Member States Briefing

December 10, 2020

COVAX Facility update

Dr Richard Hatchett (CEPI), CEO
Dr Seth Berkley (GAVI), CEO
Dr Soumya Swaminathan (WHO), Chief Scientist

COVID-19 R&D portfolio – 49 candidates in human clinical trials[1]

COVAX MoU or SoI signed[2] · CEPI agreement signed · COVAX R&D candidate · CEPI funded candidate for R&D outside COVAX R&D portfolio

Technology platform	Phase I	Phase I/II	Phase II	Phase IIb/III and III
Viral vectors	Shenzhen GIMI aAPC Merck / Themis TMV-083 Vaxart VXA-CoV2-1 ImmunityBio- hAd5-S-Fusion Merck / IAVI rVSV ReiThera GRAd-COV2 Wantai / Xiamen DelNS1 IDT MVA-SARS-2-S IIBR rVSV	Shenzhen GIMI LV-SMENP-DC		CanSino Ad5-nCoV AstraZeneca ChAdOx1-S Gamaleya Gam-COVID-Vac Janssen Ad26.COV2-S
mRNA	Walvax Biotech ARCoV	Imperial LNP-nCoVsaRNA Arcturus ARCT-021	CureVac CVnCoV	Pfizer / BioNTech BNT162 Moderna mRNA-1273
DNA	Symvivo bacTRL-Spike	Genexine GX-19 Osaka / AnGes AG0301 / AG0302 Zydus Cadila ZyCoV-D	Inovio INO-4800	
Protein-based	Medicago VLP Finlay FINLAY-FR-2 Vaxine / Medytox COVAX-19 Medigen MVC-COV1901 City of Hope COH04S1 CSL / U.Q Covaxx UB-612 Clover SCB-2019 Adimmune AdimrSC-2f	Bio E BECOV2 SpyBio RBD Finlay FINLAY-FR-1 Sanofi / GSK Rec.Pro	Anhui Zhifei RBD-Dimer Sichuan RBD	Novavax NVX-CoV2373 FBRI.SRC EpiVac
Inactivated		Inst. of Medical Biology / CAMS RIBSP QAZCOVID-IN	Shenzhen Kangtai	Sinopharm / WIBP Sinovac / Butantan CoronaVac Sinopharm / BIBP BBIBP-CorV Bharat Biotech COVAXIN

1 Candidates which have not been able to confirm the dosing of the first subject have not been included on this mapping (e.g. Providence, Kentucky, U.Tuebingen)

2 For Advance Purchase Commitment (APC)

Source: CEPI Vx landscape

First efficacy data available: overview of latest results from Pfizer/BioNTech, Moderna, AstraZeneca, Gamaleya and Sinopharm

AS OF DEC 10

	Pfizer/BioNTech	Moderna	AstraZeneca/Oxford	Gamaleya	Sinopharm
Platform	mRNA	mRNA	ChadOx 1 vector	Ad26 >> Ad5 prime-boost	Inactivated
Date of press release	November 18, 2020	November 30, 2020	November 23, 2020	November 24, 2020	December 10, 2020 (UAE Ministry of Health and Prevention)
Preliminary point estimate of vaccine efficacy	**95% (p<0.0001)**	**94.1% (p<0.0001)**	**70% (p<=0.0001) (pooled)** **90% and 62% (LH and HH regimens[1]) (p<=0.0001)**	91.4% 28 days post dose I (7days post dose 2) Statistical significance not reported	86% effective
Phase 3 study enrollment	43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate	>30,000 participants	UK trial - 12,390 subjects, 2,742 with LH (90% efficacy) UK/Brazil trial – 10,300 HH 62% efficacy	40,000 participants 22,000 vaccinated with the first and >19,000 with second doses of the vaccine	31,000 participants
Total number of cases	**170 cases (8 in vaccine group)** **10 severe cases (9 in placebo, 1 in vaccine group)**	**196 cases (11 in vaccine group)** **30 severe cases (incl. 1 death), all in placebo group**	**131 cases across 2 trials** **No severe or hospitalized cases among patients who received vaccine**	**39 cases** **No information provided on case severity**	No case reported 100% effectiveness in preventing moderate and severe cases of the disease.
Cold chain	-80^{0}C, 2-8^{0}C for up to 5 days	-20^{0}C, 2-8^{0}C for up to 30 days	Storage, transport and handled 2-8^{0}C for up to 6 months	2 versions: • Lyo 2-8^{0}C • Liquid Frozen -20^{0}C	2-8^{0}C for up to 30 days
Plans for licensure	Submitted to US FDA for EUA, EMA and WHO EUL/PQ, Temp Authorization UK MHRA	Rolling submissions to US FDA for EUA, EMA and plan to WHO for EUL/PQ	Rolling submissions to EMA, MHRA, PQ	Emergency authorization in Russia Timeline for non-Russian submissions under assessment	-

Emergency use (MHRA) on Dec. 2

1 LD – Low dose followed by High dose, HH – 2 doses of high dose formulation

Overview of COVID-19 vaccine landscape

49 candidates currently in human clinical trials[1]

8

of 9 candidates in CEPI's COVAX R&D portfolio are in human clinical trials

12

candidates are currently in Phase IIb/III and III

Nov 2020

First efficacy readouts from four candidates (Pfizer,Moderna, AstraZeneca, Gamaleya Institute), which enabled some manufacturers to start the process for emergency use authorizations (EUA) / emergency use licensure (EUL)

Dec 2020

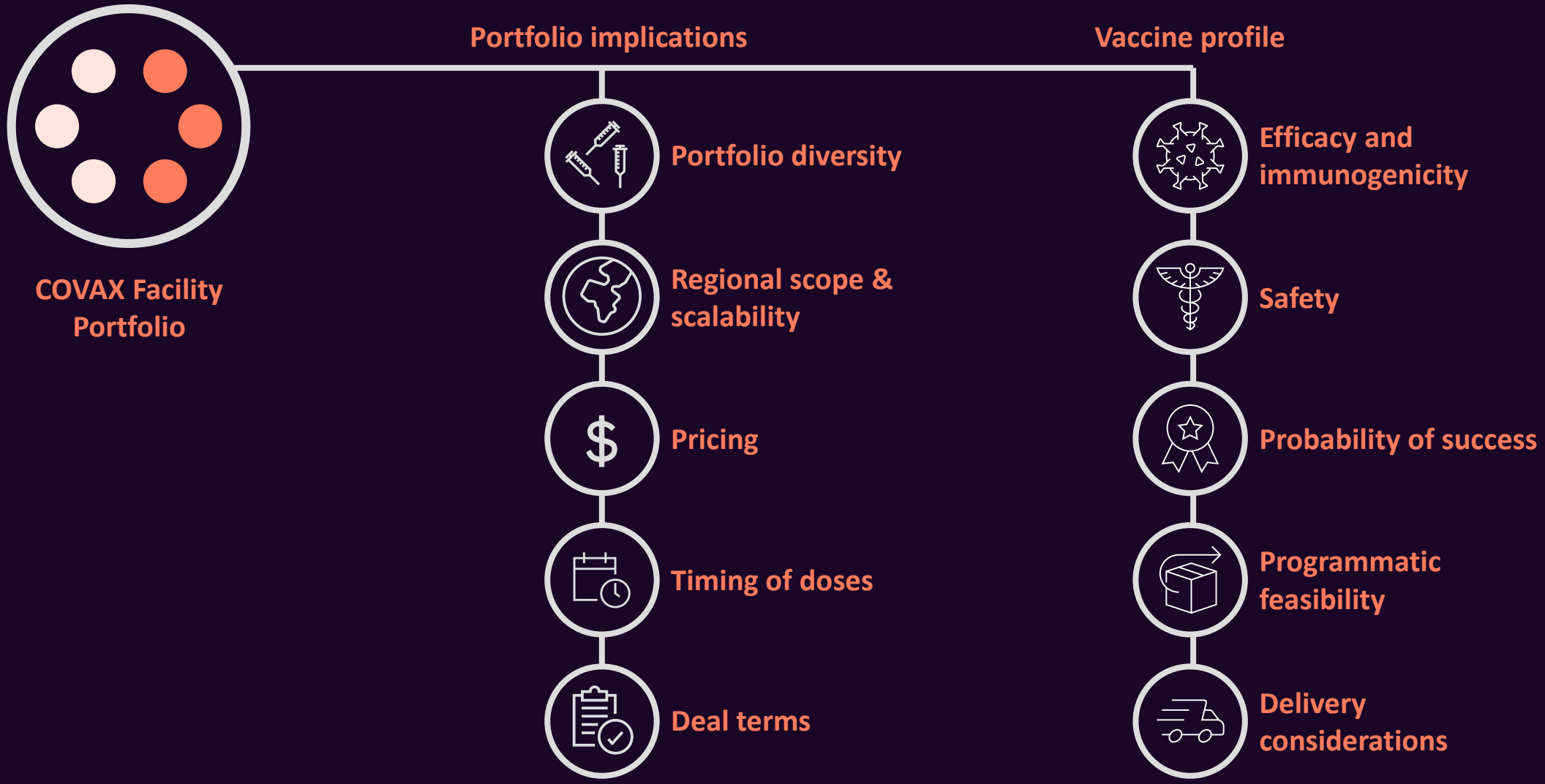
First emergency approval in UK, 1st injection of participant; emergency approval granted in Canada with vaccine rolling out next week; efficacy readout from Sinopharm

Q1/Q2 2021

expected dates for first licenses and start date for commercial distribution

1 52 candidates if candidates that have not been able to confirm the dosing of the first subject (e.g. Providence, Kentucky, U.Tuebingen) are included

COVAX Facility portfolio candidates are selected based on several criteria



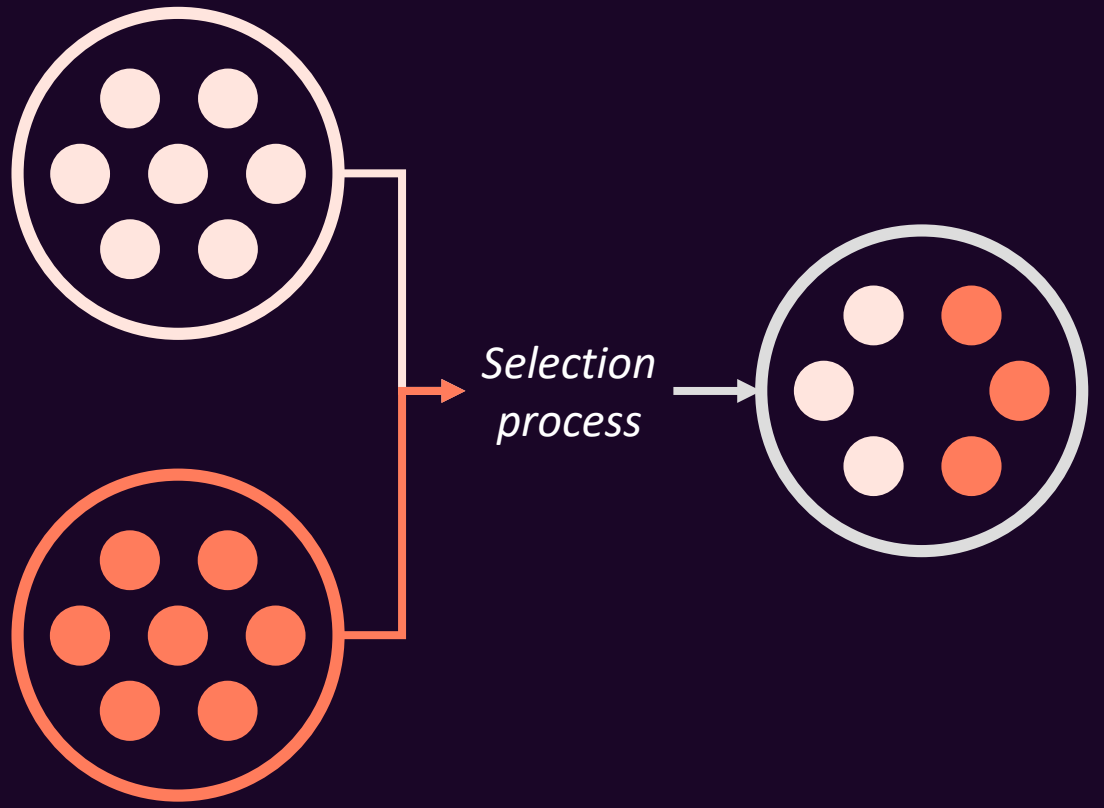
Candidates to be included in the COVAX Facility portfolio are being selected from the COVAX R&D portfolio and other clinical candidates

COVAX CEPI R&D portfolio

CEPI invests in R&D for selected promising candidates to accelerate vaccine availability

COVID-19 Vx pipeline candidates

All candidates[1] in the COVID-19 vaccine landscape in clinical development stages



COVAX Facility portfolio

Selected candidates from the COVAX R&D portfolio and other clinical candidates from the Vx landscape (*pending regulatory approval and policy recommendation*)

COVAX portfolio will include selected promising candidates across different technologies and geographies

1. Excluding those in COVAX R&D Portfolio

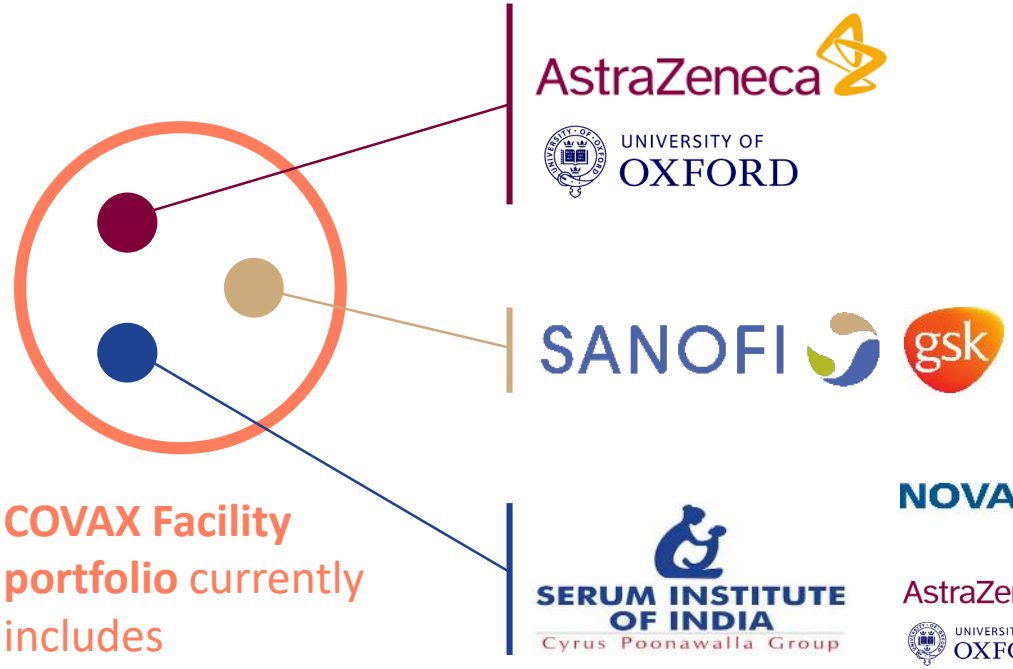
Final COVAX Facility portfolio is expected to have around 10 or more candidates across 4-5 technology platforms, with early doses available in Q1 2021

COVAX Facility portfolio

The COVAX Facility aims for a diverse and actively managed portfolio of around 10 or more vaccine candidates to achieve 2 billion doses by the end of 2021

- Diversifying technologies
- Diversifying geographies
- Diversifying vaccine characteristics
- Accounting for attrition

COVAX Facility portfolio currently includes 4 candidates with several expected near-term agreements



COVAX Facility portfolio currently includes signed commitments with 4 candidates across 2 technology platforms

SII deal gives AMC92 economies access to vaccines licensed from Novavax and AstraZeneca

To date, the COVAX Facility has signed…

Deal with **SII** to provide doses for AMC92 economies
SII / AstraZeneca collaboration announced on Aug 7, 2020[1]
SII / Novavax collaboration announced on Sep 29, 2020[2]

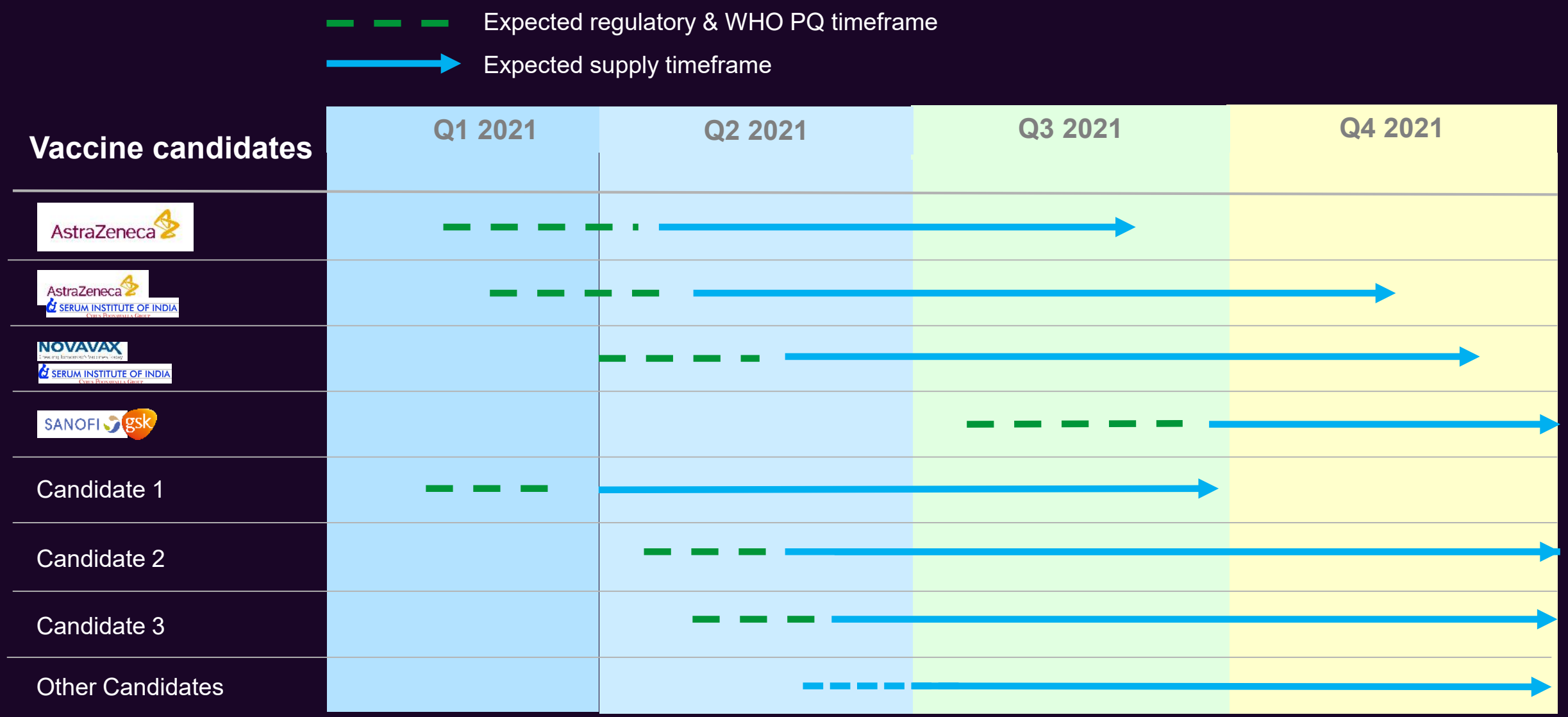
MoU with **AstraZeneca**
Announced on Jun 4, 2020[3]

Statement of Intent with **Sanofi / GSK**
Announced on October 28, 2020[4]

Several candidates are in near-term MoU agreements

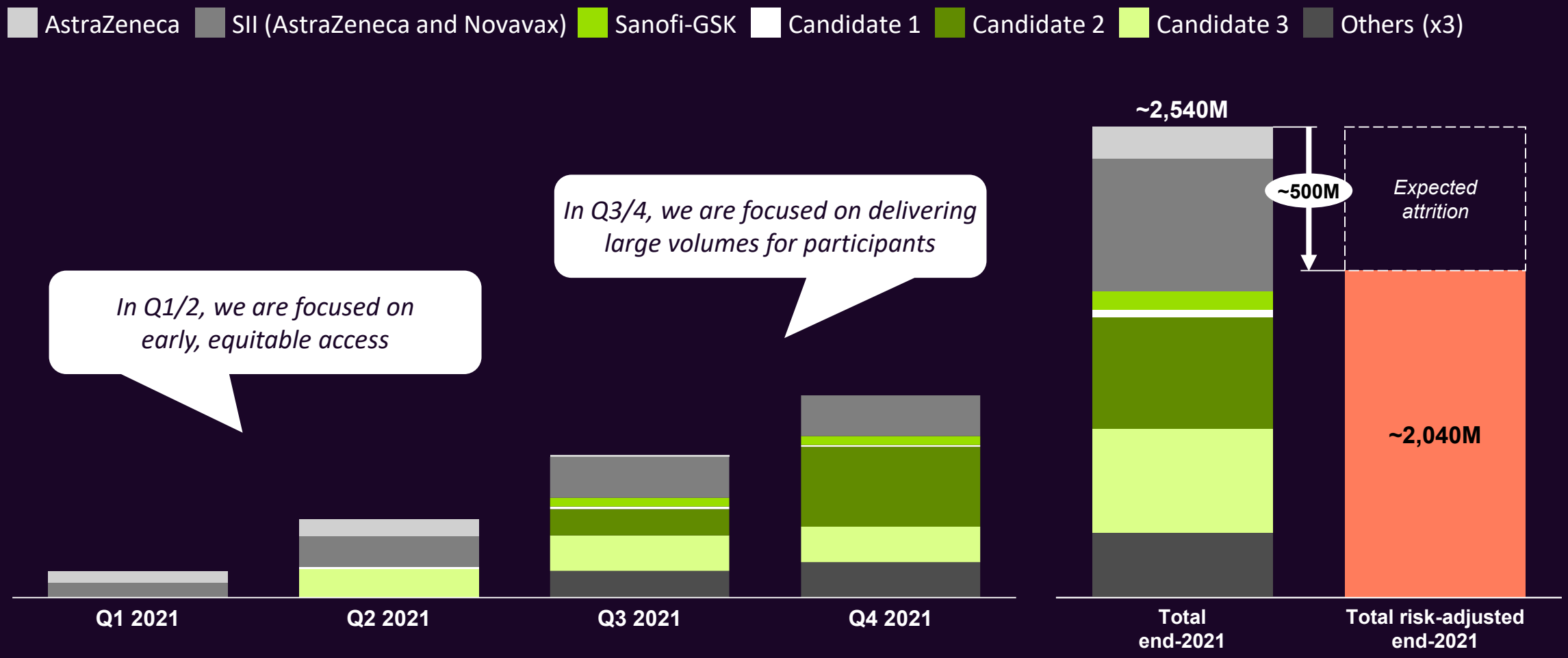
1. Gavi press release; 2. Gavi press release; 3. Gavi press release; 4. Gavi press release

COVAX Facility Portfolio – expected regulatory, supply timelines

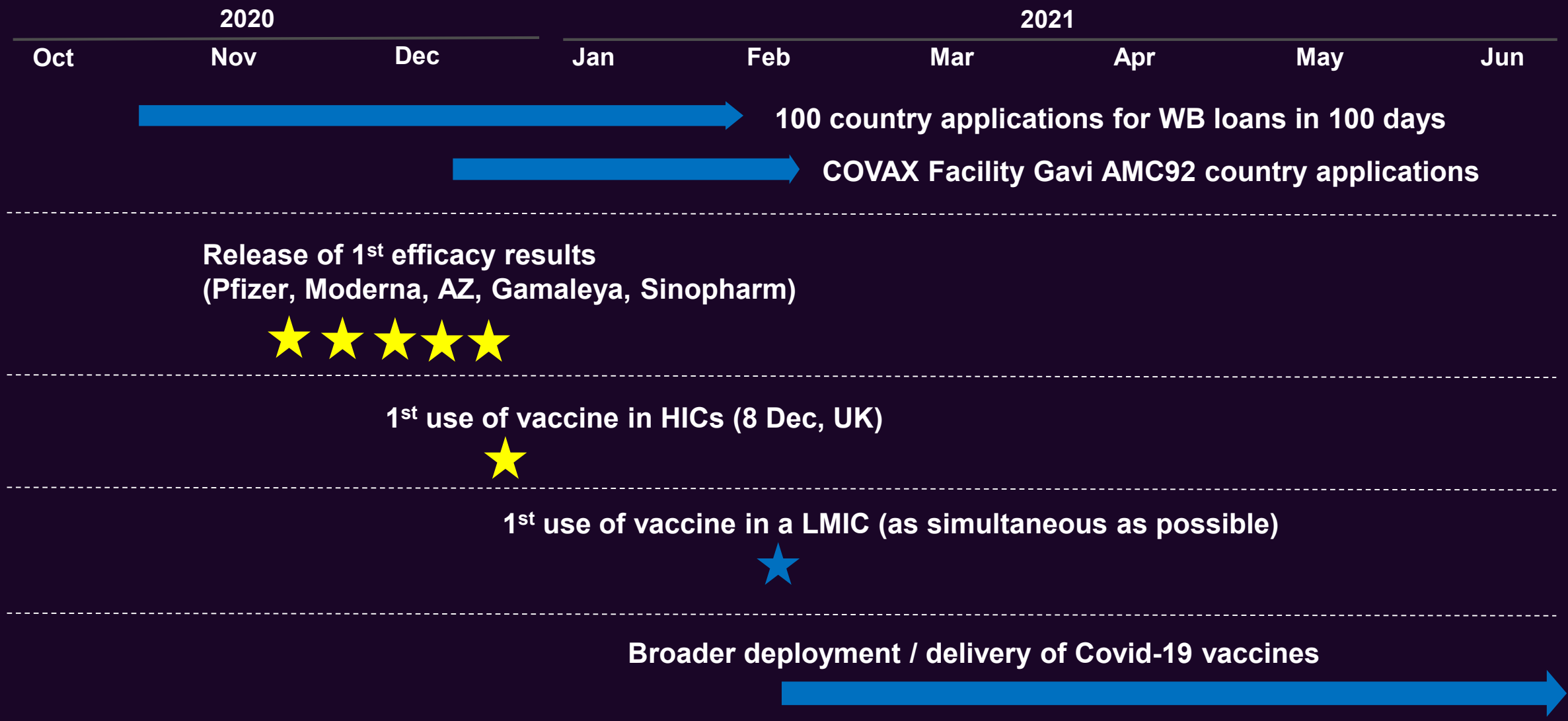


COVAX is negotiating with ~10 suppliers with the ambition of contracting enough volumes to deliver 2bn doses in 2021

COVAX Facility volumes to be contracted over time, doses per quarter (by candidate and in total, 2021)



Speed and equity are the focus



What we are doing to prepare for arrival of vaccine…

- **Engaging with manufacturers and securing supply** from a large, diversified portfolio
- **Standing up a fair and equitable allocation mechanism** that ensures all participants get vaccine from the COVAX Facility at the same time
- **Raising funding** for the COVAX AMC financial instrument to support AMC eligible participants
- **Developing a No-Fault Compensation Scheme** to ensure Indemnification and Liability issues do not delay delivery of doses to AMC economies
- **Implementing a governance mechanism** to ensure the voices of all participants are heard
- **Engaging with participants** to support COVAX and preparing for the arrival of doses

…and what you can be doing

1. **Build A National Task Force** - Form a group responsible for putting the planning together; assign a leader/focal point.
2. **Develop a national plan** - Use all partners and planning tools available
3. **Secure any necessary financing** - Work with the World Bank and other MDB financing teams to confirm eligibility, apply for financial resources if necessary
4. **Prepare for delivery now** – Focus on **indemnification and liability**, prime your **regulatory processes**, and prepare any needed infrastructure
5. **Communicate actively** - Keep an open line with the COVAX Facility

AMC92 Participants would be supported by global partners throughout their journey

Some of the steps along the journey	Support provided	Pillar partners
Development of national plan & strategy (incl., programmatic readiness)	Provision of guidelines, planning tools Decision making / application support CCE / TA support	World Health Organization, Gavi The Vaccine Alliance, unicef, PAHO Pan American Health Organization
Cost sharing	Support with cost sharing of additional doses & delivery costs	Gavi The Vaccine Alliance
National regulatory approval / registration	Global harmonization mechanisms to speed up in-country processes	World Health Organization
Indemnification & liability agreements with manufacturers	Design of compensation mechanisms	Gavi The Vaccine Alliance, World Health Organization, CEPI
Delivery of vaccines	Procurement & delivery of Vx on behalf of participants Support with in-country coordination	World Health Organization, Gavi The Vaccine Alliance, unicef, PAHO Pan American Health Organization

Overview of regulatory timeline of early roll out candidates

AS OF 9 DEC

Legend (best-case scenario)

- Approved
- By End of 2020
- By End of Feb. 2021
- From March 2021 / No info

Vaccine candidates		FDA	MHRA	EMA	Additional regulators / manufacturing sites	WHO EUL/PQ	Country reliance on PQ
Pfizer BioNTech		Dec. 11, 2020 (EUA)	**Dec. 2nd, 2020 Emergency Use[1]**	Week of Dec. 21st, 2020 (Task force meeting on Dec. 22)	*Not applicable*	End of Dec. 2020	Jan. 2021 onwards
AstraZeneca / University of Oxford	UK	*Not applicable*	21 Dec 2020 (emergency use)	*Not applicable*			
	Rest of the World	Pending	*Not applicable*	Jan. or Feb. 2021 (conditional approval)	To be determined (under active discussion)	Between March and June 2021 at latest	Between April and July 2021 at latest

1. 1st lot authorization
2. Relying on EMA approval
3. If additional regulatory sites

Reminder – Recap of critical actions to ensure country readiness and delivery

Critical actions

Priority decision making on:

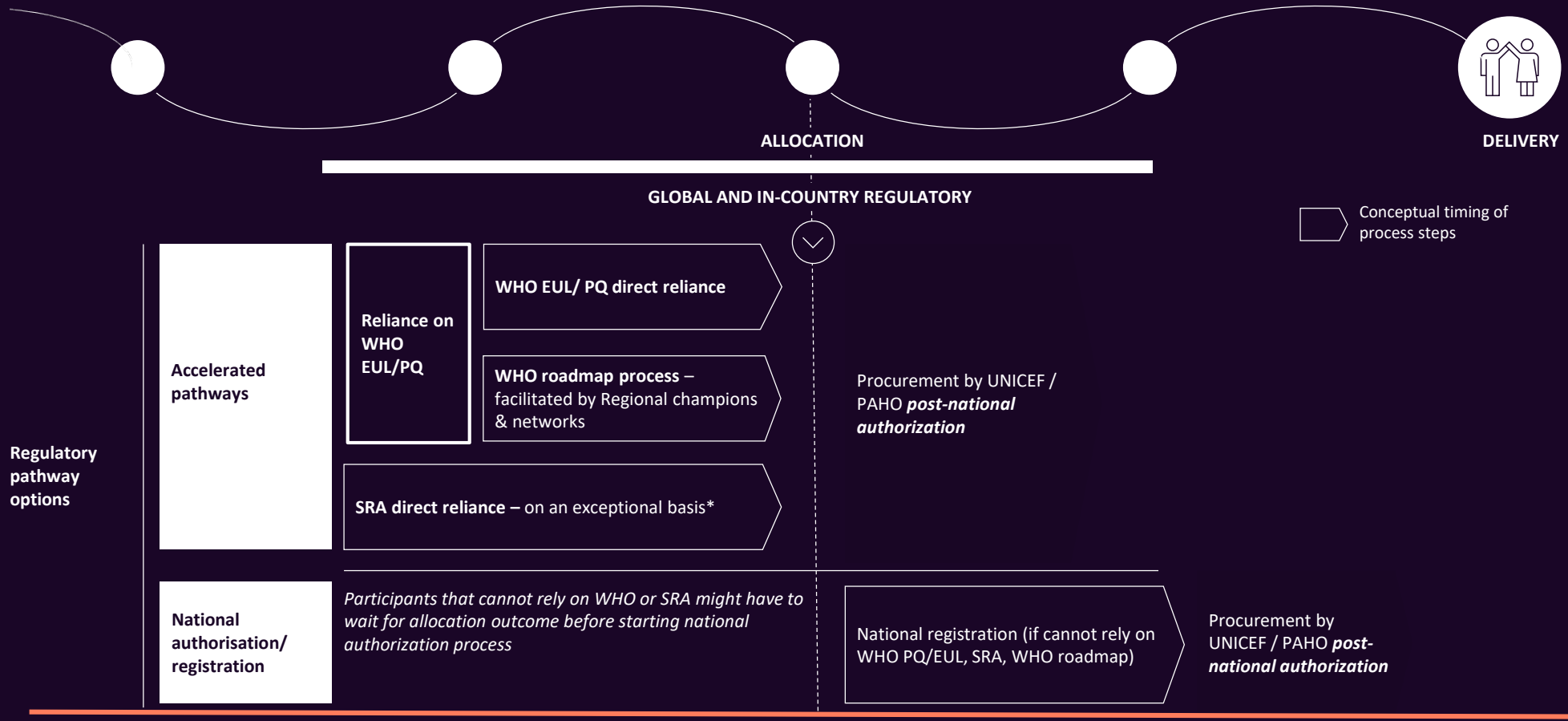
- **Policies** for use (in-country prioritization)
- **Regulatory** approvals (e.g. WHO reliance mechanism)
- **Financing** (ensuring fiscal space, consideration of WB and other loans)
- **Indemnification** & liability

Technical & operational issues

- **Country readiness assessments (cold chain, health facility, HCW etc.)**
- **National Deployment and Vaccination Plan**
- Key bottleneck **analysis**

BACK-UP

There are 4 regulatory pathways for country authorization



Our ask of you **Consider accelerated regulatory pathways to avoid delay in procurement after allocation**

* SRA reliance to be considered on an exceptional basis, as it would not necessarily include an assessment of the programmatic suitability of vaccine candidates and data sharing could not be facilitated by WHO in that case

Indemnification and liability and compensation

Details

- All vaccines supplied through COVAX will undergo a rigorous regulatory process and will be approved for general use
- Given the speed and scale of deployment, manufacturers are unwilling to self-insure for product liability claims and are requiring all participants receiving vaccine doses to indemnify them against such claims
- **Lack of such an indemnification by a participant will limit access to vaccines**
- To decrease time and transaction costs in negotiating indemnity provisions between AMC participants and manufacturers, Gavi is negotiating with manufacturers to have a consistent approach on indemnification across manufactures
- In order to limit the number of claims brought under national courts and to provide fair compensation to injured vaccine recipient, if any , COVAX partners are looking to establish a **global compensation mechanism to cover unexpected serious adverse events (SAEs)** for AMC92 participants to access

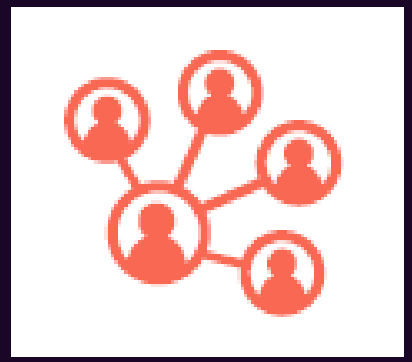
---

Next Steps

- Legal review to determine if the indemnification requirement and/or accessing the compensation mechanism requires **implementing legislation**
- If implementing legislation is required, **participant to take all necessary steps to enact such legislation as soon as possible** before supply of vaccines under COVAX begins

Vaccine policy - Priority groups for COVID-19 vaccination

Community transmission



Endorsed by SAGE, published on 19 October 2020

Vaccine availability		
Stage I: very limited (for 1-10% national population)	**Stage II: limited** (for 11-20% national population)	**Stage III: moderate** (for 21-50 % national population)
Ia: health workers at high to very high risk of acquiring and transmitting infection **Ib:** older adults defined by country/region specific age-based risk	- Older adults (not covered in Stage Ib) - Individuals with co-morbidities or health status determined to be at significantly higher risk of severe disease or death - Socio-demographic groups at significantly higher risk of severe disease or death - Health workers engaged in immunization delivery - High priority teachers and school staff	- Remaining teachers and school staff - Other essential workers outside health and education - Pregnant women - Health workers at low to moderate risk of acquiring and transmitting infection - Personnel needed for vaccine production and other high-risk laboratory staff - Social/employment groups at elevated risk of acquiring and transmitting infection (unable to effectively physically distance)