



An Overview About The Efficacy of COVID-19 Vaccines Used In Iraq

Professor

Mohammed Dakhil Al-Rekabi

University of Alkafeel, College of Pharmacy 2021

University of Alkafeel, College of Pharmacy, Najaf, Iraq.
drmdr@alkafeel.edu.iq

0 **Vaccine development**

1

0 **Types and
Mechanism of action**


2

0 **Their original efficacy**

3

0 **The new variants of
Corona virus 2**

4



vs

SAFETY

Vaccines should be free of deadly side effects

Efficacy

The efficacy of the vaccine to prevent disease or infection

Animal Study

01

Phase I Clinical Study

02

Phase II Clinical Study

03

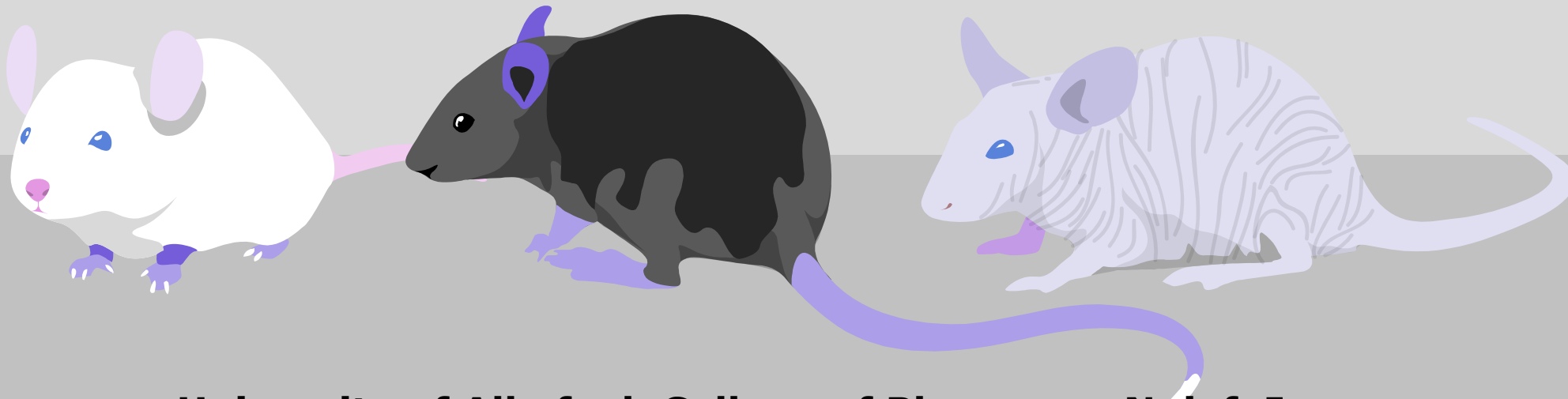
Phase III Clinical Study

04

Phase IV Clinical Study

Experimental Mice

- 1-giving the vaccine to mice
- 2- monitoring of side effects (skin irritation, fatigue, fever)
- 3- efficacy (AB production)
- 4-give the mice the virus
- 5- did the vaccine prevent the disease? If yes move to phase I





CLINICAL TRIAL

Giving Vaccines To Human

Phase 1



SAFETY

- Small sample size
- Healthy participants
- Testing the SE
- Dosage (upper and lower limit)

Phase 2



EFFICACY & SE

- Intermediate sample
- Matching
- Still looking for SE
- Is the dosage is basically effective

Phase 3



EFFICACY, EFFECTIVENESS AND SAFETY

- Large sample size
- Matching
- Monitor the effectiveness of vaccine in real life
- Monitor S&S and PCR





Ideally, a vaccine will:

- produce the same immune protection which usually follows natural infection but without causing disease
- generate long lasting immunity so that the person is protected if they are exposed to the antigen several years after vaccination





Ideally, a vaccine will:

- interrupt the spread of infection by preventing carriage of the organism in the vaccinated person

Vaccines need to be safe and the risk from any side effects should be much lower than the benefit of preventing deaths and serious complications of the disease.





Ideally, a vaccine will:

For the COVID-19 vaccines, many of these properties can be confirmed from the clinical vaccine trials.

Longer term ongoing surveillance of the disease and of those vaccinated will show whether:

- **vaccine protection is long lasting or booster or annual doses are needed**
- **the vaccine prevents a vaccinated person from carrying and spreading the virus**





COVID-19 Vaccines Used In Iraq!

Pfizer/ Biontech

AstraZeneca/Oxford

Sinopharm





is a messenger ribonucleic acid (mRNA) that contains the genetic sequence of the antigens found on the surface of the SARS-CoV-2 virus





The COVID-19 mRNA Vaccine BNT162b2 vaccine is a messenger ribonucleic acid (mRNA) vaccine.

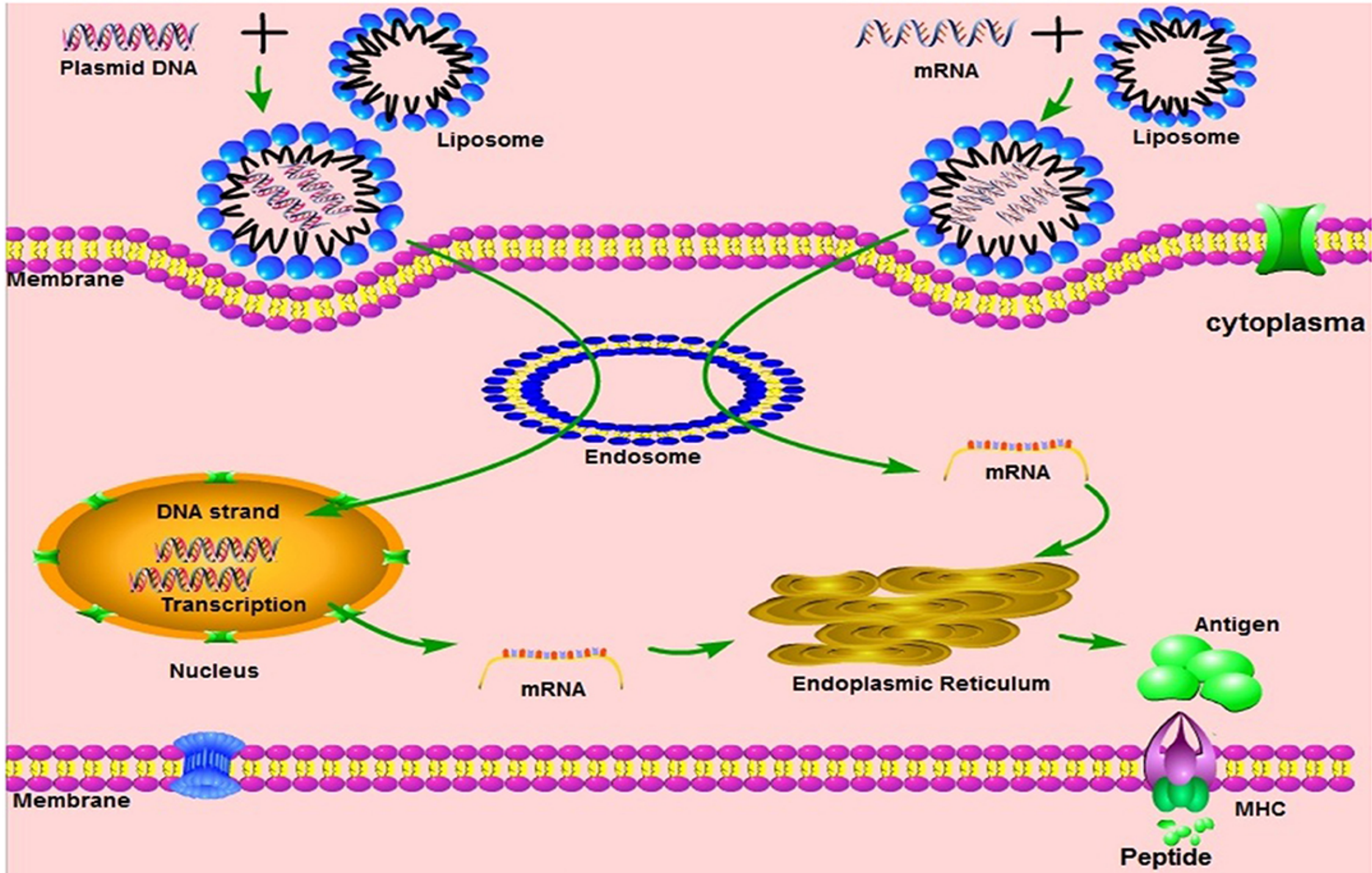
It contains the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, **wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.**

When injected, the mRNA is taken up by the host's cells which translate the genetic information and **produce the spike proteins.**

These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

As there is no whole or live virus involved, the vaccine cannot cause disease. The mRNA naturally degrades after a few days.







It is given at day zero followed by a second dose on day 21

7 days later if any symptoms developed any symptom they should test for Covid-19 (PCR)

43000 participants subdivided into two groups; vaccine and placebo group

162 participant showed a + test for Covid-19 among the placebo group, **9** cases of them showed a sever sign and symptom

Only **8** participant showed a + test for Covid 19 among the vaccine group , **1** case only showed sever sign and symptoms

Efficacy against disease = $162-8/162=95\%$ affective

Efficacy against severity of disease = $100\%-1/8=87\%$ effective





The COVID-19 mRNA Vaccine BNT162b2 should not be given to people who have had a **confirmed anaphylactic reaction to a previous dose of the same vaccine or to any components of the vaccine**

In addition to the highly purified BNT162b2 messenger RNA, the vaccine also contains:

ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)

ALC-0159 = 2-[(**polyethylene glycol**)-2000]-N,N-ditetradecylacetamide

1,2-Distearoyl-sn-glycero-3-phosphocholine

cholesterol

potassium chloride

potassium dihydrogen phosphate

sodium chloride

disodium hydrogen phosphate dihydrate

sucrose

water for injections

Polyethylene glycol (PEG) is from a group of known allergens commonly found in medicines and also in household goods and cosmetics. Known allergy to PEG is rare but would contraindicate receipt of this vaccine.





- a very small number of individuals have experienced **anaphylaxis** when vaccinated with the COVID-19 mRNA Vaccine BNT162b2 vaccine
- following close surveillance of the initial roll-out, the MHRA has advised that individuals with **a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine**, as long as they are not known to be allergic to a component (excipient) of the vaccine
- all recipients of this vaccine should be kept for observation and monitored for a minimum of 15 minutes
- facilities for management of anaphylaxis should be available at all vaccination sites





COVID-19 Vaccine AstraZeneca which is a non-replicating viral vector vaccine. It uses a weakened adenovirus as a carrier to deliver the genetic sequence for part of the SARS-CoV-2 virus into the body





AstraZeneca COVID-19 vaccine

AstraZeneca COVID-19 vaccine is a viral vector vaccine which uses a weakened adenovirus as a carrier to deliver the SARS-CoV-2 antigen.

The adenovirus has been modified so that it cannot replicate (grow and multiply by making copies of itself) in human cells and therefore cause any disease.

The genes that encode for the spike protein on the SARS-CoV-2 virus have been inserted into the adenovirus's genetic code to make the vaccine.

When the vaccine is injected, it enters the host's cells which then manufacture the spike protein.

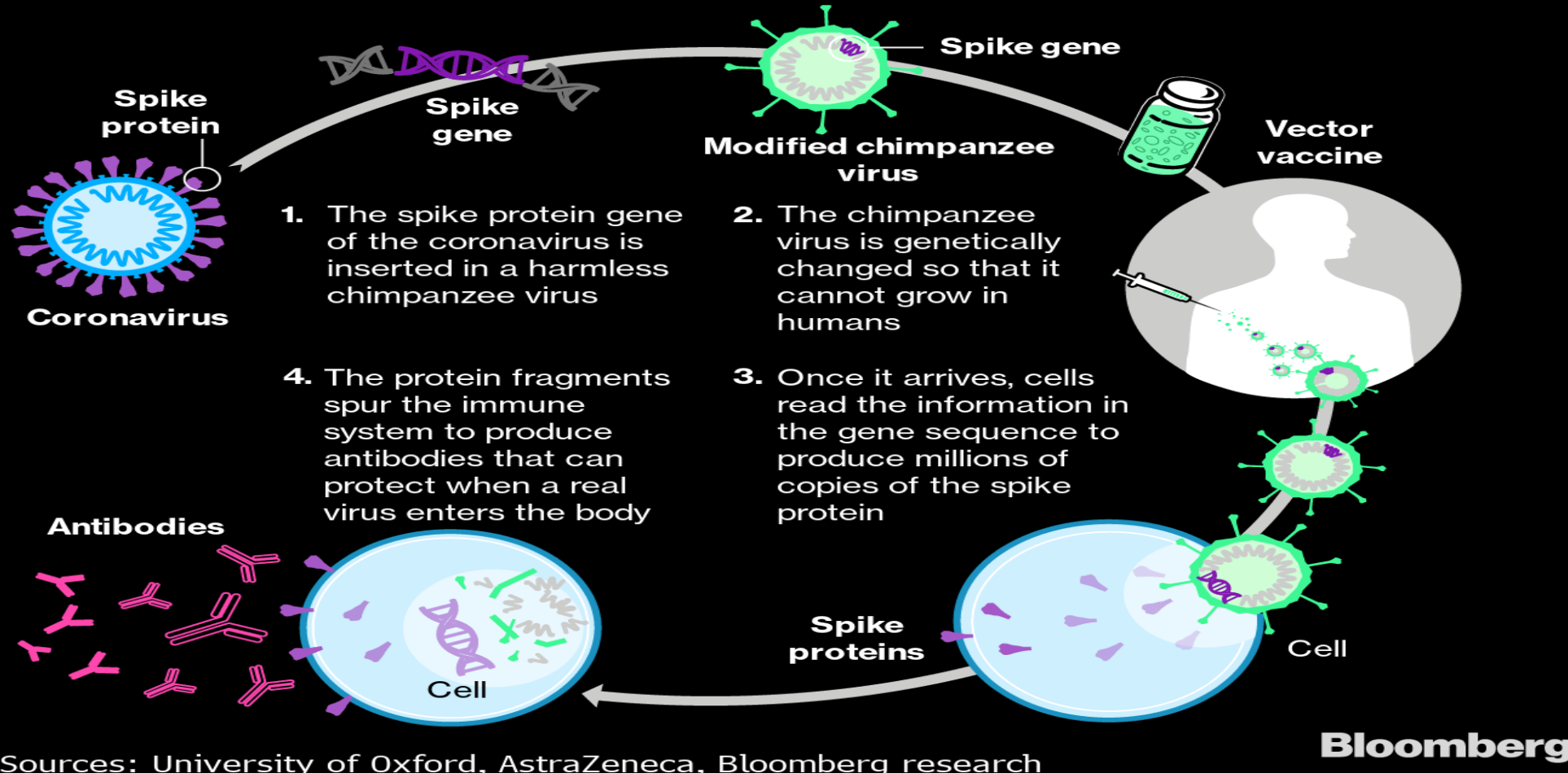
This then stimulates the immune system which reacts by producing antibodies and memory cells to the SARS-CoV-2 virus without causing disease.





How the Oxford-AstraZeneca Vaccine Works

The viral vector vaccine uses a harmless virus to transport genetic material which triggers an immune response to the coronavirus





Clinical trial summary

- It is given at day zero followed by a second dose on day 28 (updated later to be 12 weeks)
- 14 days later , they should test for Covid-19 (PCR)(not looking for classical s&s. because their end point is to prevent the infection not only the disease.

BRAZIL STUDY

- ✓ Total of about 9000 participant
- ✓ Divided into placebo and vaccine groups
- ✓ 1 full dose at day 0 and full dose at day 28
EFFICACY = 62%

UK STUDY

- ✓ Total of about 3000 participant
- ✓ Divided into placebo and vaccine groups
- ✓ Half dose at day 0 and full dose at day 28
EFFICACY= 90%

Brazil/ UK study

- ✓ Total number = 12000
- ✓ 13 case tested +
Combined EFFICACY = 70%
- ✓ No case has sever disease





BBIBP-CorV Sinopharm Vaccine

Active Corona virus injected to kidney cells of monkey(Vero cells) , it will replicate to produce huge number of the active virus which will then inactivated by beta propiolactone. It will be reinjected to Vero cells to ensure that its inactive.

BBIBP-CorV
Sinopharm \$\$\$

Inactivated Virus Vaccine
SARS-CoV2 is chemically inactivated (with a chemical called beta-propiolactone) so it cannot replicate but all the proteins remain intact.

◆ **Efficacy** : **79%** (original strain)
--% (B1.351 "SA" strain)

📅 **Dosing** : 2 doses - 21 days apart
📦 **Storage** : +2-8°C

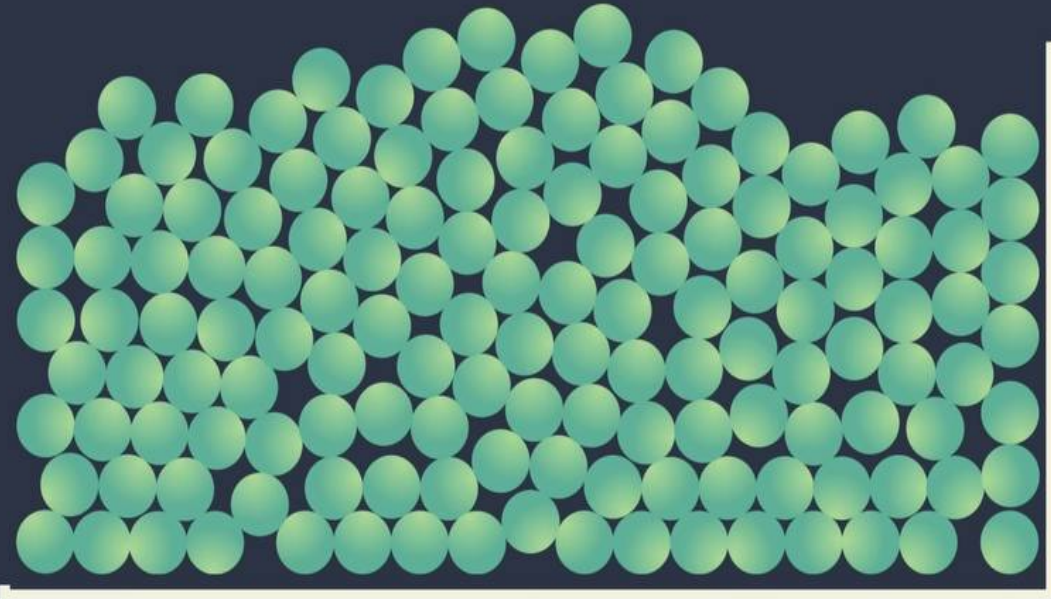
Advantages of China's COVID-19 inactivated vaccines in the world vaccine competition

- Easy to preserve**
Temporary preservation: **2 to 8 degrees centigrade**
Long-term preservation: **-20 to -18 degrees centigrade**
*Long-term preservation of US' Pfizer vaccine: -70 degrees centigrade
- Triggers fast immunoreaction**
If 2 of China Sinovac Bio-tech company's vaccines are injected with a **14-day interval** a rapid antibody reaction can be triggered in **4 weeks**
- Abundant clinical test samples**
50,000 Volunteers from **125 nationalities** are involved in the Phase-III clinical tests of China National Pharmaceutical Group's vaccine
- Easy to transport**
China's vaccine requires a relatively **high temperature**, so it can be transported easily. It can be sent to the world's **poverty affected areas** much easier than the US' vaccine

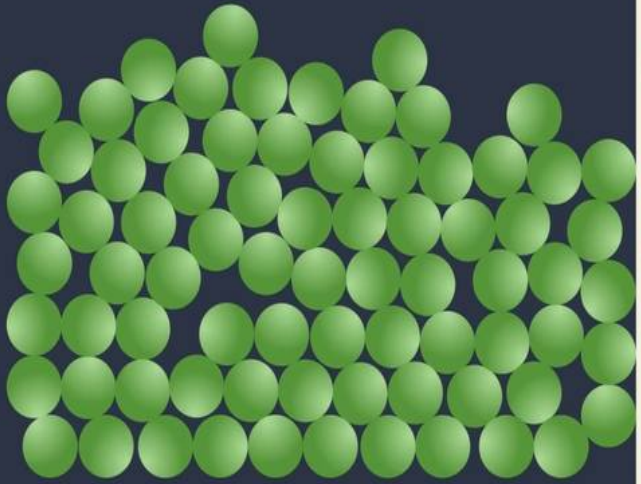
Source: Global Times, Nanfang Plus, China National Pharmaceutical Group Editor: Wu Tiantong/GT



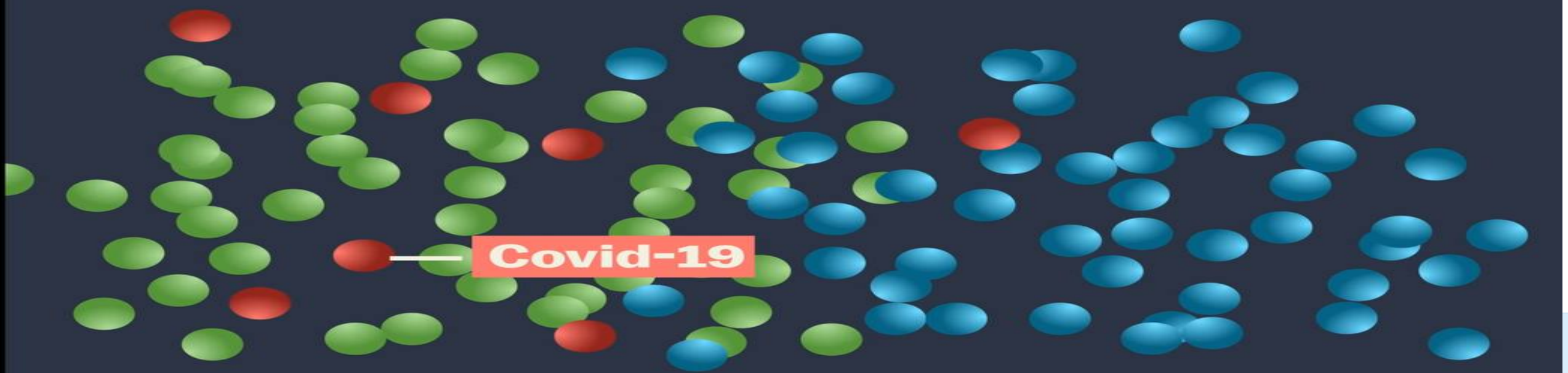
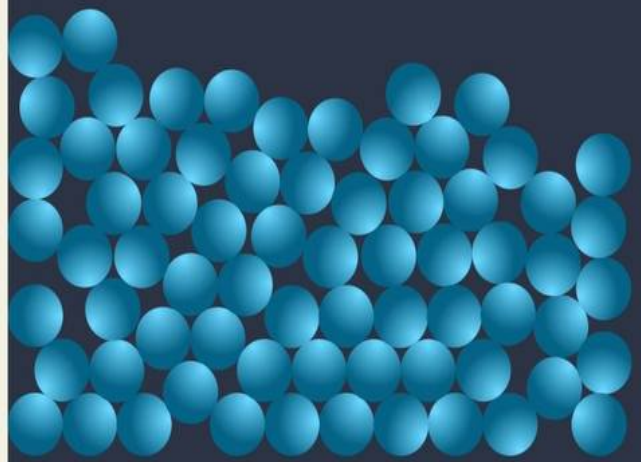
Tens of thousands



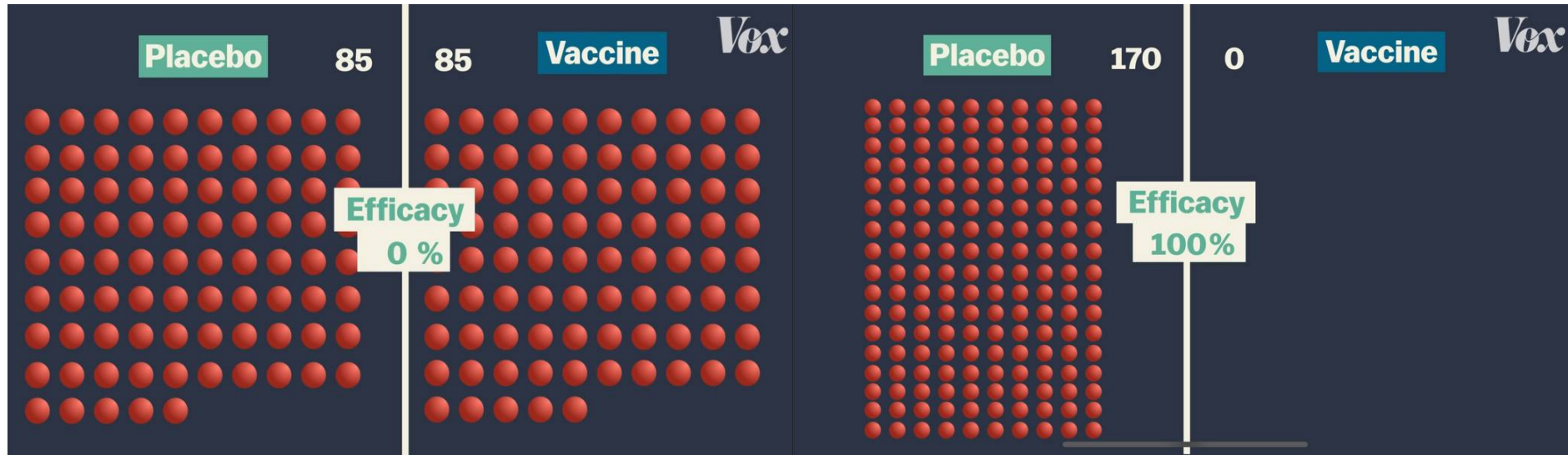
Placebo

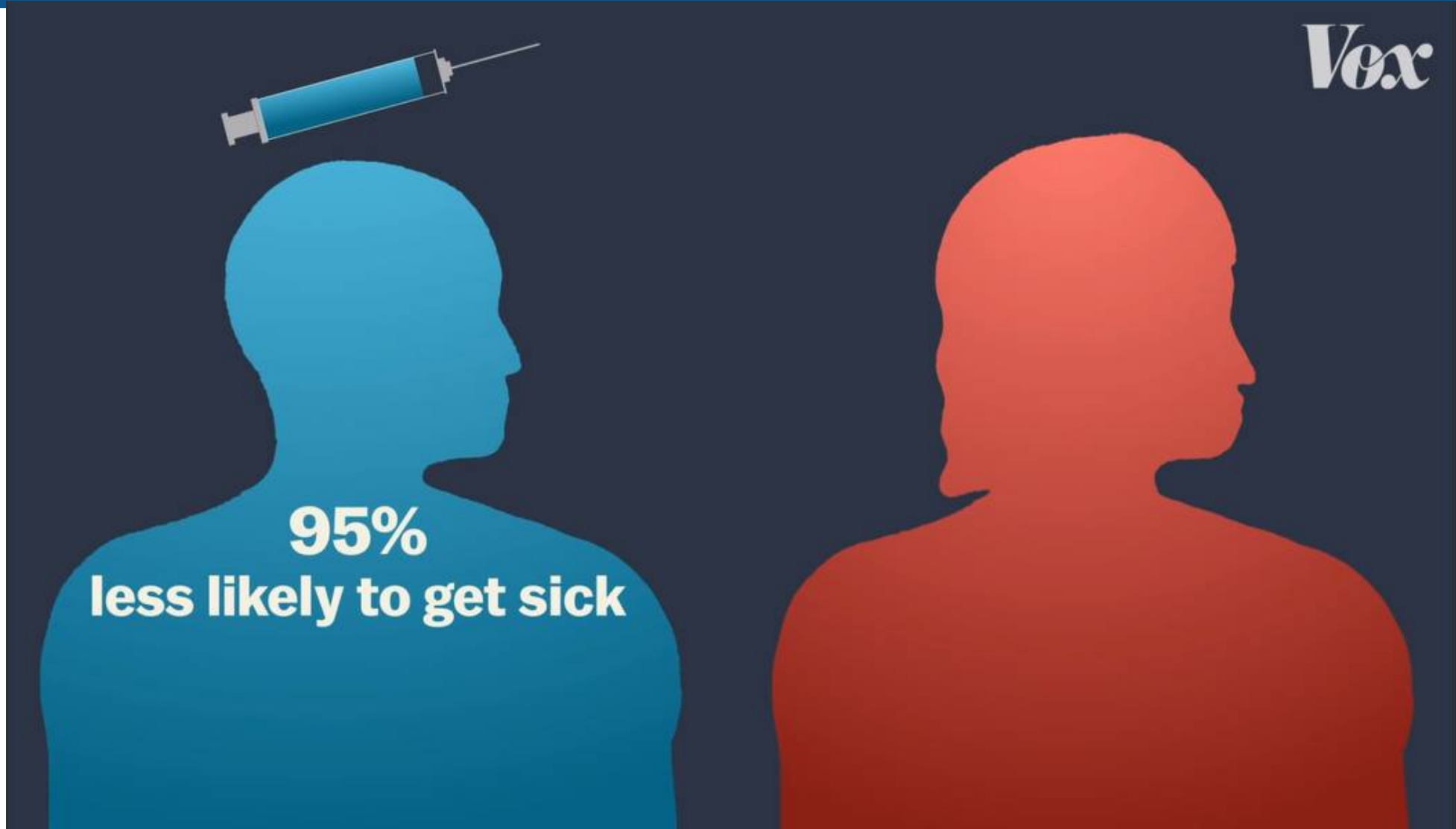


Vaccine



Covid-19

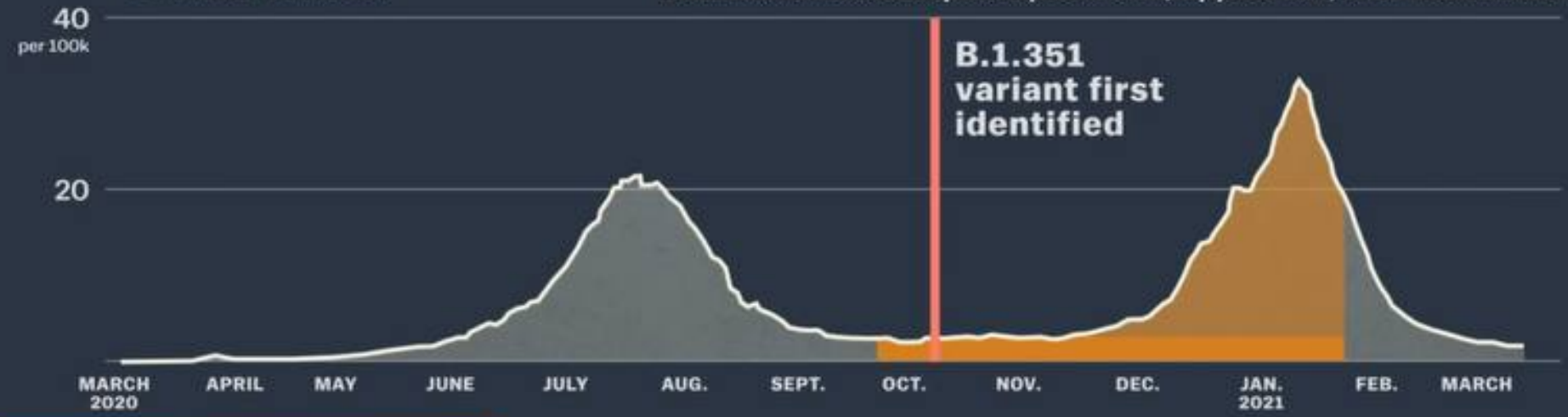






South Africa

New Covid-19 cases per capita. STAT/Applied XL, one-week trend



Johnson & Johnson

Brazil



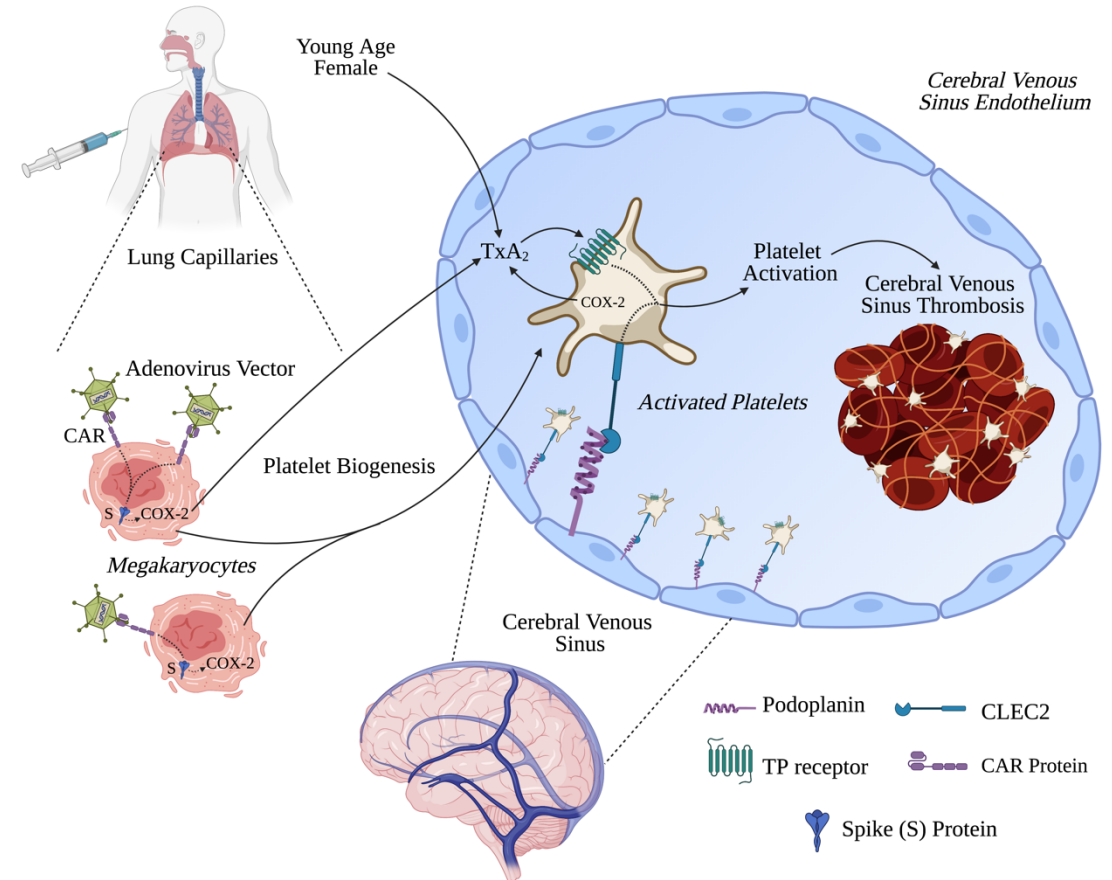
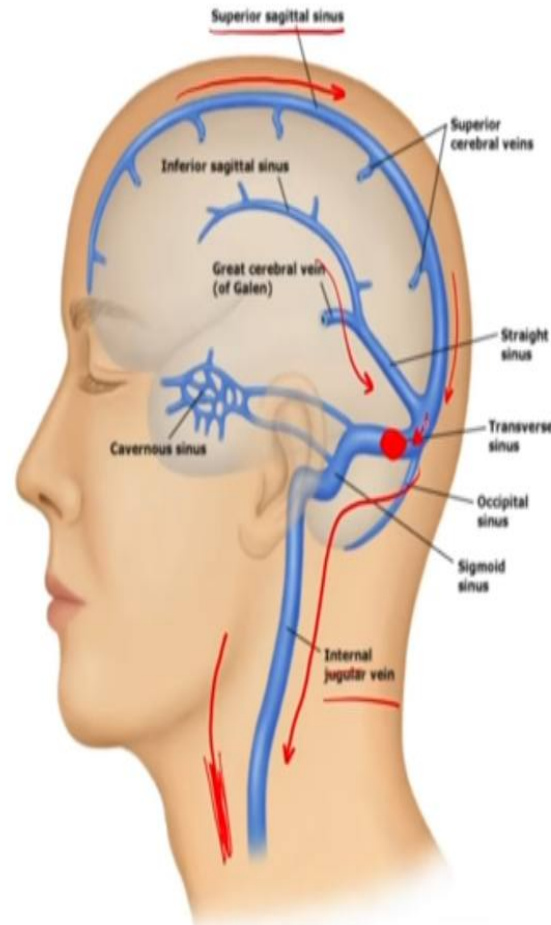


THROMBOTIC THROMBOCYTOPENIA OF ASTRAZENECA

CVST

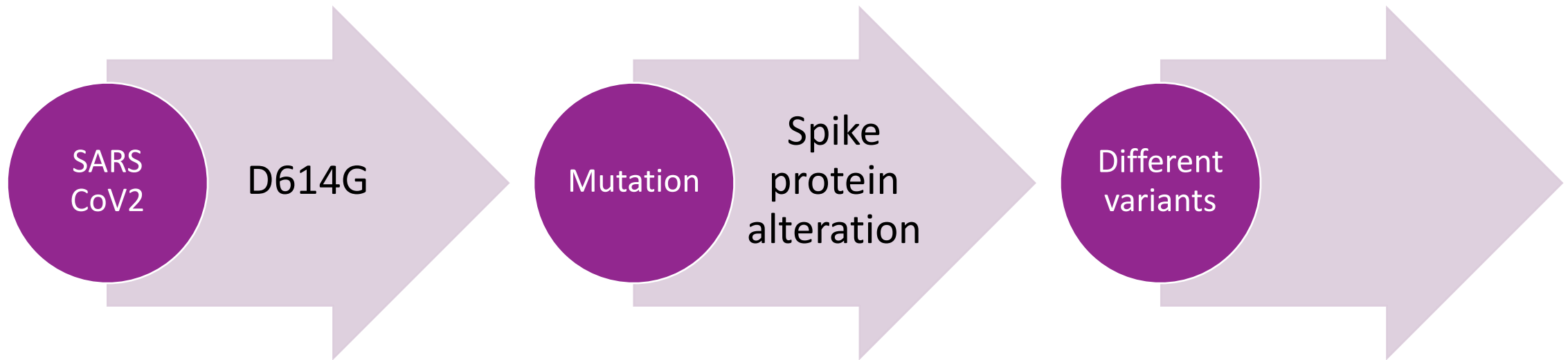
Symptoms

Headache
abnormal vision
Stroke.
Seizures





Variants of SARS CoV2 / Mutations





B.1.1.7 variant : Mostly predominant in UK

E484K

Escape mutation, help to evade the immune system

P681H

Enhances the viral entry to the cell by possibly abolishing the phosphoinhibition of s1/s2site

Y144 DEL

Reduces antibody binding affinity

N501Y

This mutation increases the binding affinity toward the human ACE-2 receptor

H69-V70 DEL

Mutation leads to conformational change in spike protein

D614G

It reduces the S1 shedding and increases the infectivity





B.1.1.318 variant : Mostly predominant in UK

E484K

P681H

Y144DEL

D614G

D796H

D796H IS AN ADAPTIVE MUTATION THAT HELPS TO ESCAPE FROM CONVALESCENT PLASMA ANTIBODIES





B.1.351 variant : Mostly predominant in SOUTH AFRICA

E484K

N501Y

K417N

D614G

K417N MUTATION REDUCES SENSITIVITY OF THE VIRUS TOWARD THE ANTIBODIES AND INCREASE THE BINDING AFFINITY TO ACE 2 RECEPTORS





B.1.429 variant : Mostly predominant in USA, CALIFORNIA

L452R

S13I

W152C

D614G

L452R MUTATION ALTERS THE DYNAMIC IN THE RECEPTOR BINDING OF RBC





B.1.525 variant : Mostly predominant in **UK-DANMARK**

E484K

Y144DEL

F888L

F888L MUTATION HAS UNKNOWN EFFECT





P.1 variant : Mostly predominant in BRAZIL

E484K

N501Y

K417T

D614G





B.1.617 variant : Mostly predominant in INDIA

E484Q

L452R

- E484Q MUTATION IS DIFFERENT FROM E484K IN ONLY ONE AMINO ACID SUBSTITUTE**





**Does the vaccine still
effective against the new
variants?**





Thank you...

