

**COVID-19 Vaccines Questions and Answers**

**1. How many vaccines are under development for coronavirus disease 2019 (COVID-19)?**

As of late November 2020, the New York Times Coronavirus Vaccine Tracker listed 55 vaccines in human trials and at least 87 preclinical vaccines were under investigation in animals. A number of antiviral medications and immunotherapies are also under investigation for COVID-19.

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

**2. What are the CDC recommendations for initial distributions of coronavirus disease 2019 (COVID-19) vaccines?**

Recommendations of the CDC’s Advisory Committee on Immunization Practices include administering the first available vaccines to healthcare workers and residents of long-term care facilities. Young children are likely to be lower priority for vaccines because it is young adults who are the main drivers of transmission in the United States.

**3. What are the technology methods used in the development of coronavirus disease 2019 (COVID-19) vaccines?**

In addition to the complexity of finding the most effective vaccine candidates, the production process is also important for manufacturing the vaccine to the scale needed globally. Other variables that increase complexity of distribution include storage requirements (i.e., frozen vs refrigerated) and if more than a single injection is required for optimal immunity. Several technological methods (i.e., DNA, RNA, inactivated, viral vector, protein subunit) are available for vaccine development. Vaccine attributes (i.e., number of doses, speed of development, scalability) depend on the type of technological method employed.

Some methods have been used in previous vaccines, whereas others are more newly developed. For example, mRNA vaccines for influenza, rabies and Zika virus have been previously tested in animals.

**Vaccine Platform Characteristics:**

Platform	Attributes	Doses	Vaccine Candidate (Manufacturer)
mRNA	Fast development; low-to-medium manufacturing scale	2	BNT-162b2 (Pfizer, BioNTech); mRNA-1273 (Moderna)
DNA	Fast development; medium manufacturing scale	2	INO-4800 (Inovio)
Viral Vector	Medium speed of development; high manufacturing scale	1 or 2	AZA-1222 Ad5-CoV (AstraZeneca; Oxford University); Ad26.COVS.2.S (Johnson & Johnson)
Protein subunit	Medium-to-fast development; high manufacturing scale	2	NVX-CoV2372 (Novavax)

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**4. What is the BNT-162b2 coronavirus disease 2019 (COVID-19 vaccine)?**

Referred to as the genetic-code vaccine, this vaccine requires storage and shipping frozen at ultra-cold storage of -70°C. This vaccine also requires reconstitution and once thawed, maintains stability in the refrigerator for up to 5 days. There is only a 2 hour window of stability at room temperature. This vaccine requires 2 injections, 21 days apart.

The vaccine was well tolerated across all populations, and no serious safety concerns were observed. The only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8%; headache occurred in 2% of participants. Short-term mild-to-moderate pain at the injection site was the most commonly reported reaction and severe pain was reported in less than 1% of participants across all age groups. In mid-October 2020, the FDA allowed Pfizer to expand the phase 3 trial to include adolescents 12 years and older.

**5. Which coronavirus disease 2019 (COVID-19) vaccines are likely to be available first?**

On December 18, 2020, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the mRNA-1273 SARS-CoV-2 vaccine in individuals 18 years and older, after its Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to recommend (20 yes, 0 no, 1 abstention) the EUA on December 17.

On December 11, 2020, the FDA granted EUA for the BNT-162b2 SARS-CoV-2 vaccine in patients 16 years and older after its VRBPAC voted to recommend (17 yes, 4 no, 1 abstention) the EUA on December 10.

**6. What is the mRNA-1273 coronavirus disease 2019 (COVID-19) vaccine?**

The mRNA-1273 (Moderna) vaccine is a “genetic code” vaccine. Shipping and long-term storage require freezing at -20°C and may be maintained for 6 months. After thawing, standard refrigerator temperatures of 2-8°C may be maintained for 30 days. The vaccine may be kept at room temperature up to 12 hours. This vaccine requires 2 injections, 28-days apart however requires no dilution.

**7. What is the AZD-1222 coronavirus disease 2019 (COVID-19) vaccine?**

The AZD-1222 vaccine is a “viral vector” and Phase 3 trials were temporarily put on hold globally on September 6, 2020 after a study participant in the United Kingdom was diagnosed with transverse myelitis. The trial was delayed in the United States pending further FDA review of data from this and results of previous trials with technology. As of October 23, 2020, phase 3 trials have resumed. This vaccine only requires refrigeration (not freezing) and requires 2 injections 28-days apart.

**8. What is the Ad26.COVS.S coronavirus disease 2019 (COVID-19) vaccine?**

The Ad26.COVS.S vaccine is a “viral vector” vaccine that requires refrigeration (not freezing) and requires 1 dose. The phase 3 trial (ENSEMBLE) for adenovirus serotype 26 (Ad26) recombinant vector-based vaccine (JNJ-78436735; Johnson & Johnson/Janssen) was launched in September 2020

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with a goal of 60,000 participants in the United States, South Africa and South America. Antibodies to COVID-19 were observed after a single injection in 99% of participants 18-55 years in an interim analysis of phase 1/2a clinical trials. A second phase 3 trial was announced November 16, 2020 to observe effects of 2 doses of the vaccine instead of just 1 dose.

**9. What is the NVX-CoV2372 coronavirus disease 2019 (COVID-19) vaccine?**

The NVX-CoV2372 vaccine is a “subunit vaccine” and requires 2 injections 21 days apart. The U.S. phase 3 trial began in late 2020 with plans to enroll up to 30,000 participants.

**10. Which coronavirus disease 2019 (COVID-19) vaccines are still in earlier phases of development?**

There are currently approximately 17 vaccines in earlier phases of development. Additional vaccine candidates are in various stages of development and clinical testing. Examples of these vaccines can be viewed here: <https://www.medscape.com/answers/2500139-201133/which-coronavirus-disease-2019-covid-19-vaccines-are-still-in-earlier-phases-of-development>

**11. Which noninjectable coronavirus disease 2019 (COVID-19) vaccines are under development?**

There are currently at least 5 non-injectable vaccines under development, and most began Phase 1 trials in the fall of 2020. The list of uninjectable vaccines can be viewed here: <https://www.medscape.com/answers/2500139-201134/which-noninjectable-coronavirus-disease-2019-covid-19-vaccines-are-under-development>

<https://emedicine.medscape.com/article/2500139-questions-and-answers>

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