# How Vaccines Are Made



## The Vaccine Research and Development Process

Before vaccines are produced, they go through a long process of research and development. Often, this takes 10 to 15 years! New vaccines and vaccine technologies are studied every day. For example, researchers spent 25+ years researching the mRNA platform used to create COVID-19 vaccines. After development, the vaccine is carefully tested in clinical trials before being approved for use in the public. **Here's how it works:**

### Step 1: Testing

Researchers test vaccines in human cells in petri dishes first. If it's promising, they move on to testing in mice and adjust as needed to make sure it is safe and effective.

### Step 2: Clinical Trials

The next step is clinical trials that start with just a few people but if successful grow to include thousands of healthy volunteers. Clinical trials measure how safe the vaccine is in humans and monitor closely for common side effects. The exact type of trial used for vaccine research largely depends on what researchers are trying to learn and what can be done safely and ethically.

#### Do all trials include a saline placebo?

When a vaccine doesn't already exist for a disease, a placebo is used to test against the new vaccine. The placebo is often saline, or salt water. But when a vaccine does exist, the existing vaccine is used to test against the new vaccine instead. That's because **it would be unethical to deprive someone of a potentially life-saving treatment that already exists.** Sometimes an adjuvant or another vaccine is used as a placebo. This helps keep the study "blind" (so both the researcher and participant are unaware whether the participant received the new vaccine or the placebo) because it can still prompt common vaccine side effects like redness and pain at the injection site.

### Step 3: FDA Review

The Food and Drug Administration (FDA) reviews all the data from the research and development process and votes on whether or not to approve and license the vaccine.

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## Step 4: Recommendation

Professional organizations meet to decide on whether to recommend it to the US population (or just a specific group of people at risk for that vaccine-preventable disease).

## Step 5: Safety Monitoring

After the vaccine becomes publicly available, researchers continue to monitor the vaccine while it's in use to ensure it continues to be safe. There are multiple vaccine safety monitoring systems in use in the U.S.

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Vaccines defend against pathogens like bacteria or virus. They are made using products from, pieces of, or genetic instructions to make pieces of a pathogen. Every vaccine ingredient is carefully tested for safety. Whole bacteria or viruses are weakened or killed before they are used. This allows your immune system to train and develop antibodies, or defenders, against the pathogen without getting sick. First, researchers determine how the pathogen will be modified to make it safe and effective. Next:

1. An antigen is *made*. An antigen is the active ingredient – something that causes the immune system to produce memory cells and antibodies that protect against future infection. Antigens are made from viruses or bacteria. In some vaccines, instead of a physical antigen, a genetic "blueprint" is used that instructs your own cells to safely manufacture the antigen temporarily. mRNA COVID-19 vaccines are an example of this.
2. The antigen is *separated* out from the cells used to create it.
3. The antigen is *combined* with other vaccine ingredients, including stabilizers, preservatives, and sometimes adjuvants:
   - **Stabilizers** increase the vaccine's storage life. These keep the vaccine from changing when it is exposed to heat, light, or humidity.
   - **Preservatives** prevent contamination of vaccines, such as bacteria that might grow in vials that hold multiple doses.
   - **Adjuvants** help boost the body's immune response to a vaccine. Without them, some vaccines would be less effective and require more doses.

   Typically, vaccines only have trace amounts of these components. They have much less than children encounter in their daily environment, food, and water.

# The Bottom Line

Vaccine trials are designed to answer specific questions while prioritizing patient safety, vaccine efficacy, and ethics. Vaccines are carefully studied, before and after approval, to ensure safety. This means you can be confident in the decision to vaccinate your child and ***Immunize For Good!***

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