 AMC target (ramp up)

There are 92 Self-Financing participants

	Optional Purchase Arrangement	Committed Purchase Arrangement	Total
Number of participants	66	26	92
Total population in participants (mn)	2,798	241	3,039
Population to be vaccinated (mn)	228	46	274
Total number of doses (mn)	458	92	550


Self-financing participant
AMC donor
Funded participant (AMC92)
Oversight
Advisory
Operations
Commitment agreement
Grant agreement
Application for support
Gavi Alliance
Gavi Board
AFC
MSDC
COVAX Facility
COVAX Shareholders Council
Executive Committee
AMC Engagement Group
AMC Stakeholders Group
COVAX Consensus Group
Office of the COVAX Facility
Procurement coordinator
Independent Product Group
Procurement Reference Group
Allocation
The Joint Allocation Taskforce will prepare a Vaccine Allocation Decision (VAD) proposal for review and validation by the Independent Allocation Validation Group (IAVG). Once validated, the VAD is passed to the Office of the COVAX Facility for implementation.
ACT Accelerator COVAX Pillar Coordination
CEPI
WHO
Gavi

At the end of September, the Gavi Board approved several decisions in relation to support to the 92 AMC participants

With regards to the COVAX Facility and access to vaccine the Board took the following decisions:

- **Approved** the proposal for vaccine cost-sharing up to $1.60-2.00 / dose for AMC92 participants, with a goal of mobilising resources from multilateral development banks, and noting that inability to meet cost-sharing will not prevent or delay provision of doses
- **Requested** the Secretariat to return in December with a proposal for vaccine and delivery support to India under COVAX AMC92

With regards to delivery support for the 92 COVAX AMC participants:

- **Approved** the allocation of $150M of Gavi core resources to be made available for CCE and TA support to the 56 Gavi-eligible participants and India (priority), as well as additional AMC92 participants on a case-by-case basis.
- **Noted** the proposed approach to not invest in at-scale deployment of UCC equipment at this time, while supporting the Secretariat continuing to explore mitigation strategies

The Board approved the cost-sharing approach, noting flexibility to ensure that cost-sharing does not prevent introduction for any participant

COVAX

Goals

- Foster **participant ownership and solidarity** in the global fight against COVID-19
- **Mobilise additional resources** for the AMC

Cost-sharing approach (acute phase)

- Seek to **mobilise multilateral development bank financing** to support cost-sharing
  - World Bank recently approved **$12B** in COVID-19-related financing, which participants may leverage for their cost-sharing contributions
- Ensure that there will be **flexibility** as needed so that cost-sharing for vaccines **does not prevent or delay introduction** of the vaccine for any participant

Operationalising cost-sharing

- Further **details on how cost-sharing will be operationalised** are still being finalised
- **More information** on the structure, timeline, and process for cost-sharing, including multilateral development bank engagement, will be shared in the coming weeks

Cold Chain Support – Per the Gavi Board's decision, we are now operationalizing CCE support for the AMC 92 participants

Support Eligibility

- Per Gavi Board decision, priority will be for the 56 Gavi-eligible participants (+ India through a dedicated mechanism);
- Remaining 35 AMC participants will be eligible for CCE support, based on need and availability of funding

Areas of Support

- Focus will be on equipping participants to meet **vaccine storage needs at upper levels of the supply chain** (national, regional);
  - Limited support for lower levels (e.g. district) will likely be available, where justified;
- This support includes deployment and installation "service bundle" per Cold Chain Equipment Optimization Plan (CCEOP); remote temperature monitoring; exploring additional services (e.g. short-term cold storage rentals to bridge capacity gaps)

Key Processes & Timelines

Application Preparation

- The application process is expected to be similar to the CCEOP mechanism, but heavily streamlined to reduce number of documents and complexity;

Data Collection

- Participants will need updated Cold Chain Inventories for target levels of the cold chain; tools are being prepared by UNICEF and WHO to collect / update this data.

Timelines

- Application package targeted for sharing to participants by early November;
- First application review window targeted for December;

TA Support – Also operationalizing TA support for the AMC 92 participants, with the priority on ensuring readiness to access and deliver vaccines

Principles for Technical Assistance Support

- TA support accessible to all AMC92 participants, differentiated based on participant needs and available resources
- Focus investments on preparation and readiness activities
- Utilising expanded partners to complement support provided by core partners, where applicable, based on the principle of comparative advantage

For Core Partners

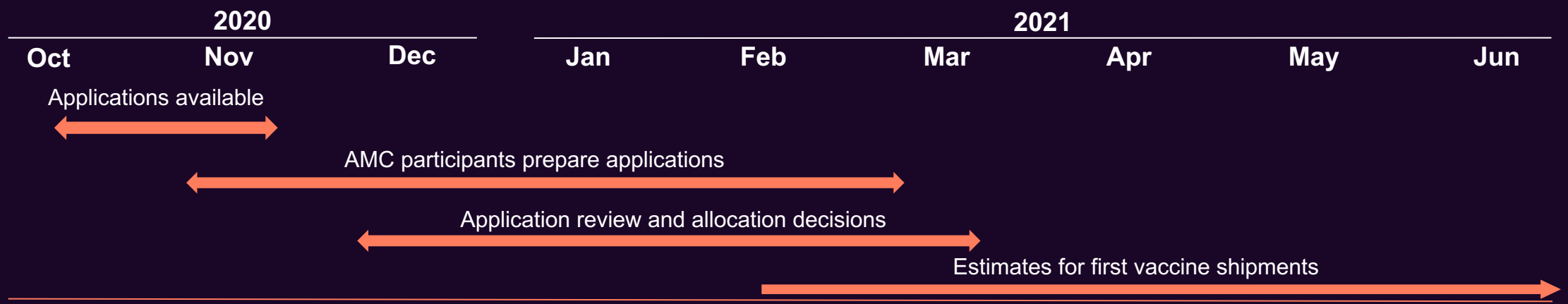
- Support to be provided at **global, regional and country office level**
- WHO and UNICEF to bring detailed proposals to Partners' Engagement Framework-Management Team (PEF-MT) meeting on 22 October 2020
- Grants to core partners rolled out by **November 2020**

For Expanded Partners

- RFP will be issued to identify expanded partners
- Support to expanded partners available by **December 2020**
- Focus areas to include the following:
  - Planning and co-ordination
  - Resources and funding
  - Regulatory aspects
  - Service delivery planning
  - Training and supervision
  - Surveillance and monitoring
  - Vaccine, cold chain, and logistics (e.g. CCE mapping)
  - Safety surveillance
  - Advocacy, social mobilization and communication

AMC92 application timeline and components leading to first vaccine shipments

Timeline



Application components

	Component	Purpose
Vaccine	**Terms and Conditions**	Affirm access to AMC benefits Agree to legal terms and responsibilities of AMC participation
	Vaccine support	Request for Facility support on vaccine cost
	Vaccine allocation request	Indicate product preferences and readiness for inclusion into allocation model (National Deployment and Vaccination Plan)
	Cost sharing	Allocate funds (e.g., from MDB) toward cost sharing
	Indemnity agreements	Sign indemnity agreements with manufacturers
CCE/TA	**Cold chain equipment support**	Request CCE support based on needs
	Technical Assistance	Request TA support based on needs

Facilitated by streamlined application process

15

The COVAX Facility has started to secure doses

Ongoing discussions with diverse range of manufacturers for COVAX Portfolio

- IFPMA, DCVMN, biotechs from across the world, using different technology platforms
- Complementing investments made by partners (CEPI, BMGF)
- CEPI portfolio has other candidates with access agreements

Portfolio management process launched to build diverse, large portfolio

- UNICEF-PAHO RFP being launched
- IPG & PRG being established
- 'One Team' approach to transactions

Initial funding for AMC has enabled commitments for AMC92 supply

Commitments for AMC participants	Volumes
Serum Institute India [AZ and/or Novavax candidates]	200m + option for substantial additional doses
AstraZeneca	150m – 300m subject to SFP/AMC volume split

Volumes for SFPs to be secured in upcoming transactions now that SFP funding has just been put in place

Vaccine pipeline: latest developments

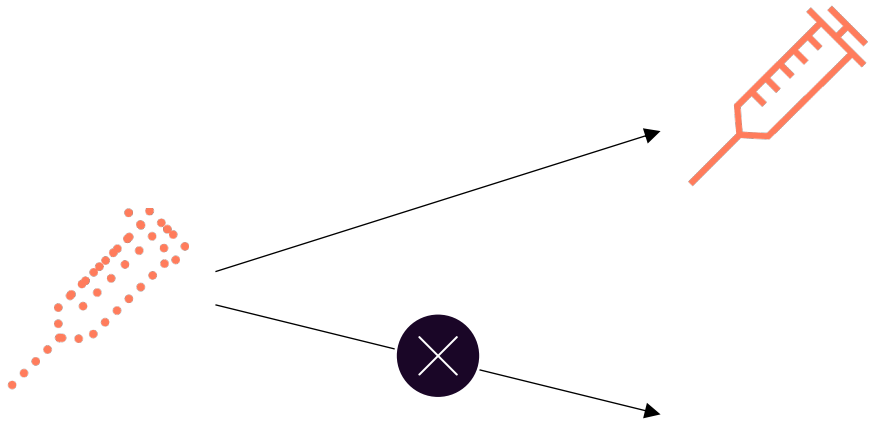
Melanie Saville, CEPI

Dominique Maugeais, Gavi

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

Many vaccines in development – none guaranteed to succeed

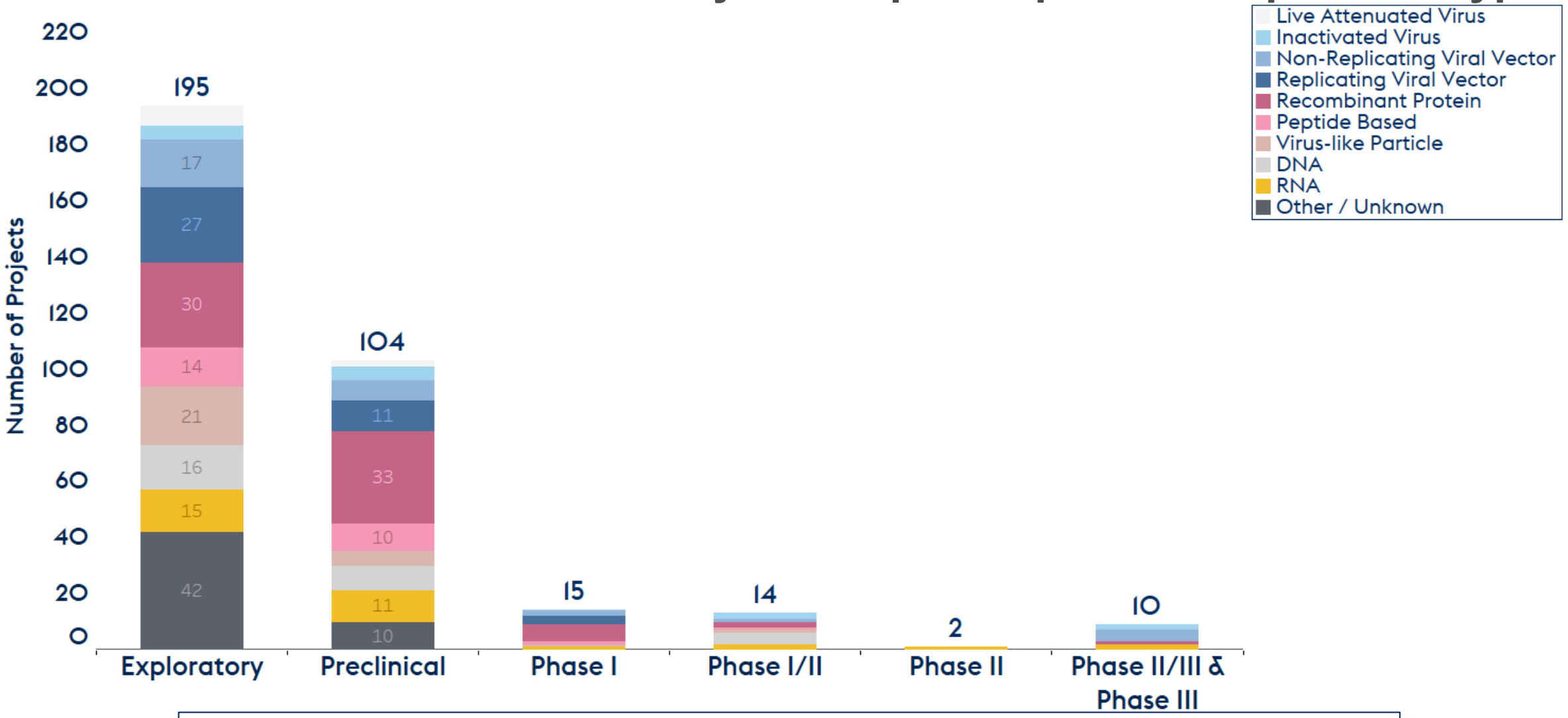
No single manufacturer has the capacity to supply the global volume required



Individual deals might fail

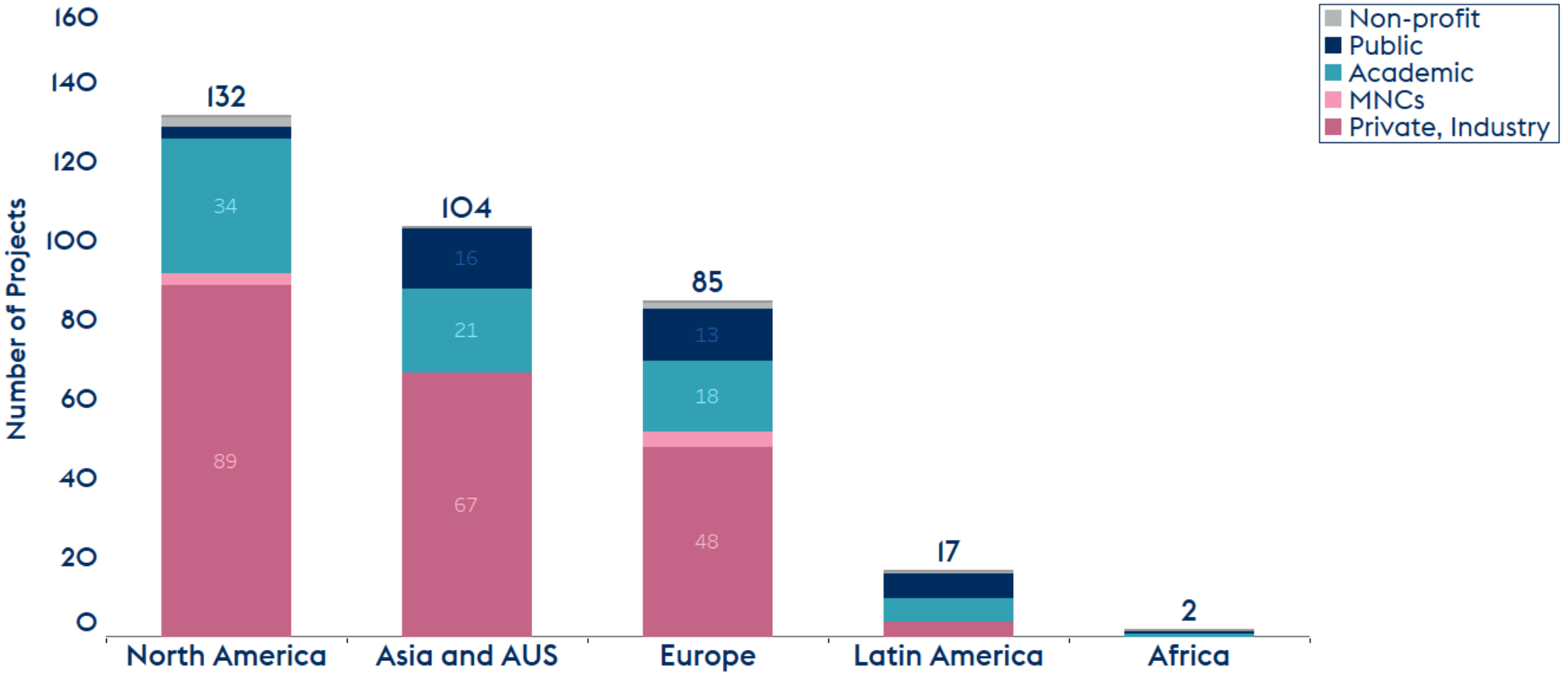
A diversified portfolio is needed to diversify risk and create capacity to scale

An ongoing COVID-19 landscape assessment is maintained to keep abreast of vaccine candidates – by development phase and platform type



- **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
- Start of **clinical phases** is defined as first subject dosed

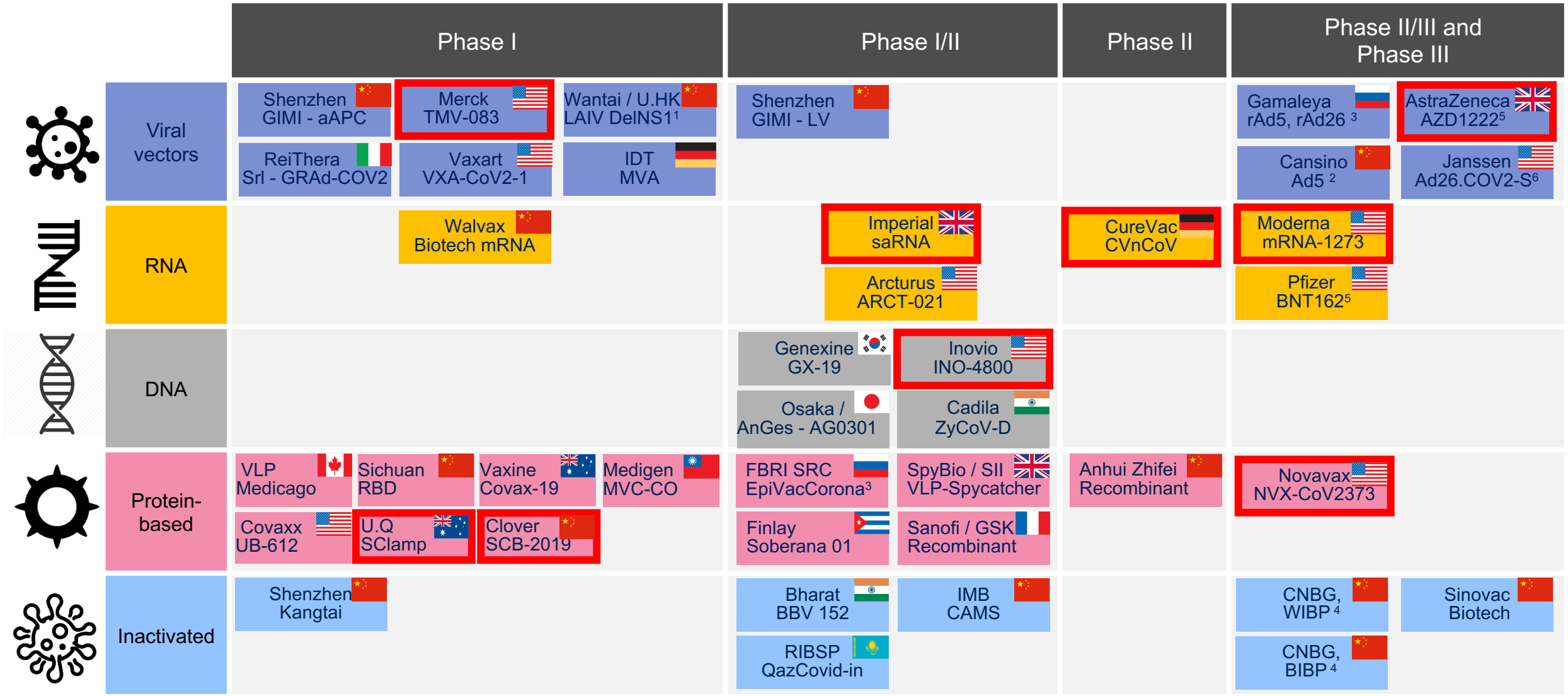
An ongoing COVID-19 landscape assessment is maintained to keep abreast of vaccine candidates – by geography and developer type



Date: 21 October 2020

The COVAX R&D&M portfolio consists of 9 candidates in clinical development

COVAX-funded



[1] *U.HK programme distinct from CEPI-funded programme*
[2] *Cansino has been approved for military use in China*
[3] *Gamaleya (rAd5, rAd26) and FBRI SRC (EpiVacCorona) has been conditionally registered in Russia*
[4] *Emergency use approval in China and UAE*
[5] *Under regulatory rolling review*
[6] *Under study pause*

COVAX vaccine portfolio currently consists of 9 projects, 8 in the clinic

COVID-19	DNA / mRNA			Viral vector			Protein		
	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
Current phase	Phase I/II	Phase III	Phase II	Phase I	Phase III	Preclinical	Phase III	Phase I	Phase I

Speed

Scale

Access

Speed, Scale, Access

Early clinical data for COVAX candidates

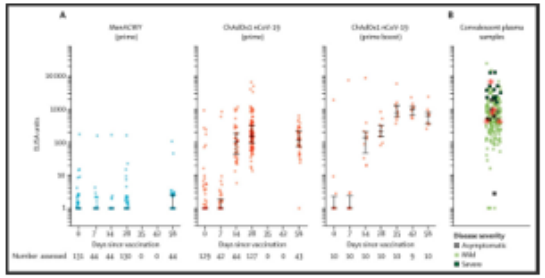
IMMUNOLOGY

- Binding and neutralizing antibody induced with all published candidates
- Cellular immune responses also regularly induced
- Level of response is difficult to compare due to lack of standardisation of assays

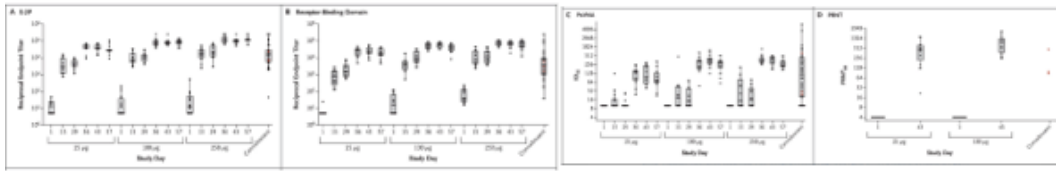
SAFETY PROFILE

- Vaccines have shown to be generally well tolerated
- Several trials have been paused to evaluate safety events.

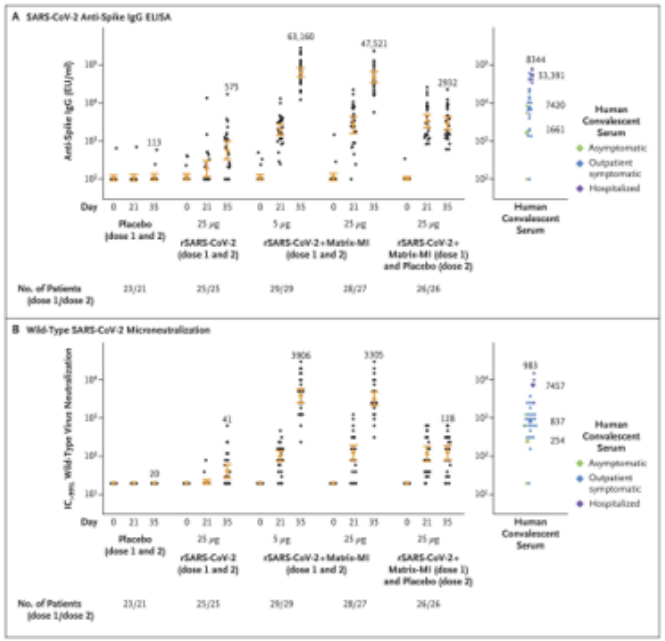
From Folegatti et al The Lancet 2020. (Oxford/AZ)



From Jackson et al. NEJM 2020 (Moderna)



From Keech et al. NEJM 2020 (Novavax)



COVAX SWAT teams are being set up as a joint platform to accelerate COVID-19 Vaccine development and manufacturing by addressing common challenges together – Developers & multilateral organisations (CEPI, WHO, BMGF, NIH et. al.)

Timely and targeted

Addresses specific cross-developer technical challenges as they are raised and/or identified on an ongoing basis

Multilateral

Establishes a dialogue and global joint effort across different COVID-19 vaccines organizations (incl. Industry and other global networks)

Knowledge-based

Identifies and collates most relevant materials and insights across the broader COVID-19 ecosystem to accelerate vaccine development and manufacturing

Resource-efficient

Coordinates between different organizations/ initiatives to limit duplications and ensure expertise is efficiently leveraged

SWAT teams | **Enabling sciences** › **Clinical Development & Operations** › **Manufacturing**

RAG

Update on the allocation framework and policy

Kate O’Brien, WHO

Overarching principles to ensure equitable access to health products in the context of COVID-19

Solidarity: Joining forces to confront this unique challenge together and overcome this pandemic

Accountability: Clearly defined roles and responsibilities to ensure procedural justice

Transparency: To build and maintain trust

Responsiveness to public health needs: Health products are carefully selected and allocated to address the public health need

Equity and fairness: to inform the allocation process together with public health needs

Affordability: Consideration is given to pricing and procurement strategies to improve affordability of health products

Collaboration: Collaborative efforts amongst relevant global and national stakeholders is enhanced to accelerate and scale-up the response

Regulatory and procurement efficiency: Agile and comprehensive regulatory and procurement approaches are incorporated to improve timely access to safe, efficacious and quality health products for all countries in need

The Global Allocation Framework builds on the cross-cutting principles, and informs allocation mechanisms

A

Overarching principles for access

Global principles to ensure fair and equitable access to products

Presented in May 2020

B

Global Allocation Framework

A global Allocation Framework for all COVID-19 products

Final working draft shared on 9 September 2020

C

Fair and equitable Allocation Mechanisms

Mechanisms tailored for each product

Draft for Vaccines: shared 9 September 2020

Draft Allocation Mechanism for Vaccines

Groups identified on this slide are 'indicative' and do not constitute WHO policy

Goal

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

Indicative Target groups

Health and social care workers

All countries receive doses to cover 3% of their population (in tranches)

This would be enough to cover all workers involved in health and social care work in most countries

High-risk adults

All countries receive additional doses to cover a total of 20% of their population (in tranches)

This could include the elderly, adults with comorbities or others depending on locally relevant risk factors

Further target groups

Countries receive doses to cover more than 20% of their population.

This would cover additional target groups.

Timing

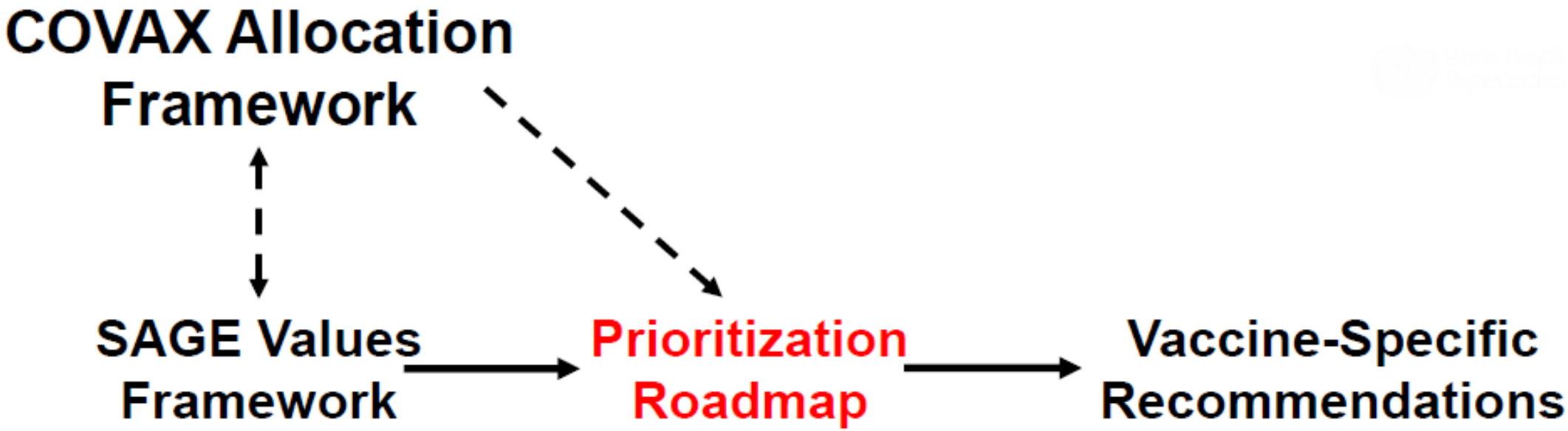
Phase 1: Countries receive doses proportionally to their total population*

Phase 2: Timing is based on country need, vulnerability and COVID-19 threat

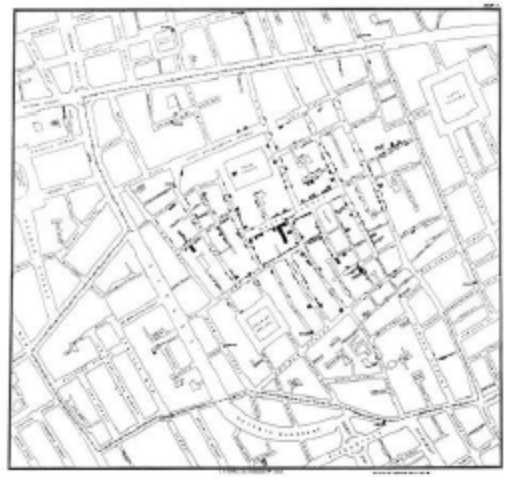
A buffer will also be set aside for humanitarian deployment based on immediate needs

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

Allocation, prioritization and recommendations



Prioritization dimensions



Epidemiologic Scenario

Overall Public Health Strategy

Vaccine Supply Scenarios

WHO SAGE policy development: steps and processes

		Status update
1.	**Values Framework** for the allocation and prioritization of COVID-19 vaccination: Principles, objectives and target groups of a COVID-19 vaccination programme	Endorsed by SAGE and published on Sept. 14, 2020[1]
2.	**Guidance on prioritization of target populations** under supply constrained situations: development of use case scenarios of limited vaccine under different epidemiological settings	Endorsed by SAGE at plenary meeting October 5-7 and published on Oct. 20, 2020[2]
3.	**Policy recommendations on the use of COVID-19 vaccines** once authorized; under consideration of product-specific data and attributes, and with consideration of the regulatory status (emergency use or full registration)	Timelines depends on registration by participants or Emergency Use Listing/ prequalification by WHO; process iterative as products come along

1. Available on: https://www.who.int/immunization/policy/sage/en/)
2. Available on: https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf?Status=Temp&sfvrsn=bf227443_2&ua=1

Main elements of the values framework

Overarching goal: “COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.”

Core principles: Human well-being; equal respect; global equity; national equity, reciprocity, legitimacy

Objectives: Eleven objectives for vaccination that correspond to the six core principles

From values to priority groups: Listing of (unranked) about 20 different priority groups in accordance with vaccination objectives and their relevance to core principles

Roadmap towards prioritization of target populations:

To support country planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability in different epidemiologic settings

Key assumptions:

- Vaccines are licensed and meet all minimum criteria of WHO TPP;
- Vaccines have at least minimal level efficacy in older age groups; idem for other subpopulations;
- NPI continue to be used;
- Vaccine effect on transmission less relevant for early scenarios, but information becomes available at some point;
- No account has been taken of seroprevalence and the possible degree of population protection already established.

	Community transmission	Cluster of cases/ sporadic transmission	No cases, risk of importation
Very limited supply (1-10%)	Contextualized and targeted public health strategies		
Limited supply (11-20%)			
Moderate supply (21-50%)			

Roadmap towards prioritization of target populations:
example for community transmission

Strategy: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.

Stage I (1-10%)

Stage Ia (initial launch)

- Health workers at *high to very high risk* of acquiring and transmitting infection

Stage Ib

- Older adults defined by age-based risk specific to country/region

Stage II (11-20%)

- Older adults not covered in Stage I

- Individuals with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death

- Sociodemographic groups at *significantly higher risk* of severe disease or death

- Health workers engaged in immunization delivery

- High priority teachers and school staff

Stage III (21-50%)

- Remaining teachers and school staff

- Other essential workers outside health and education sectors

- Pregnant Women

- Health workers at *low to moderate risk* of acquiring and transmitting infection

- Personnel needed for vaccine production and other high-risk lab staff

- Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance

Discussion/Q&A

All

Thank you

FOR FURTHER INFORMATION…

COVAX Facility:
https://www.gavi.org/covax-facility …. and https://www.gavi.org/vaccineswork

COVID-19 vaccines:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines

Country readiness and delivery:
https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery

To sign up for our mailing list: CSO_COVAX@who.int