

**Published: January 2021**

## **Eight reasons why COVID-19 vaccines have been created so quickly - and why they're safe and effective**

Remarkable technology has fuelled the development of the various COVID-19 vaccines being produced around the world. Let's explore the reasons for their rapid development and explain the rigorous process that each vaccine goes through before being approved for use.

How well do you understand the processes that COVID-19 vaccines (and all other vaccines) go through to ensure their ultimate safety? Here's a summary of the journey:

First, they go through a rigorous, multi-phase testing process including large, phase 3 clinical trials that involve tens of thousands of people. These trials are specifically designed to identify any common side effects or other safety concerns.

### **What are clinical trials?**

Clinical trials refer to research that is done to answer a specific question about a medical product. These trials typically start with early research and then progresses to small-scale, late-stage and large-scale research. In a **phase 1** clinical trial, the safety of a medical product like a medicine or vaccine is studied, normally in a small number of healthy volunteers. In **phase 2**, researchers look at the medicine's efficacy and the optimal doses needed. If all goes well, the trial proceeds to phase 3 (involving 3 000 or more participants). In **phase 3**, the focus is on showing and confirming the evidence found in the previous phases and to prove that a medicine or vaccine is safe, beneficial and effective for its intended purpose in a larger population of people.

Once a clinical trial has shown that a vaccine is safe and effective, a series of independent reviews of the efficacy and safety evidence is required. **Efficacy** refers to the extent to which the vaccines are beneficial for people to take. These include regulatory review and approval in the country where the vaccine is manufactured.

All this needs to happen before the World Health Organization (WHO) considers a vaccine for what is called 'pre-qualification'.

Vaccines that pass each level of scrutiny are then reviewed by an external panel of experts convened by the WHO. This panel, which is independent from the vaccine producer, analyses the clinical trial results of each vaccine along with other information and recommends whether the vaccine should be used, and if so, how the vaccine should be used.

## **Eight fascinating reasons why the COVID-19 vaccines available to us have been created in such a short time**

1. The genetic sequencing information about SARS-CoV-2 (the virus that causes COVID-19) was published on 11 January 2020. Immediately, scientists began using this information to design mRNA vaccines.
2. Vaccine developers had a head start on the academic research into coronaviruses due to past SARS and MERS outbreaks, which prompted lots of research into these virus types. This is also why we were able to develop a test for COVID-19 so quickly.
3. Various steps in the vaccine development process - from safety trials and efficacy trials to manufacturing and distribution planning - happened simultaneously rather than one after the other. This was due to the high priority of the vaccine development process and massive funding available, which together ensured that every step of the process was completed in full.
4. Two prominent COVID-19 vaccines (those from Pfizer and Moderna) are based on messenger RNA (mRNA) technology. Another vaccine (the one developed by AstraZeneca) is based on DNA technology. To manufacture most traditional vaccines, they must be grown in laboratory cultures. This process can take months. Fortunately, DNA and mRNA vaccines do not rely on this long process of growing the virus in the lab. Instead, the developers of DNA and mRNA vaccines use insights into the virus's genetic sequence, which significantly speeds up the manufacturing process. This is because these vaccines can be produced using readily available materials.
5. Importantly, the massive financial investment put towards development of the vaccines across the world has fuelled the pace of development. This investment has funded research and large clinical trials to prove efficacy and safety.
6. There was an abundance of trial participants (unlike in the case of a vaccine developed for a rarer disease), which meant the trials happened faster than in the case of other vaccines. These unsung heroes played a huge role in accelerating the process of vaccine development and testing.
7. All parties involved in vaccine developments worked around the clock on this global priority.

### **Did you know that the technology that the current COVID-19 vaccines are based on has been around for decades?**

Global efforts to develop a vaccine against COVID-19 began after the genetic sequencing of SARS-CoV-2, the virus that causes COVID-19 disease. The results were published on 11 January 2020.

While it's the first time that mRNA technology is being used in a vaccine, researchers have been studying this technology for decades. Interestingly, most research into using mRNA to stimulate the immune system has so far been focused on cancer. Tumour mRNA is used to help people's immune systems recognise and respond to the proteins produced by their specific tumours.

In fact, there are now hopes that this technology could really boost efforts to immunise people against other diseases, like malaria, HIV and even the flu. Some experts believe that we are entering the era of RNA vaccines in a broad sense.

And, according to the US Centers for Disease Control and Prevention: "Future mRNA vaccine technology may allow for one vaccine to provide protection for multiple diseases, thus decreasing the number of shots needed for protection against common vaccine-preventable diseases."