
The COVID-19 vaccine race – weekly update

Scientists around the world are working faster than ever to develop and produce vaccines that can stop the spread of COVID-19. Since the emergence of this novel coronavirus in December 2019, 20 vaccines have started to be rolled out in countries worldwide. Here is an at-a-glance overview of those vaccines and recent developments of those vaccine candidates in clinical trials.

25 August 2021

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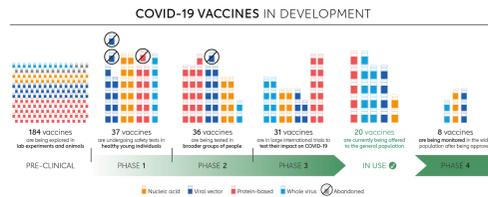
- On 23 August the US Food and Drug Administration (FDA) granted full approval to the Pfizer/BioNTech vaccine for people 16 and older, moving it beyond emergency-use status in the US.
- Vaxine/CinnaGen and SK Bioscience

have both registered a new phase 3 trial.

- Around the world, there are now 112 COVID-19 vaccine candidates undergoing clinical trials and 184 candidates in pre-clinical development.

When candidate vaccines make it to human clinical trials, they first go through phase 1 trials primarily to test the vaccine's safety, determine dosages and identify any potential side effects in a small number of people. Phase 2 trials further explore safety and start to investigate efficacy on larger groups. Phase 3 trials, which few vaccines ever make it to, are much larger, involving thousands or tens of thousands of people, to confirm and assess the effectiveness of the vaccine and test whether there are any rare side effects that only show up in large groups. The final stage, phase 4 trials, is conducted after national regulatory approval and involves further monitoring in a wide population over a longer timeframe as a form of post-marketing surveillance (pharmacovigilance). However, not all vaccines that have been approved for domestic use are in phase 4 trials. Regulators in many countries have their own individual procedures and timelines for providing emergency use authorisations, relying on various types of evidence at different clinical trial phases. Some national regulators, including those in Russia and China, began approving vaccines for (limited or widespread) public use even before phase 3 trials were completed. The World Health Organization (WHO) lists candidates at various stages of clinical trials.

Here is a more in-depth look at the candidate vaccines that are in phase 1 trials or beyond.

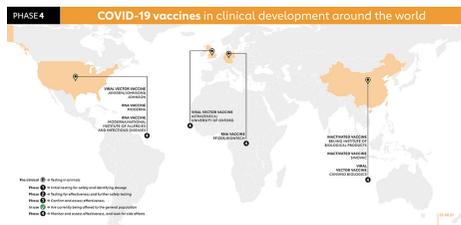


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- There are four types of COVID-19 vaccines: here's how they work
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Filter the different clinical phases

Phase 4



MODERNA (USA)

RNA VACCINE

The Moderna vaccine is also known as Spikevax or mRNA-1273. It is developed

by Moderna, in Cambridge, Massachusetts, and funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the US National Institutes of Health. The vaccine is administered in two doses four weeks apart. It was tested in phase 1 trials on volunteers at the Kaiser Permanente Washington Health Research Institute in Seattle. Moderna has run phase 2 trials on participants of a wide range of ages and started phase 3 trials in July 2020. The final trial enrolled 30,000 healthy people from across the United States. In February, a phase 4 trial was launched as part of a national cohort study in collaboration with the Danish Ministry of the Interior and Health. The United States currently authorises its use for people 18 and older, while the European Medicines Agency authorised giving it to children aged 12 to 17 years in July. It was listed for emergency use by the WHO in April 2021. A phase 2 study was carried out in August 2021 to elicit an antibody response in kidney transplant recipients who have failed to respond to two doses of vaccine. This vaccine needs to be kept in refrigerators, or freezers for longer storage.

ASTRAZENECA/UNIVERSITY OF OXFORD (UK)

VIRAL VECTOR VACCINE

The AstraZeneca vaccine is administered in two doses. It was developed by the University of Oxford,

and has been granted emergency use authorisation by the European Medicines Agency, the WHO as well as national regulators worldwide. This vaccine is fridge-stable meaning that it can be easily transported anywhere in the world. At about US\$ 4 per dose for lower-income nations, it is also being made available for a fraction of the cost of others. It was tested in phase 3 clinical trials with more than 10,000 people from across the UK, including children and older people. The vaccine was also tested in Brazil, the United States and India, with South Africa carrying out the first COVID-19 vaccine trial in Africa. In February 2021, a phase 4 trial was launched as part of a national cohort study in collaboration with the Danish Ministry of the Interior and Health.

In March 2021, the University of Oxford registered a further phase 1 trial in the UK with 30 adult participants to investigate the delivery of its ChAdOx1 vaccine using a nasal spray. ChAdOx1 is currently being delivered by intramuscular injection as part of the UK's national rollout. By using a different technique that administers the vaccine to the site of infection, researchers at Oxford intend to investigate whether this results in enhanced protection, especially against transmission and mild disease. On 27 June, a new phase 2/3 trial was carried out to demonstrate the safety and characterise the immunogenicity of the Beta variant vaccine, called AZD2816.

■ PFIZER/BIONTECH (GERMANY)

RNA VACCINE

The vaccine is administered in two doses three weeks apart. In December 2020, the UK became the first country in the world to approve this vaccine and it is now in use worldwide. It also became the first vaccine to receive emergency use listing from the WHO in December 2020. BioNTech, working together with Pfizer, started testing its BNT162 vaccine in humans in global trials, initially in Germany, and then started trials in the USA. BioNTech has also entered into a €100 million debt financing agreement with the European Investment Bank in order to scale-up the production of the vaccine in Europe. On 27 July 2020, it announced the launch of a phase 2/3 trial with 30,000 volunteers in the USA and other countries including Argentina, Brazil and Germany. In September, it said it would expand its phase 3 US trial to 44,000 participants. At the start of October 2020, BioNTech and Pfizer started recruiting for a phase 3 trial in South Africa and by early November had reported promising interim results. Its final efficacy analysis confirmed strong efficacy. In February, a phase 4 trial was launched as part of a national cohort study in collaboration with the Danish Ministry of the Interior and Health. The United States Food and Drug Administration (FDA) has authorised its use for 12 to 15 years olds in the United States. On 23 August 2021, the FDA granted full approval to the vaccine for people 16 and older, moving it beyond

emergency-use status in the US – the first vaccine to do so. A Phase 2 study was carried out in August 2021 to elicit an antibody response in kidney transplant recipients who have failed to respond to two doses of vaccine. On 12 August 2021, the United States FDA authorised the use of booster shot in transplant recipients. This vaccine requires freezer storage.

- **SINOVAC (CHINA)**

-  **INACTIVATED VACCINE**

Sinovac conducted phase 3 trials involving volunteers in Brazil, Indonesia and Turkey. Although it is not yet approved by regulators, shipments have already arrived in Indonesia, ready for rollout. A report in July said that the Chinese government has given the Sinovac vaccine emergency approval for limited use. The city of Jiaxing has reportedly offered the vaccine to health workers and other high-risk groups for US\$ 60. The company began phase 4 trials in February 2021. A Phase 2 study was carried out on 12 July 2021 to determine the safety and immunogenicity of booster doses. A phase 3 study is due to be conducted in late August 2021 to evaluate the efficacy of the vaccine in participants aged 6 months to 17 years.

- **CANSINO BIOLOGICS INC. (CHINA)**

-  **VIRAL VECTOR VACCINE**

The Ad5-nCoV vaccine candidate uses a harmless non-replicating viral vector to carry vaccine antigens into the human body – this is the same platform that the vaccine developer CanSino Biologics Inc, based in Tianjin, used for its Ebola vaccine. The COVID-19 vaccine was jointly developed with the Institute of Biotechnology of the Academy of Military Medical Sciences. On 25 June 2020, the Chinese military approved the vaccine for a year as a “specially needed drug”. On 9 August 2020, the Saudi health ministry announced that CanSino would run a phase 3 trial in Saudi Arabia; later in the month the company also started a trial in Pakistan and Russia. In May 2021, the company registered a phase 4 trial with 300 adult participants who have been primed with either one or two doses of inactive SARS-CoV-2 vaccine. On 5 August 2021, Reuters reported that antibody levels in people inoculated with this vaccine could drop to around 30 percent after six months.

- **BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS (CHINA)**

-  **INACTIVATED VACCINE**

The Beijing Institute is part of China’s state-run Sinopharm Group, and developed its vaccine called BBIBP-CorV, in collaboration with the Chinese Center for Disease Control and Prevention. In phase 3 trials in the UAE, 5,000 people received BBIBP-CorV. In

May 2021 the vaccine was listed for emergency use by the WHO, paving the way for global use. The Institute has launched a phase 4 trial for the vaccine. A phase 3 trial is due to be conducted in October 2021 to assess the safety, immunogenicity and efficacy of two doses of the vaccine, followed by a booster dose in adults 18 years of age and older.

- **JANSSEN/JOHNSON&JOHNSON (USA)**

VIRAL VECTOR VACCINE

J&J has developed vaccines for Ebola and other diseases with Recombinant Adenovirus Serotype 26 (Ad26) and has now made one for the coronavirus. It launched phase 1/2 trials in July 2020, and in September a phase 3 trial with 60,000 participants in Latin America. It hopes to make up to a billion doses in 2021. Janssen began phase 3 trials in the UK in November last year. J&J has committed 500 million doses of this vaccine to the COVAX initiative for distribution worldwide. In January, the company announced that the vaccine had an efficacy of 66% in Latin America, 57% in South Africa and 72% in the United States, with 100% efficacy against severe disease in all trials. In June 2021, the company launched a phase 4 trial in the Netherlands. J&J is among the vaccines in the COVAX portfolio.

- **MODERNA/NATIONAL INSTITUTE OF ALLERGIES AND**

INFECTIOUS DISEASES (US)

RNA VACCINE

In collaboration with the National Institute of Allergies and Infectious Diseases (NIAID), US-based Moderna initially launched a phase 1 trial to test their second COVID-19 vaccine, mRNA-1273.351. The vaccine specifically targets the SARS-CoV-2 Beta variant, which was first identified in the Republic of South Africa. The mRNA-1273.351 vaccine candidate will be given to trial participants in vaccination schedules alone, sequentially, or co-administered with Moderna's first candidate, mRNA-1273, which has already been approved and rolled out in the US. A phase 2 trial, which is also testing the efficacy of the vaccine against COVID-19 in cancer patients, was launched in April 2021 with 120 participants. In June, Moderna launched a phase 4 trial for mRNA-1273.351 in Belgium. On 11 August 2021, results from a phase 2/3 trial suggested that the vaccine was safe to use and efficacious in preventing COVID-19 in adolescents between 12 and 17 years old. On the same day, results from a phase 3 trial of a third-dose vaccine in adult transplant recipients showed that the booster enhanced their immune response. The United States Food and Drug Administration has authorised the use of booster shot in transplant recipients.

- ✓ In use
- Phase 3
- Phase 2/3
- Phase 2
- Phase 1/2
- Phase 1

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The views expressed in this article are those of the author alone and not Gavi, the Vaccine Alliance.

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