


Vaccines Families Can Trust	"Vaccines Families Can Trust" was created and translated October 20, 2023 by the Multilingual Health Education Alliance (M-HEAL). [English]	
	This document is based on recommendations of the U.S. Centers for Disease Control and Prevention as of Feb. 10, 2023	
How Vaccines are Tested and Approved		
Testing in the Laboratory	<p>Scientists spend many years testing a vaccine in the laboratory to see if it can protect someone from a specific disease.</p> <p>If the test results look good, the U.S. Food and Drug Administration (FDA) can approve safety tests with people.</p>	
Phase 1 Testing with People: Safety & Dose	<p>During the first phase of testing with 20-100 volunteers, scientists study vaccine safety and side effects. They also determine the right dose of the vaccine.</p>	
Phase 2 Testing with People: Side Effects & Immune Response	<p>During the second phase of testing with hundreds of volunteers, scientists learn which side effects are most common. They also check the body's response to the vaccine to ensure it is strong enough to prevent the disease.</p>	
Phase 3 Testing with People: Benefits	<p>During the third phase of testing with thousands of volunteers, scientists compare how well the vaccine protects people who receive the vaccine compared to people who do not. Scientists also look for more side effects and any vaccine safety problems.</p>	
If the vaccine is successful in all three phases, the FDA reviews all of the scientific data to consider approving the vaccine for use in people.		
The FDA approves the vaccine IF:	<ul style="list-style-type: none"> • It's safe and it works • The benefits outweigh the risks • The vaccine manufacturer meets safety regulations 	
Vaccine manufacturing facilities are required to undergo FDA safety and quality checks throughout manufacturing.		
Doctors and other experts make recommendations for using the vaccine	<p>The Advisory Committee on Immunization Practices (ACIP) reviews all the scientific data about the vaccine. They make a recommendation to the CDC about whether or not to use it and who (children, for example) should get it. The CDC Director then decides if the vaccine will be added to the U.S. vaccine schedule.</p>	
After this, vaccines are continuously monitored for safety.		
<ul style="list-style-type: none"> • Vaccine manufacturing facilities continue to undergo FDA safety and quality checks • Anyone can submit a report to the CDC about a serious health problem they experienced after vaccination • Scientists use medical data from millions of people to keep looking for vaccine safety problems • If a vaccine is found to be unsafe, the FDA and CDC withdraw their approval, and the vaccine can no longer be given in the United States. 		