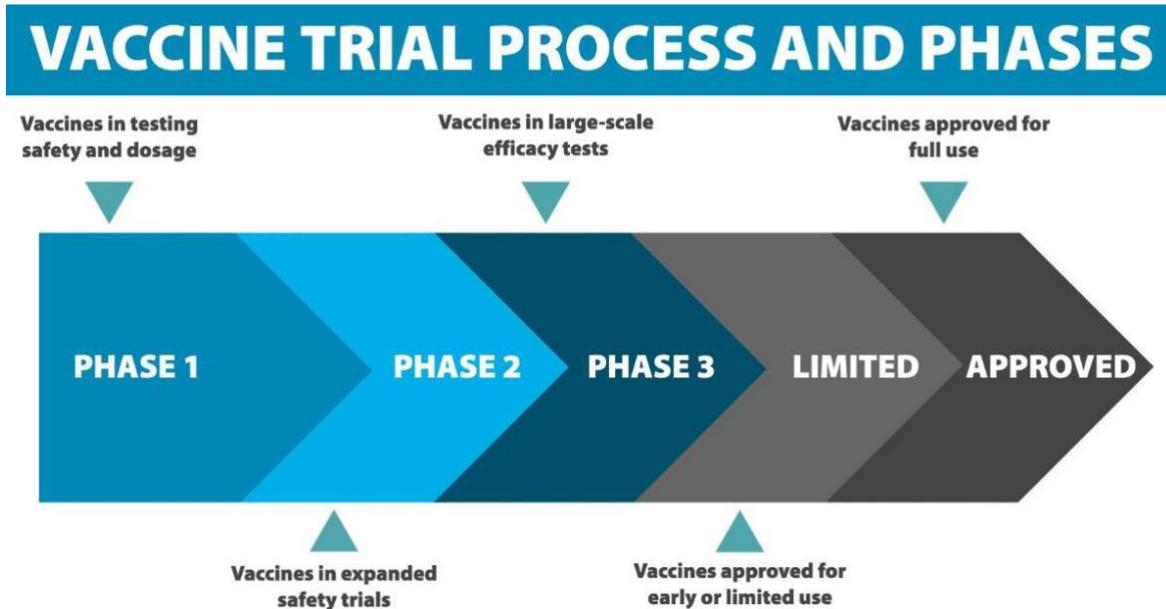


COVID-19: Steps to Approve a Vaccine

Before vaccines become available to the public, they must first undergo vigorous review for safety and effectiveness. Below are the steps for vaccine approval.



Preclinical

Scientists test a new vaccine on cells and then give it to **animals** such as mice or monkeys to see if it produces an immune response.

Phase 1 Safety Trials

Scientists give the vaccine to a **small number of people** to test safety and dosage and to confirm that it stimulates the immune system.

Phase 2 Expanded Trials

Scientists give the vaccine to **hundreds of people** split into groups, such as children and the elderly, to see if the vaccine acts differently in them. These trials further test the vaccine's safety and ability to stimulate the immune system.

Phase 3 Efficacy Trials

Scientists give the vaccine to **thousands of people** and wait to see how many become infected, compared with volunteers who received a placebo. These trials can determine if the vaccine protects against the coronavirus. Phase 3 trials are large enough to reveal evidence of relatively rare side effects that might be missed in earlier studies.

Approval

Regulators review the trial results and decide whether to approve the vaccine or not. During a pandemic, a vaccine may receive emergency use authorization before getting formal approval. Once a vaccine is licensed, researchers continue to monitor people who receive it to ensure it's safe and effective.

Vaccines Undergo Rigorous Scientific Review

Vaccine approval must be driven by science. Independent advisory committees to the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) review vaccine safety and effectiveness data before any vaccine is approved or allowed for distribution under [Emergency Use Authorization](#). Colorado relies on the CDC's [Advisory Committee on Immunization Practice \(ACIP\)](#) to provide guidance on distribution and use of potential COVID-19 vaccines.

Distribution Process

While the State is planning to act swiftly, the distribution process could take several months, or potentially more than a year, to distribute to everyone who wants a vaccine. Because the initial supply of vaccine is very limited, it will be distributed first to people most at risk for COVID-19, such as health care workers, first responders and staff/residents of long-term care facilities and nursing homes. The next phase of vaccinations will be available to higher risk individuals and essential workers. The final phase will be for the general population.

[Click to view the Phased Distribution Approach table.](#)