

CENTERS FOR MEDICARE & MEDICAID SERVICES



Medicare & Clinical Research Studies





You may have the choice to join a clinical research study to diagnose or treat an illness. If you join a covered clinical research study, Medicare will help pay for some of your costs.

What are clinical research studies?

Clinical research studies (also called clinical trials) may involve diagnostic tests, surgical treatments, medicine, or new types of patient care. These studies may:

- Study how well new treatments and tests benefit patients
- Compare different treatments for the same condition to see which treatment is better
- Study new ways to use existing treatments

These studies help doctors, researchers, and patients see if the new care improves patient health.

Should I join a clinical research study?

Before you decide to join a study, it's important to think about the benefits and risks that might be involved.

Benefits may include:

- Your health care may be provided by top doctors or facilities
- You may have access to new drugs and treatments before they're widely available
- Your health care will be monitored closely for any side effects
- You can take a more active role in your own health care



Should I join a clinical research study? (continued)

- You may be among the first to benefit if the approach being studied is found to be helpful
- You'll have the chance to make an important contribution to research that may help other people who have the same illness

Risks may include:

- You may experience serious side effects from new drugs and treatments that your doctors can't reasonably anticipate
- You may get drugs and/or treatments that aren't effective, or are less effective, than current approaches
- You may not benefit from a new approach that may benefit others
- Studies may require a lot of your time and frequent trips to the study site

Before you agree to take part in a study, someone involved in the study will explain it to you. Then you'll be asked to sign an informed consent form. This form describes the clinical research study and what's being tested. The form will also explain any anticipated risks.

Before you sign the form, ask questions so you understand and are comfortable with what will happen during the study. You should feel free to ask any questions or bring up any issues you have about the study at any time.



What's a placebo, and will I be given one?

A placebo is an inactive substance (like a sugar pill) or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested in a clinical research study.

Many clinical research studies compare a new treatment with an existing treatment (a treatment currently known for a disease based on past research). In some of these studies, patients are randomly put in one group or another. If there isn't an existing treatment, a study may compare a new treatment with a placebo to find out if the new treatment has any effect on the condition being studied. You'll be told if you might be given a placebo before you decide whether to take part in the study. Once you're in the study, you won't know if you're taking the placebo or the drug being tested.

Will I have to pay for any part of the study?

Medicare pays for routine costs of items and services in covered research studies. Examples of these items and services include:

- Room and board for a hospital stay that Medicare would pay for even if you weren't in a study
- An operation to implant an item that's being tested
- Treatment of side effects and complications that may occur as a result of the study



Will I have to pay for any part of the study? (continued)

Medicare **won't** pay for:

- The new item or service that the study is testing unless Medicare would cover the item or service even if you weren't in a study
- Items and services the study gives for free (many times the treatment will be provided free by the study sponsor)
- Items or services used only to collect data and not used in your direct health care (like monthly EKGs for a condition that usually requires only a yearly EKG)
- Coinsurance and deductibles

I'm in a Medicare health plan. Can I still be in a clinical research study?

Yes. If you're in a Medicare Advantage Plan (like an HMO or PPO) or other Medicare health plan, you can get the same coverage for clinical research studies as a person in Original Medicare, as described in the previous section.

Once you join a Medicare-covered clinical research study, Medicare will pay for your covered services as if you were in Original Medicare. This means that your Medicare health plan can't keep you from joining a clinical research study. However, you should tell your plan before you start a study. That way, the plan can still keep track of your health care services.



Will my employer group health plan cover the costs in a clinical research study?

Whether your employer plan covers all or some of the costs depends on the following:

- The rules of your employer plan
- Whether the employer plan or Medicare pays your bills first

Before you join a study, check with your employer plan or your benefits administrator to find out what will be covered. For more information on who pays first, visit www.medicare.gov/publications to view the publication “Medicare and Other Health Benefits: Your Guide to Who Pays First.” You can also call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Will my Medicare Supplement Insurance (Medigap) policy pay for my costs if I’m in a clinical research study?

If Medicare covers the routine costs of your study, then your Medigap policy must pay the same as it would for any other Medicare-covered services.

However, if Medicare doesn’t cover a certain cost of the study, in most cases your Medigap policy won’t provide any benefits. You should contact the insurance company that provides your Medigap policy for more information.



I'm in a Medicare drug plan. If I join a clinical research study that tests a prescription drug, will my plan cover the cost of the drug?

The drug might be covered under very limited circumstances, so contact your plan for more information.

Where can I get more information?

To find out more about clinical research studies, you can:

- Talk to your doctor.
- Visit www.clinicaltrials.gov. This website is a service of the National Institutes of Health (NIH), and it lists government and private studies across the country. It also has more information to help you understand clinical research studies.



Where can I get more information? (continued)

To find out about cancer research studies, these resources are available through the National Cancer Institute:

- Call 1-800-4-CANCER (1-800-422-6237) for free cancer information and help finding cancer clinical research studies. TTY users should call 1-800-332-8615.
- Visit www.cancer.gov/clinicaltrials. This website lists studies for patients with cancer and detailed information about cancer clinical research studies. If you don't have a computer, your local library or senior center may be able to help you find this information.