Global updates on COVID-19 vaccine landscape

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Friday Health Talk, Ministry of Health and Sports
20 November 2020

Disclosure

Acknowledging

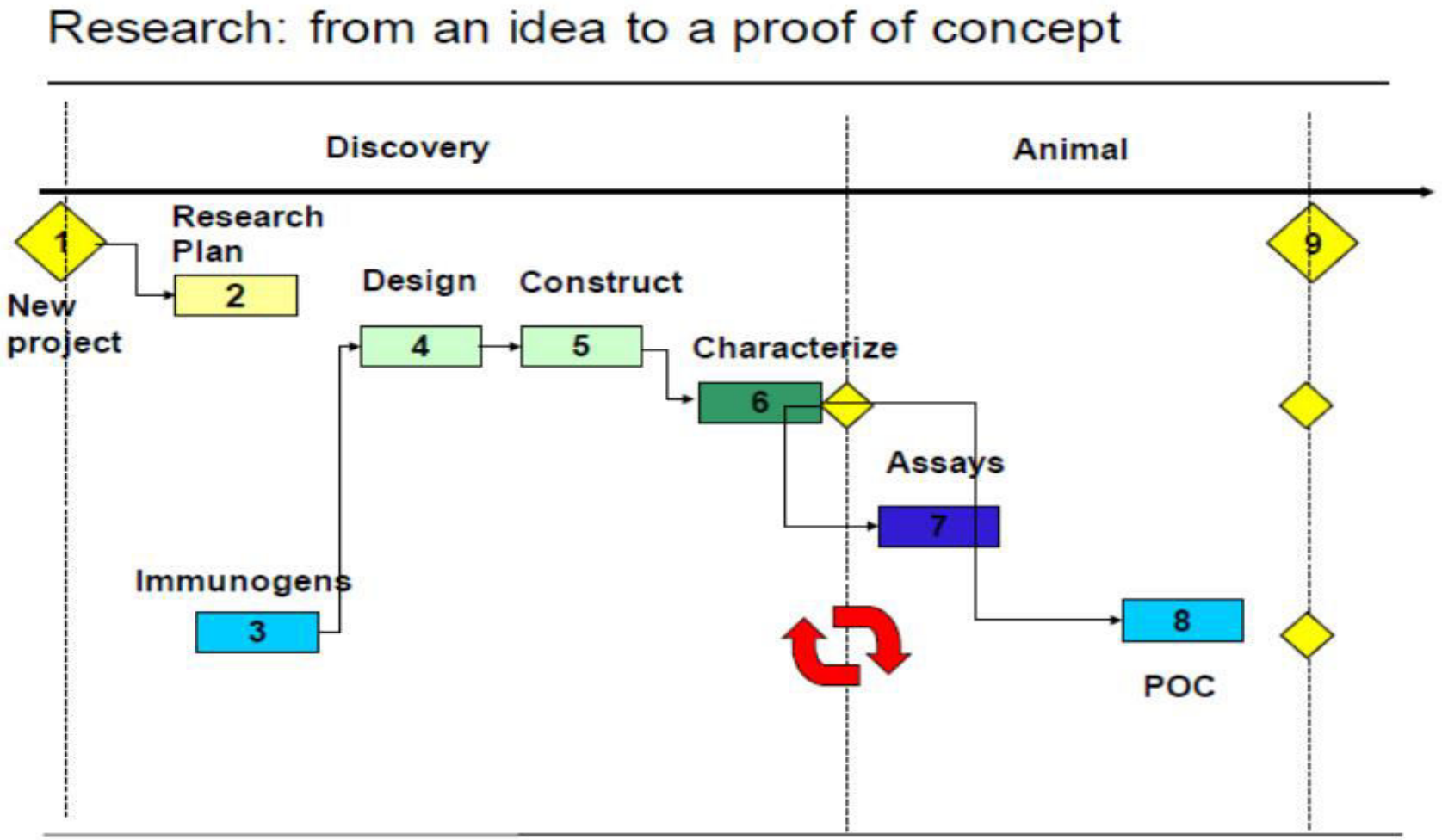
- Advanced Vaccinology Course (ADVAC)
- WHO
- Gavi- COVAX
- Colleagues from cEPI, WHO and UNICEF (Myanmar)

for the slides.

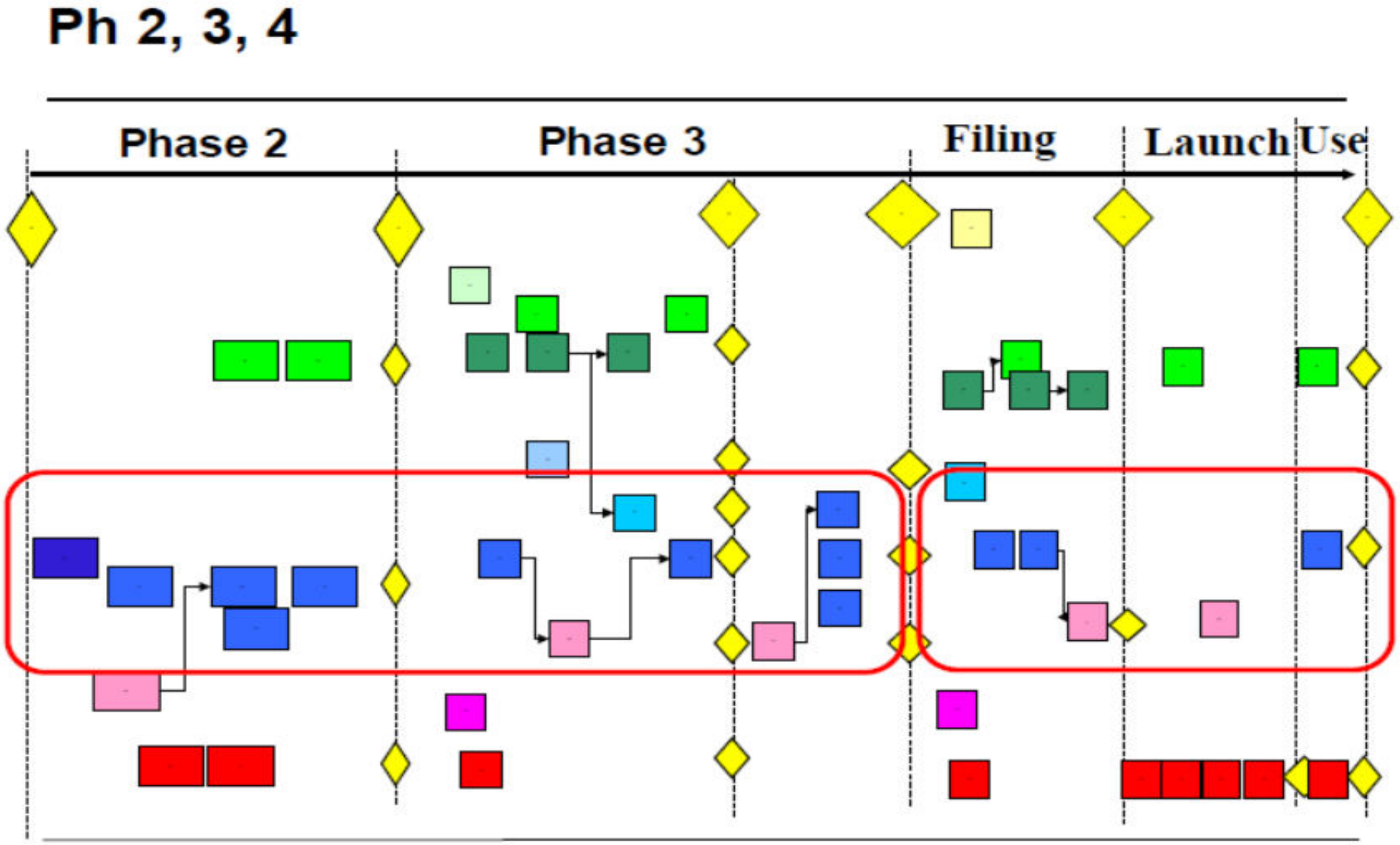
Contents

- Clinical development of a vaccine programme
- COVID-19
  - Global updates
  - Country updates
- COVID-19 vaccine pooling strategy
- Overview of COVID-19 vaccine landscape globally

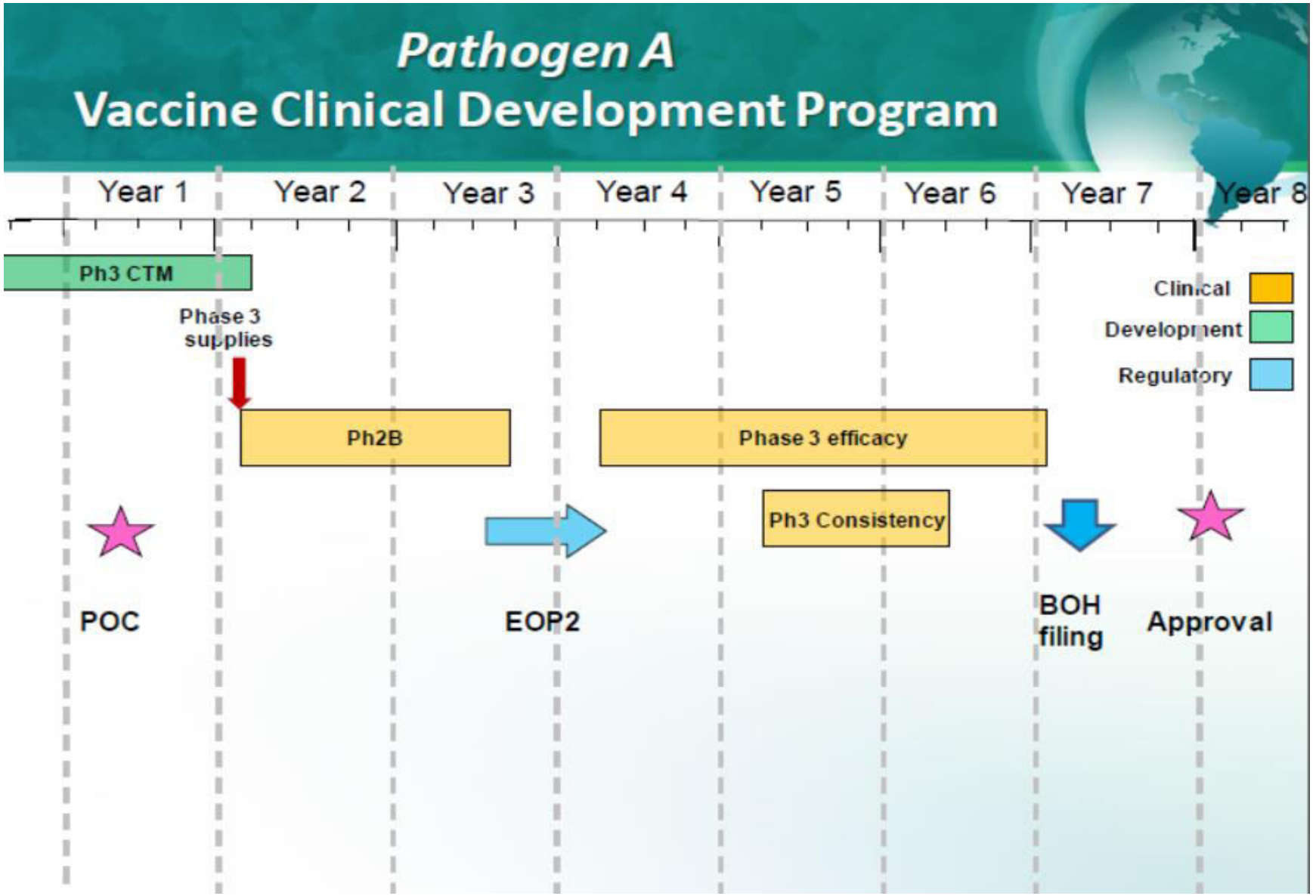
Clinical development of a vaccine programme



Clinical development of a vaccine programme contd.



Clinical development of a vaccine programme contd.



Clinical development of a vaccine programme contd.

- The development of a vaccine is long (15 + years), risky (1% ideas become products), complex (multiple expertise), complex (management of // activities well timed), complex (changes outside the project such as epidemiology, competition, political background…) and complex (global).

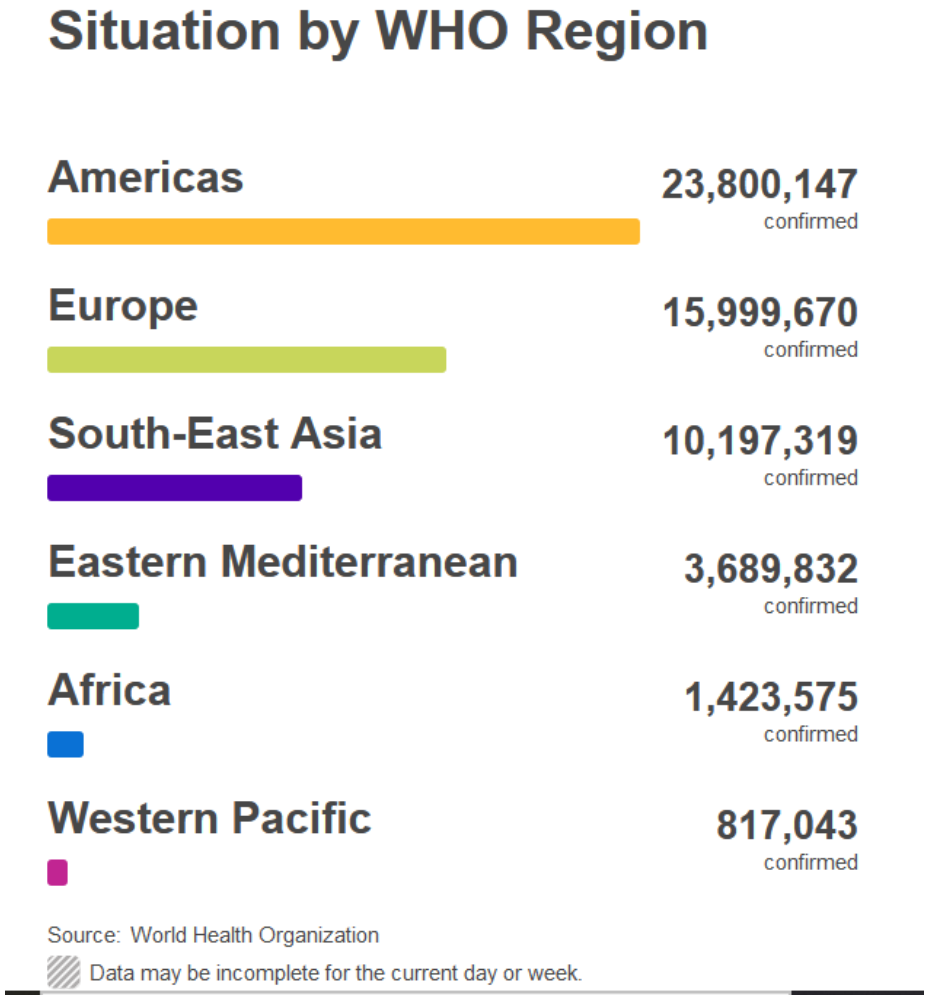
- Multiple Go / No Go along the way, as key decision points

- A decision to "stop or go" depends on the quality of information and quality of analysis, previous experience, spirit of entrepreneurship, willing to take risk or be conservative, and … intuition.

Global situation of Covid-19

as of 19 November 2020

Globally,
55,928,327
confirmed cases
of Covid-19,
including
1,344,003 deaths



Data as of 19 November 2020

Ministry of Health and Sports (Myanmar)
Department of Public Health
Central Epidemiology Unit

(18 November 2020)

Situation Report -225

Coronavirus Disease 2019 (COVID-19)

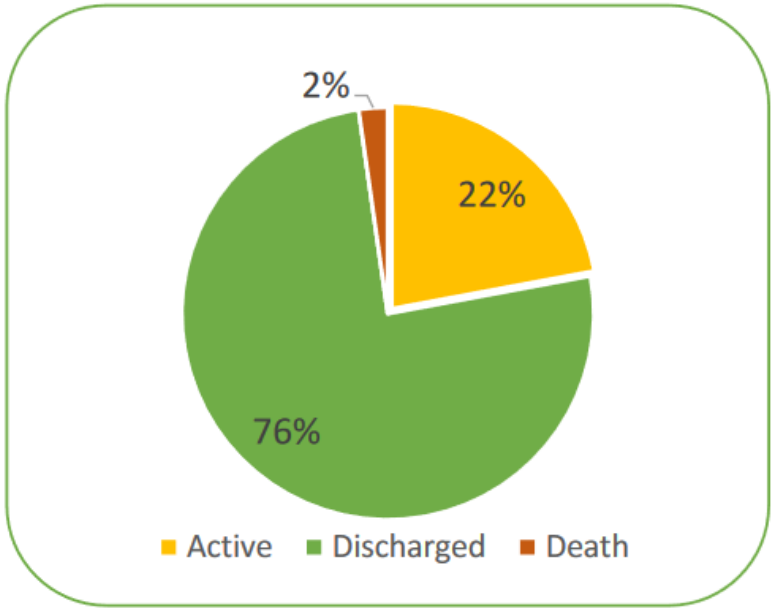
Myanmar Situation

Data as reported by States and Regions by 17 November 2020

Total Tested-930,082

71,730	858,352
Confirmed Cases	Negative
54,274	**1,625**
Discharged	Death

Current Situation of Confirmed cases (23.3.2020-17.11.2020), n=71,730



COVID-19 confirmed cases by two phases (23.3.2020 – 17-11-2020), n=71,730

Covid19 vaccine pooling strategy

- Effective vaccines against COVID 19 are urgently required to protect and restart economies around the world.
- To facilitate this, WHO hosted the launch of the access to COVID-19 tools (ACT) Accelerator for development of tools like diagnostics, therapeutics and vaccines.
- Within the (ACT) Accelerator, COVAX facility is a mechanism designed to guarantee rapid, fair and equitable access to COVID-19 vaccines worldwide.
- COVAX is co-led by Gavi (the Vaccine Alliance), the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, working in partnership with developed and developing country vaccine manufacturers.
- The goal of COVAX is to deliver two billion doses of safe, effective vaccines by end 2021, which have passed regulatory approval and WHO prequalification.

Overview of COVID-19 vaccine landscape

42

candidates currently in human clinical trials

8

of the 9 candidates from CEPI R&D portfolio are in human clinical trials

10

candidates are currently in phase IIb/III and III

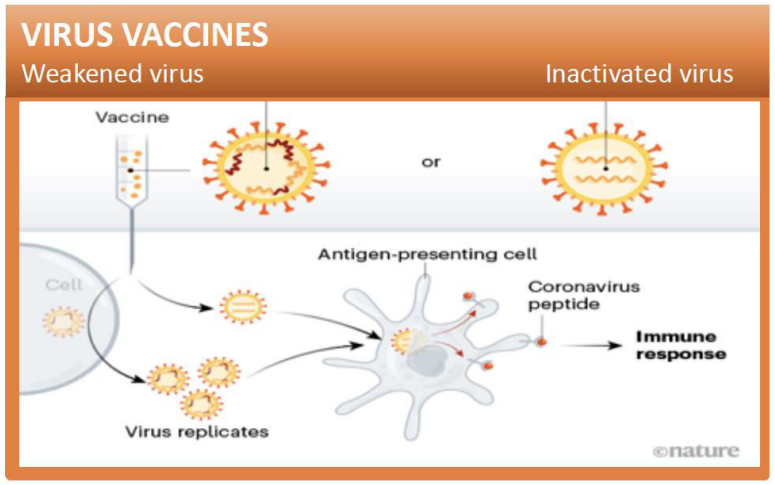
9 Nov 2020

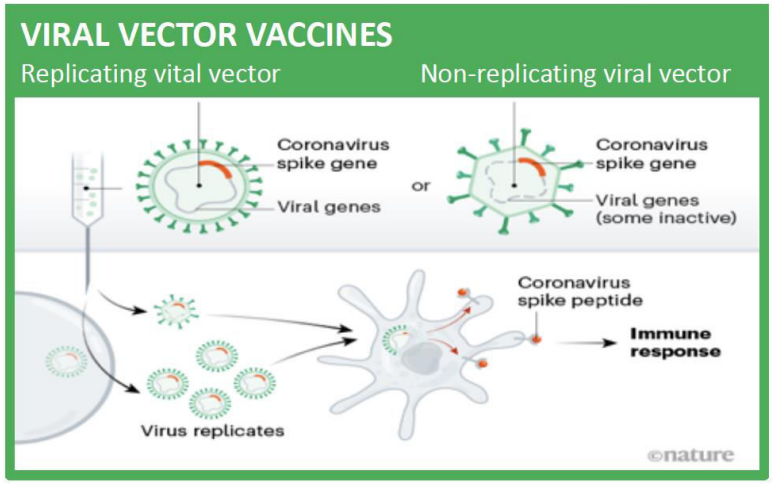
date of 1st efficacy data readouts, which are needed to start process for emergency use authorizations (EUA) / emergency use licensure (EUL) *(subject to safety and efficacy data)*

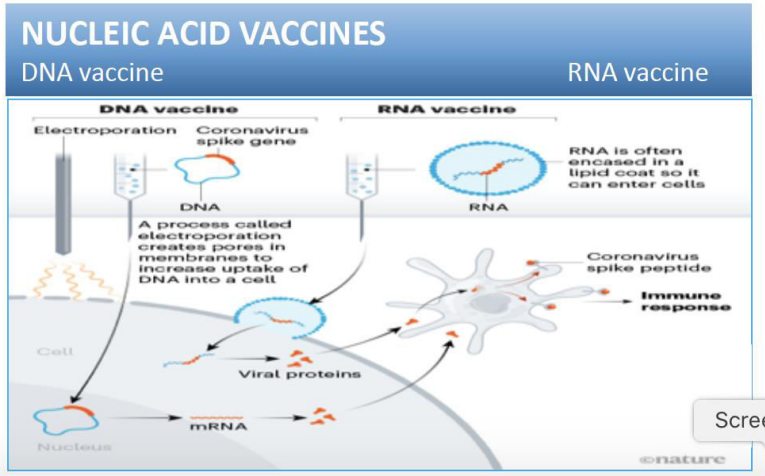
Q1/Q2 2021

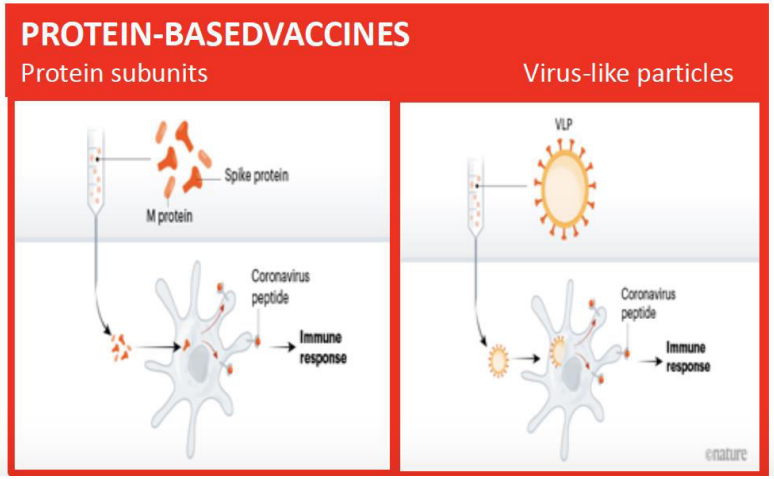
expected dates for first EUA/EULs and start date for commercial distribution

Types of COVID-19 candidate vaccines being developed



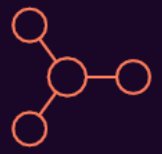






Screenshot

Technology in development

Technology	Description
 Viral vector	**Viruses that have been engineered to carry DNA** – containing the sequence for disease-specific antigen from the target virus – **into human cells**
 Nucleic Acid (DNA and mRNA)	**Genetically engineered plasmid containing the DNA sequence** for disease-specific antigen **Messenger RNA** containing sequence for a disease-specific antigen
 Protein-based	**Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response
 Inactivated	**Chemically "killed" virus or subunits of the virus** grown under controlled conditions

COVAX

9

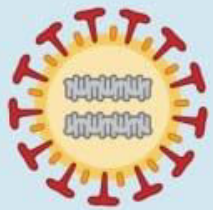
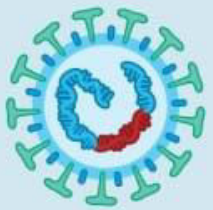
Type of vaccine	Description	Pros	Cons	Example
Inactivated virus vaccines	An inactivated version of the target pathogen. The virus is detected by immune cells, but unable to cause disease.	Induces strong immune response	Requires lots of virus	Rabies
Live-attenuated	Consist of a living but weakened version of the target pathogen.	Same response as natural infection	Not recommended for pregnant women and immunocompromised individuals	Measles
Viral-vector vaccines (replicating and non-replicating)	A virus is genetically engineered or modified to contain antigens from the target pathogen. When the nucleic acid is inserted into human cells, they produce copies of the virus' protein, which stimulate a protective response from the host immune system.	Rapid development	Prior exposure to viral vector may reduce immunogenicity	Ebola
Nucleic-acid vaccines	RNA or DNA vaccines include a target pathogen protein that prompts an immune response. When the nucleic acid is inserted into human cells, RNA or DNA is then converted to antigens.	Strong cellular immunity, rapid development	Relatively low antibody response	None
Virus-like vaccine	Empty viral shells that are similar to the target pathogen, without genetic material. The viral shells stimulate a protective response from the host immune system.	Fast and relatively inexpensive	May be less immunogenic	HPV
Protein sub-unit vaccines	These vaccines use fragments of the target pathogen that is important for immunity.	May have fewer side effects than whole virus	May be poorly immunogenic, complex process	Hepatitis B

Notes: DNA – deoxyribonucleic acid; RNA – ribonucleic acid.

WHO

Types of coronavirus vaccine approaches

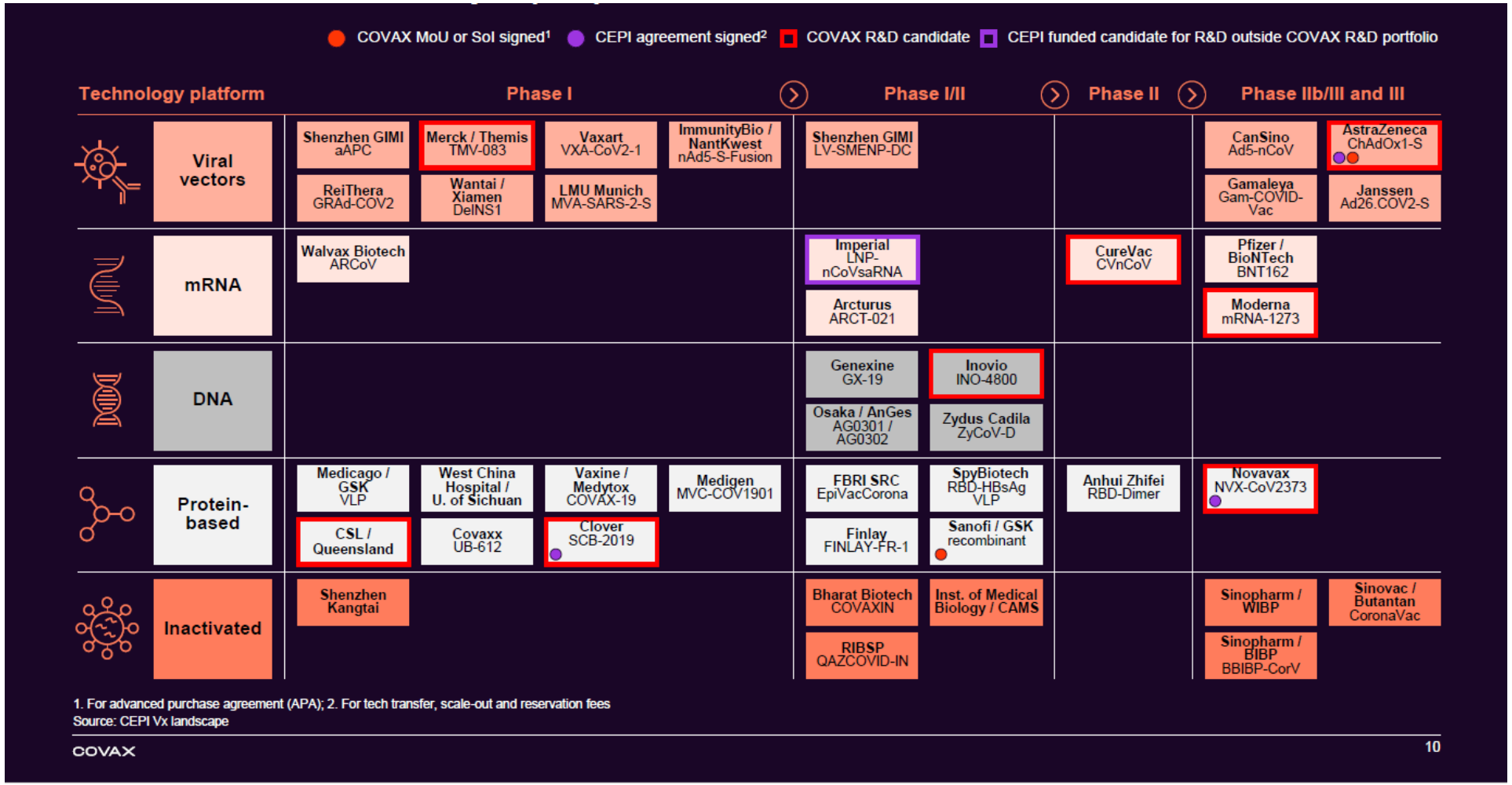
Scientists are casting a wide net to see what works best against the novel coronavirus.

Types of vaccines	DNA and RNA	Live attenuated	Inactivated	Subunit	Viral vector
					
How it works	This vaccine uses DNA or RNA molecules to teach the immune system to target key viral proteins.	This is a weakened version of the actual virus.	An inactivated vaccine uses the whole virus after it has been killed with heat or chemicals.	This vaccine uses a piece of a virus' surface to focus your immune system on a single target.	This approach takes a harmless virus and uses it to deliver viral genes to build immunity.
Advantages	Easy and quick to design.	Stimulates a robust immune response without causing serious disease.	Safe because the virus is already dead and is easy to make.	Focuses the immune response on the most important part of the virus for protection and cannot cause infection.	Live viruses tend to elicit stronger immune responses than dead viruses or subunit vaccines.
Disadvantages	Never been done before. There are no licensed DNA or RNA vaccines currently in use.	May not be safe for those with compromised immune systems.	Not as effective as a live virus. Some previous inactivated vaccines have made the disease worse; safety for the novel coronavirus needs to be shown in clinical trials.	May not stimulate a strong response, other chemicals may need to be added to boost long-term immunity.	Important to pick a viral vector that is truly safe. An immune response to the viral vector could make the vaccine less effective.
Existing examples	• None	• Measles, Mumps and Rubella • Chickenpox	• Polio	• Pertussis • Hepatitis B • Human papillomavirus (HPV)	• Ebola • Veterinary medicine
Group testing this approach for COVID-19	• Moderna (RNA) • Inovio (DNA)	• Codagenix • Indian Immunologicals Ltd.	• Sinovac • Sinopharm	• Novavax • AdaptVac	• University of Oxford & AstraZeneca • CanSino Biologics • Johnson & Johnson

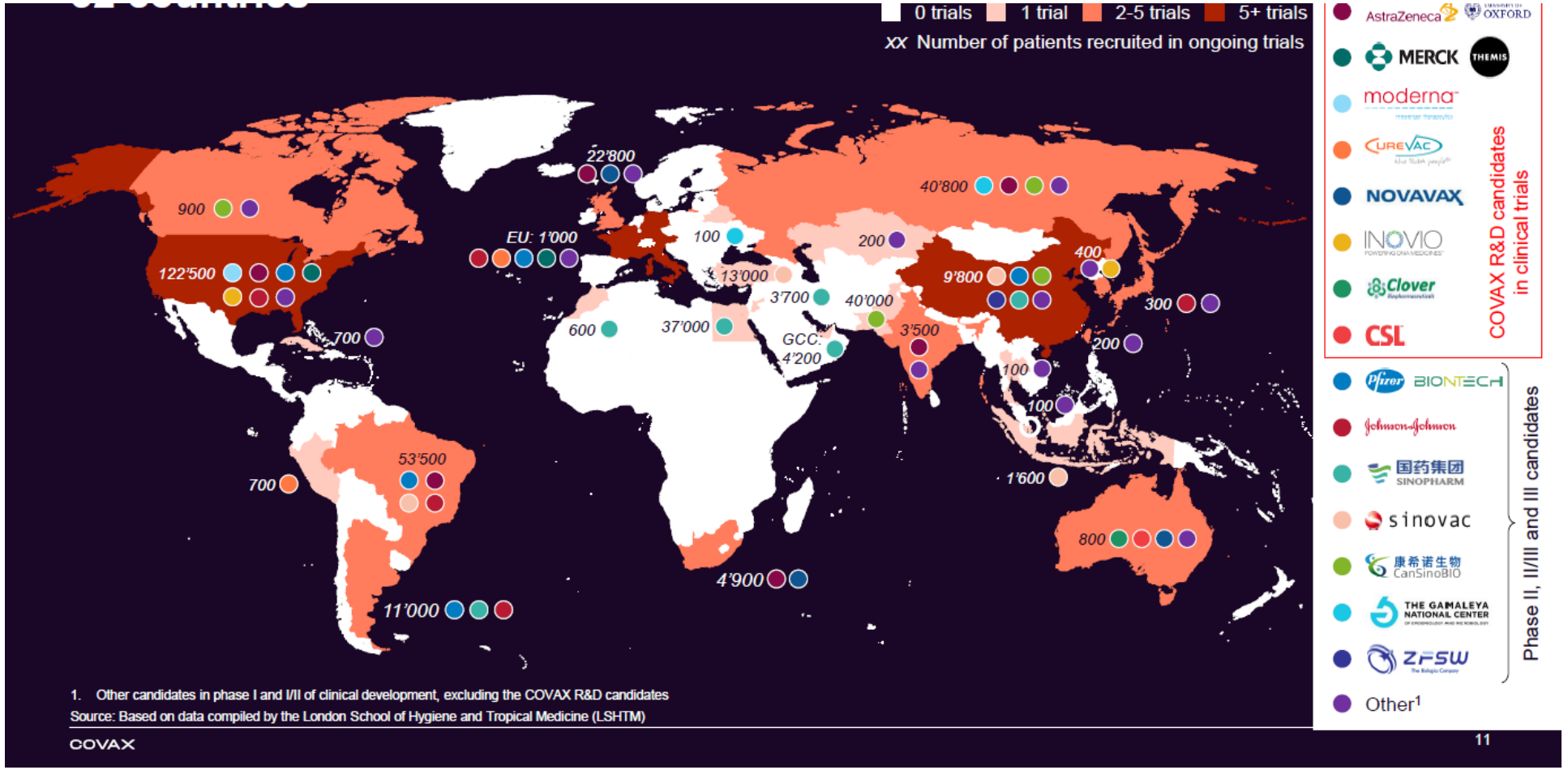
Sources: CDC; NIAID; FDA

MICHELLE GUERRERO and JONATHAN WOSEN U-T

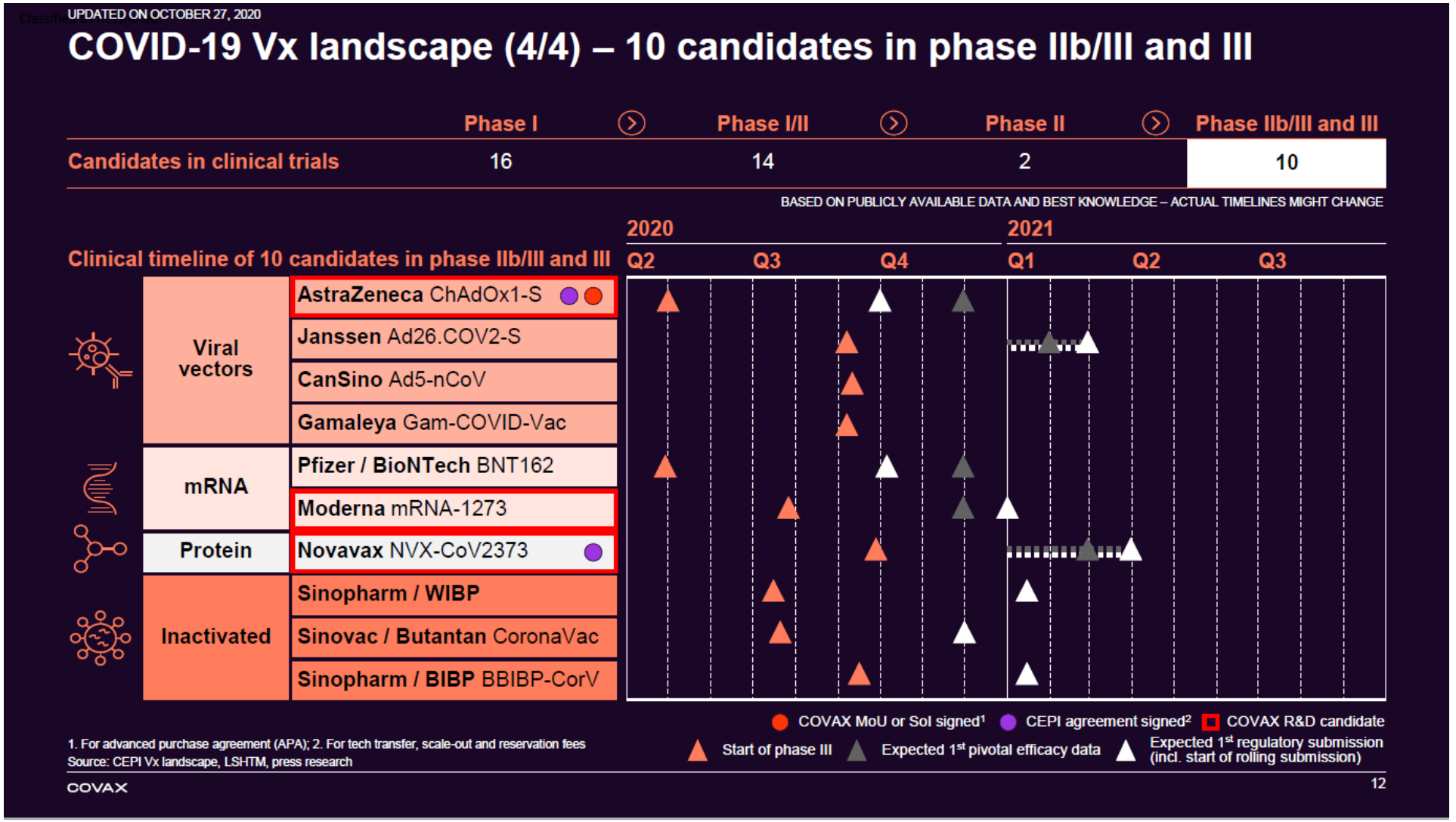
42 candidates in human trials



Human trials in 32 countries



10 candidates in phase IIB/III and III

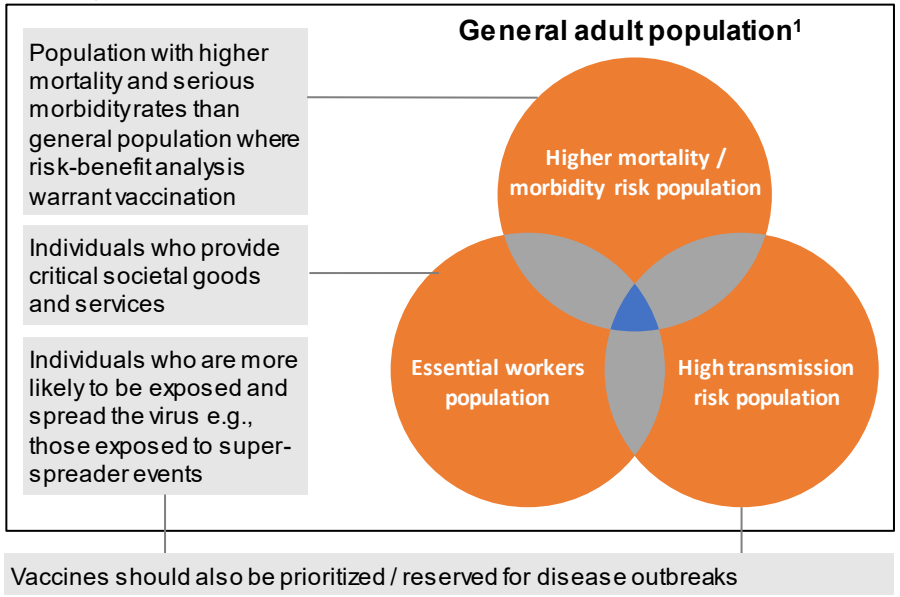


There are three priority populations which include multiple potential target groups: June 2020

WHY

Priority populations are defined by the rationale for their vaccinations i.e., why would you want to vaccinate this population?

Priority populations



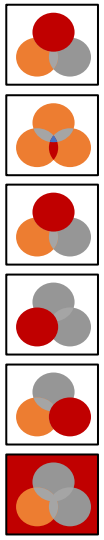
1. Non-adult populations require further consideration

WHO

Target groups are who you would want to vaccinate and are defined by a common characteristic (e.g., age, health status, occupation) which allows you to identify them

Examples of potential target groups

(ordering does not imply sequencing or prioritization)



- **Elderly (>65 years)**
- **Workers in health and social care settings**
- **<65 with co-morbidities**
- **Other essential workers**
- **Adults in densely populated areas**
- **Rest of adult population**

Prioritization of target population- October

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 II (11-20%)	Stage III (21-50%)
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	- 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	- 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

Review of COVID-19 candidate vaccines that are currently in phase (3) trial

No	Vaccine developer/ manufacturer	Vaccine platform	Doses	Timing of doses	Route	Efficacy and safety	storage	Price	Production
1	**BioNTech /Fosun Pharma/Pfizer**	RNA	2	0,28 days	IM	90% safety	-75˚C	less than $20 a dose	50 M doses in 2020 1.3 B doses in 2021
2	**Moderna /NIAID**	RNA	2	0,28 days	IM	95% Safe > 65	-20˚C	$32-$37 per dose	500 M to 1 B doses in 2021
3	**S.Putink V Russian**	Adeno viral vector based	2		IM	92% • Pain • Hyperthermia • Asthenia • Muscle and Joint pain	-18˚C	Not known yet	2 M in 2020 to 15 M in 2021 Application for WHO PQ

No	Vaccine developer/ manufacturer	Vaccine platform	Doses	Timing of doses	Route	Efficacy and safety	storage	Price	Production
4	Wuhan Institute of Biological Products/ Sinopharm	Inactivated	2	0,21days	IM	Pain, fever Low rates	Not known yet	Not known yet	batch production exceeds 3 million doses, annual production capacity after the mass production reaches 100-120 million doses
5	**Beijing Institute of Biological Products/ Sinopharm**	Inactivated	2	0,21days	IM	97% -one time 100%- 2 times	Not known yet	Two doses will cost about 1,000 yuan (about $144)	batch production exceeds 3 million doses, and the annual production capacity after the mass production reaches 100-120 million doses
6	Sinovac China	Inactivated	2	0,14days	IM	appeared to be safe for older people, according to preliminary result,	Not known yet	$60 for emergency use ($13.60) per dose when it becomes available in the southeast Asian country.	

No	Vaccine developer/manufacturer	Vaccine platform	Type	Doses	Timing of doses	Route	Efficacy and safety	storage	Price	Production
7	CanSino Biological Inc./Beijing Institute of Biotechnology	Non-Replicating Viral Vector	Adenovirus Type 5 Vector	1	-	IM	Not known yet	Not known yet	Not known yet	Not known yet
8	**University of Oxford Vaccine Sii, United Kingdom (AstraZeneca)**	Non-Replicating Viral Vector	ChAdOx1-S	2	0,28days	IM	Not known yet	Not known yet	USD 13 for two doses (cheaper in UK) low- and medium-income countries, USD 3.36	100-300 million doses
9	**Janssen Pharmaceutical Companies**	Non-Replicating Viral Vector	Adenovirus Type 26 vector	1 2	0 0,56 days	IM	Not known yet	Not known yet	Not known yet	Not known yet

No	Vaccine developer/ manufacturer	Vaccine platform	Type	Doses	Timing of doses	Route	Efficacy and safety	storage	Price	Production
10	**Novavax**	Protein Subunit	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M	2	0,21 days	IM	Not known yet	Novavax spike is stable for many weeks at 2°C to 8°C	Not known yet	Serum Institute will develop two billion doses of Novavax's vaccine candidate annually.
11	**COVAXIN (Bharat Biotech)**	Inactivated	Whole-Virion Inactivated	2	0,28days	IM	found to be safe	Not known yet	Not known yet	hoped to launch it only in the second quarter of next year
12	**Gamaleya Research Institute**	Non-Replicating Viral Vector	Adeno-based (rAd26-S+rAd5-S)	2	0,21 days	IM	Not known yet	Not known yet	Not known yet	**Russia** tends to produce 30 m doses this year

References

- *Source: WHO DRAFT landscape of COVID-19 candidate vaccines –12 Nov 2020 (48 candidate vaccines)*
- *https://www.pfizer.com/science/coronavirus*
- *www.genengnews.com › covid-19-candidates › sinoph*
- *in.reuters.com › article › us-health-coronavirus-vaccine..*
- *www.ox.ac.uk › news › 2020-06-05-oxford-university-.*