

# Women in Clinical Trials

A clinical trial is a research study that tests how medical treatments work. Clinical trials help to show if medical products, tests, and other treatments are safe and effective.

Clinical trials are done with people not animals. Some clinical trials use healthy people to test new treatments. Other trials use people who have a specific health problem that the research is studying. Whether you are a healthy or patient volunteer, you may not get any direct benefit from being in the clinical trial. The treatments may not work for you.

Use this fact sheet to help you talk to your healthcare provider about whether a clinical trial is right for you.

## Why should women participate?

Medical products can affect men and women differently. Sometimes women have different side effects. It is important that women participate to show if products are safe and work well in both men and women.

More women are included in clinical trials than in the past. However, women still need to participate. Your participation may benefit other women by helping doctor's learn more about women's health.

## What should I know before I participate?

Talk to the researcher to get the facts about the clinical trial before you join. Find out:

### The Purpose and What Will Happen

- the purpose of the study
- the drugs, tests, and treatments you will receive
- how long the study will last and how many times you will have to come
- how they will keep your information private
- what happens when the study ends

### Possible Risks and Benefits

- the benefits and the risks/ side effects of the treatments
- any other treatments you could get
- if you can take your other medicines

### Costs

- the costs you may have to pay
- what will your insurance cover
- if the study offers child care or transportation



# Women in Clinical Trials (continued)



## Contact Person

- who you should contact if you have questions or problems
- how you will get the results

## What is informed consent?

Informed consent is the process of learning the key facts about the clinical trial before you join. Make sure that you have your questions answered before you agree to participate.

Being in a clinical trial is your choice. You should not feel pressured to join. You have the right to quit at any time.

## What is FDA's role?

FDA does not run clinical trials. FDA, other government agencies, and review boards set rules to protect people who participate in clinical trials. FDA also inspects some clinical trials for products regulated by FDA.

## How does FDA use clinical trials data?

FDA uses the information from clinical trials and other sources to decide if a product is safe and effective. FDA reviews the information for certain kinds of new products before they are approved to be sold to the public. Not all products are tested in clinical trials.

## How can I learn more about clinical trials?

- FDA has a website to help patients and their doctors learn about clinical trials, drug safety, and much more. Visit the FDA patient network at:  
**[www.patientnetwork.fda.gov](http://www.patientnetwork.fda.gov)**
- The National Institutes of Health (NIH) also has a website where you can search for clinical trials and learn more about participating in clinical research. Visit the website at:  
**[www.nih.gov/health/clinicaltrials/index.htm](http://www.nih.gov/health/clinicaltrials/index.htm)**

**To get other women's health materials, go to:**

**[www.fda.gov/womens](http://www.fda.gov/womens)**