

ALL ABOUT CLINICAL TRIALS



The treatments and medications available for food allergies today did not just appear overnight. They have been carefully tested and thoroughly evaluated. Patients with food allergies and their families have given their time to help researchers find better ways to treat and manage the disease.

What is a Clinical Trial?

A clinical trial is a controlled research study that tests new medications to ensure they are safe, determine the best dosage(s), and assess whether they achieve their desired effect. Nearly all medicines that your doctor can prescribe went through a series of rigorous clinical trials.

Clinical trials are usually conducted at major medical centers. Funding for a study may come from different places, including the federal government, nonprofit organizations, and pharmaceutical or biotechnology companies.

In a clinical trial, researchers look for answers to the following questions:

- ✖ Is this medication safe?
- ✖ Does it help people?
- ✖ What side effects could it cause?
- ✖ Does it work for people from different backgrounds (for example, different races, ethnicities, and ages)?

How Does a Clinical Trial Work?

Before a clinical trial even begins, the medication must show positive results in a laboratory setting or in animal studies. After that, there are typically four trial phases:

- ✖ **Phase 1:** The new medication is given to a small group of people to make sure it is safe, find the best way to give it (such as a shot, pill, or other method), and learn about any side effects it may cause.
- ✖ **Phase 2:** Researchers study how well the medication works in people, how different doses affect patients, and gather more information about its safety and possible side effects.
- ✖ **Phase 3:** In this phase, the medication may be compared to treatments that are already available. Participants are often randomly placed into different groups. Some receive the medication being tested, while others receive a placebo, which looks like the medication but does not contain any active medicine. This helps researchers determine whether any changes in symptoms, side effects, or health outcomes are caused by the medication.
- ✖ **Phase 4:** After the medication is approved by the Food and Drug Administration (FDA) and available to the public, researchers continue to study long term safety, effectiveness, and best use of the treatment across the full range of patients.

Benefits and Risks

There are benefits and risks to being part of a clinical trial. It is important that you understand both the possible benefits and risks before joining a study. You always have the right to say yes, no, or change your mind.

Possible Benefits

- ✖ Access to a new medication that is not otherwise available to the public
- ✖ Close monitoring by a team of doctors, health professionals and researchers
- ✖ The chance to help others with a medical condition/disease

- ✦ Payment you for your participation, time and travel (in some cases)

Possible Risks

- ✦ Side effects, including possible negative or serious side effects that require medical attention
- ✦ The treatment may not work for you or your specific medical condition
- ✦ If you are in a trial with different groups, you may not be receiving the standard treatment or medication (for example, you may receive the placebo)
- ✦ The time and potential expenses of attending additional study-related appointments and travel to clinical trial sites

Privacy in Clinical Trials

Your personal information is protected in a trial. Whenever possible, your personal information (name, birthdate, email, etc.) is removed from your medical information. That means that your name cannot be connected to your information. Additionally, trials must have the following:

- ✦ Informed consent, which explains what happens during the trial and how your data is used and protected
- ✦ Approval from an ethics review board to make sure the study is safe and ethical
- ✦ Continuous monitoring to protect your privacy and well-being

Clinical Trials and Food Allergy

Food allergy research is growing quickly, and clinical trials help answer important questions about treatments, causes, diagnosis, daily management, and long-term outcomes.

What to Ask Before Joining a Food Allergy Clinical Trial

- ◆ What is the research and why is it being done?
- ◆ Who will be monitoring my care during this trial?
- ◆ What will I have to do?
- ◆ What are the possible benefits?
- ◆ What are the possible risks, including adverse side effects?
- ◆ Does this study have different groups? If so, are some participants getting a placebo?
- ◆ Will I ever be told if I am getting the real medication?
- ◆ What are the chances I get the experimental drug rather than a placebo?
- ◆ How could this help me now or in the future?
- ◆ Where will I have to go?
- ◆ What is the time commitment?
- ◆ How long is the study?
- ◆ What safety steps are in place?
- ◆ How is my privacy protected?
- ◆ Will it cost me anything?
- ◆ Is there compensation for my time? If so, how much and when will I receive it?
- ◆ Can I leave the trial at any time?
- ◆ Does participation affect my current medical care?
- ◆ Who do I contact with questions, including adverse side effects?

Clinical trials for food allergy need participants of all backgrounds, races, ages, cultures, and lived experiences. This helps researchers see if a medication or treatment will work AND be safe for patients from all different backgrounds. When more people participate, diversity increases and the results become stronger for everyone.

Where to Find a Food Allergy Clinical Trial

FARE's website lists several resources that you can use to find a clinical trial. You can search by location, participant age, allergen(s), type of study, and more. Go to foodallergy.org/resources/clinical-trials.

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