

Women in Clinical Trials

Make a Difference For Yourself
and For Women Like You.



Clinical trials are research studies that help to show whether a test or treatment works and is safe. There are many ways you can take part in a trial. Some trials ask you questions about treatments you already take. In other trials, you take a new drug. Some clinical trials use healthy people. Others use people who have a specific health problem.

Ask your healthcare provider if a clinical trial is right for you.

Are Women in Clinical Trials?

Yes. Women are already in clinical trials. However, women from diverse backgrounds still need to participate. Women of all ages, racial and ethnic groups, and women with disabilities or chronic health conditions should think about being in a clinical trial.

You can help by considering a trial for yourself. You can make a difference by helping doctors learn more about women's health.

Why Should Women Participate?

Medical products can affect men and women differently. It is important that women participate because women sometimes have different side effects. A woman's body can also affect how drugs and devices work.

FDA Office of Women's Health
www.fda.gov/womeninclinicaltrials

15 Things You Should Know Before You Join a Clinical Trial

Being in a clinical trial is your choice. You should not feel pressured to join. **You have the right to quit at any time.** There are rules to protect people in clinical trials

Informed consent is the process of learning the key facts about the clinical trial before you join. This list is not everything you need to know, but it will help you start the conversation. Make sure that you have your questions answered before you agree to participate. Find out:

The Purpose and What Will Happen

1. The purpose of the study
2. The drugs, tests, and treatments you may receive

3. How long the study will last and how many times you will have to come
4. How they will keep your information private
5. What happens when the study ends

The Possible Risks and Benefits

The trial may provide treatments or screenings, but there is no promise that your health will get better. The medicine, test, or treatment may not work for you.

6. The benefits of the treatments
7. The risks and side effects of the treatments
8. Any treatments or other options for people with your disease
9. If you can take your other medicines

Any Other Support or Possible Costs

- 10.** What treatment or services the study will pay for
- 11.** If the study offers child care or transportation
- 12.** The costs you may have to pay
- 13.** What your insurance will cover

How to Get More Information

- 14.** Who you should contact if you have questions or problems
- 15.** How you will get the results

What is FDA's Role?

The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use. FDA does not develop new treatments or conduct clinical trials.

The FDA Office of Women's Health is partnering with the NIH Office of Research on Women's Health on an initiative to promote the participation of diverse women in clinical trials. To learn more about these activities, go to:

www.fda.gov/womeninclinicaltrials

