

# CORONAVIRUS



## COVID-19 VACCINE FACT SHEET

Coronavirus (SARS-CoV-2) is a highly contagious disease that spreads easily from person to person whether symptomatic or not.

Although most people who become infected only develop mild to moderate symptoms, the percentage of people who develop severe or life-threatening symptoms has overwhelmed healthcare systems in even the wealthiest countries. Mathematically, there are simply not enough ICU beds, ventilators or healthcare personnel to treat all those who need advanced care.

The COVID-19 vaccine will prevent illness, disability and death, as well as help stop the spread of the disease and bring an end to this pandemic. Getting vaccinated is safer than building immunity by contracting COVID-19.

### **How is the vaccine developed and how does it work?**

There are many different types of vaccines, but they all work to build your body's immunity by imitating the infection they are meant to protect against. Vaccines safely expose the body's immune system to an inactive, killed or cut apart virus or microorganism of interest that cannot actually cause the infection. In response to receiving a vaccine, the body is then primed to produce T-lymphocytes, antibodies and other immune factors against the real virus or microorganism.

It typically takes a few weeks for the body to produce immunity after vaccination, and some may experience mild symptoms (such as a fever) known as reactogenicity. Mild symptoms are normal and expected as the body builds immunity. If you got the vaccine and are exposed to someone with the actual virus, it is possible to become infected if your body has not had enough time to build immunity.

### **How were COVID-19 vaccines developed so quickly when other vaccines took years or even decades?**

The short answer is technology. In January 2020, the first novel coronavirus genome sequence was made publicly available, deposited in the GenBank database and uploaded to the Global Initiative on Sharing All Influenza Data (GISAID). Scientists with the knowledge and ability had everything they needed to begin vaccine development. In addition, advances in manufacturing platforms, structure-based antigen design, computational biology, protein engineering and gene synthesis make it possible to develop vaccines more quickly and with precision.

### **Have COVID-19 vaccines been rigorously tested?**

Yes. All vaccines, including COVID-19 vaccines, must go through a rigorous approval process that involves different phases of clinical trials or scientific study. If, at any point, a significant side effect or risk occurs, the study is stopped and the event is investigated before the study can proceed. Clinical trials evaluate investigational COVID-19 vaccines in tens of thousands of study participants to generate the scientific data and other information needed by the Food and Drug Administration (FDA) to determine safety and effectiveness. These clinical trials are conducted according to the rigorous standards set forth by the FDA.

Clinical trials also provide additional information on common short-term side effects and risks, examine the relationship between the dose administered and the immune response, and provide initial information about the effectiveness of the vaccine. In phase 3 trials, the vaccine is generally administered to thousands of people in randomized, controlled studies involving broad demographic groups — giving scientists critical information on effectiveness and the immune response in people who receive the vaccine compared to those who receive a control, such as a placebo.

The FDA's evaluation for emergency use authorization (EUA) for a COVID-19 vaccine includes chemistry, manufacturing and control information. Sufficient data must be submitted to ensure the quality and consistency of the vaccine. The FDA uses all available tools and information — including records reviews, site visits and previous history — to assess compliance with current best manufacturing practices.

### Are COVID-19 vaccines safe?

Yes. Once any COVID-19 vaccine receives its EUA, it will be considered safe. The FDA will not issue an EUA for a vaccine if the safety data is in question. Before an EUA can be issued for a vaccine, the FDA must first determine that the known and potential benefits outweigh the known and potential risks. An EUA request for a COVID-19 vaccine is submitted to the FDA based on a final analysis of a phase 3 clinical trial efficacy or an interim analysis of the trial (i.e., an analysis performed before the trial ends and once the data have met the pre-specified success criteria for the study's primary efficacy endpoint).

An EUA submission includes all safety data accumulated from phase 1 and 2 studies, with an expectation that phase 3 data includes a median follow-up of at least two months after completing the full vaccination regimen. In addition, the EUA request includes a phase 3 safety database of more than 3,000 vaccine recipients who represent a high proportion of participants enrolled in the phase 3 study who have been monitored for serious adverse events for at least one month after completing of the full vaccination regimen.

Both the Pfizer and Moderna vaccines have applied for emergency use authorization from the FDA. Safety and effectiveness data for the Pfizer and Moderna vaccines are available on the [FDA website](#).

Once the EUA is issued, the vaccine development process is not complete. The FDA expects the vaccine manufacturer to continue active follow-up for safety — including deaths, hospitalizations, and other serious or clinically significant adverse events — among individuals who receive the vaccine under an EUA to inform ongoing benefit-risk determinations to support continuation of the EUA. The FDA also expects manufacturers that receive an EUA to continue their clinical trials to obtain additional safety and effectiveness information and pursue full licensure. **It is important to note that if an adverse event occurs in reaction to a vaccine, it typically happens immediately or within seven days of the vaccination.**

### Are there any known side effects of the COVID-19 vaccines?

At this time, the vaccines may present minimal side effects that include pain, soreness and redness at the injection site; body aches; fatigue; and mild fever that may present for up to 48 hours following the injection. To date, no serious safety or health concerns regarding the vaccine have been reported. The Pfizer and Moderna vaccines are molecular RNA based (not a live virus) and both vaccines have a 95% efficacy rate in comparison to a 40-60% efficacy rate of the influenza (flu) vaccine. The vaccines provide antibodies and T-cell immunity against the SARS-CoV-2 virus.

### What are the checks and balances on the FDA's final decision?

Although the final decision to issue an EUA to a vaccine manufacturer rests with the FDA commissioner and professional staff, the FDA also considers input from the Vaccines and Related Biological Products Advisory Committee. This committee is comprised of scientific and public health experts from around the country and helps ensure clear public understanding of the scientific data and information that the FDA evaluates in making a decision about whether to authorize a vaccine for emergency use for the prevention of COVID-19.

### What else is known about these first vaccines?

Both vaccines are messenger RNA (mRNA) vaccines, a new technology not previously used commercially to prevent infections. These vaccines do not alter DNA. Messenger RNA vaccines function on the premise that mRNA coded for coronavirus antigen can be delivered to human cells and, once there, can be used for production of antigen within the cell. This is unique in that it leads to a robust immune response without the introduction of live, killed or subunit portions of coronavirus. However, because mRNA is highly vulnerable in the body and can be quickly degraded, it needs the protection of a tiny fat bubble for delivery. This delivery method is also a new way to deliver vaccines into the body that has not been previously used in commercial vaccines.

### Learn More About COVID-19 Vaccines

[The Centers for Disease Control and Prevention \(CDC\)](#)

[World Health Organization \(WHO\)](#)

[Food and Drug Administration \(FDA\)](#)