
CANCER FACTS

National Cancer Institute • National Institutes of Health
Department of Health and Human Services

TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement

Key Points

- The agreement allows TRICARE beneficiaries to participate in certain cancer prevention and treatment clinical trials sponsored by the National Cancer Institute (NCI) (see Introduction).
- Costs for screening tests to determine clinical trial eligibility and costs related to participating in the trial are covered under this agreement (see Question 8).
- More information about participating in clinical trials is available from NCI's Cancer Information Service, NCI's Cancer.gov Web site, and the regional Department of Defense cancer trials demonstration project coordinator (see question 9).

An interagency agreement between the Department of Defense (DoD) and the National Cancer Institute (NCI) gives TRICARE* beneficiaries more options for cancer care and greater access to the latest advances in cancer prevention and treatment through clinical trials. Known as the DoD/NCI Cancer Clinical Trials Demonstration Project, this agreement was signed in June 1999. It represents the first time that a national health plan has agreed to provide coverage for patients to participate in cancer prevention trials.

The DoD/NCI clinical trials agreement allows cancer patients who are beneficiaries of TRICARE, the medical program of the DoD, to participate in phase II and phase III

* TRICARE provides medical coverage for active duty members, qualified family members, CHAMPUS-eligible retirees and their family members, and survivors of all uniformed service members.



NCI-sponsored cancer prevention clinical trials (including screening and early detection) and treatment clinical trials and have the associated medical costs reimbursed. Phase II trials study the safety and effectiveness of an agent or intervention, and evaluate how it affects the human body. Phase III trials compare a new agent or intervention (or new use of a standard one) with the current standard therapy. More than 25,000 cancer patients enroll in NCI treatment clinical trials each year.

During a cancer clinical trial, patients are cared for in the same facilities where standard care is provided. These facilities include more than 2,000 sites throughout the United States, including military hospitals, clinics, cancer centers, community hospitals, and doctors' offices. Costs for screening tests to determine clinical trial eligibility, and the associated costs of participation in cancer clinical trials are covered for qualified TRICARE members. Family members of active duty personnel, as well as TRICARE-eligible retired service members and their families, may participate in trials at military treatment facilities or in civilian health care settings. Active duty members may participate in NCI-sponsored clinical trials at military treatment facilities.

DoD's primary medical mission is to provide medical services and support to the Armed Forces during military operations. DoD also offers health services during peacetime to members of the Armed Forces, their family members, and others entitled to DoD medical care. The DoD administers health benefits to about 8.7 million beneficiaries through its direct care system at military hospitals and clinics, as well as care purchased from civilian providers who are reimbursed by DoD.

Questions and Answers About the DoD/NCI Clinical Trials Agreement

1. What are clinical trials?

Clinical trials are research studies conducted with people to find better ways to prevent, detect, diagnose, and treat diseases such as cancer. The DoD/NCI clinical trials agreement allows TRICARE beneficiaries to participate in NCI-sponsored phase II and phase III cancer prevention and treatment trials. Under this agreement, cancer prevention clinical trials will include not only studies designed to prevent cancer but also studies to screen for cancer and to find cancer in its early stages (early detection).

2. What happens in phase II and phase III cancer prevention clinical trials?

- A **phase II** cancer prevention trial focuses on learning whether the agent being studied (medicine, vitamin, mineral, food supplement, or a combination of these) has an effect on preventing a particular type of cancer. It may also involve the use of cancer screening tests or evaluation of a method to better detect a cancer.
- A **phase III** cancer prevention trial compares promising new agents with a standard agent or a placebo (an inactive substance that looks the same as, and is administered in the same way as, a drug in a clinical trial). Some phase III trials evaluate cancer screening tests to see if they can decrease the cancer death rate.

3. What happens in phase II and phase III cancer treatment clinical trials?

- A **phase II** cancer treatment trial usually focuses on a particular type of cancer and provides preliminary information on the anticancer effect of a new drug or therapy.
- A **phase III** cancer treatment trial compares a new treatment (or new use of a standard one) with the current standard treatment.

4. Why participate in a cancer prevention clinical trial?

People who do not have cancer can take part in cancer prevention clinical trials to try to prevent the disease from occurring. Some people who have had cancer can participate in prevention trials to try to reduce the chance of either developing a new type of cancer or to prevent the cancer from recurring (coming back). Prevention clinical trials are important because through research, scientists hope to determine what steps are effective in preventing cancer or finding cancer early.

There are two kinds of cancer prevention clinical trials. *Action studies* (doing something) focus on finding out whether actions people take, such as exercising more or quitting

smoking, can prevent cancer. *Agent studies* (taking something) focus on examining whether taking certain medicines, vitamins, minerals, or food supplements (or a combination of them) can prevent cancer.

5. Why participate in a cancer treatment clinical trial?

Patients take part in cancer treatment clinical trials in hopes for a cure, a longer time to live, or a way to feel better. Often, patients feel that taking part in clinical trials benefits others by improving future cancer treatment options. Cancer treatment studies lead to advances in cancer treatment, which may become the future standard care. Many clinical trial participants may be the first to receive new treatments before they are widely available. No cancer patient goes without treatment or receives a placebo (inactive substance) when there is a standard cancer therapy available.

6. Where do patients receive care?

When participating in a DoD/NCI clinical trial, patients are closely monitored and cared for in the same facilities where standard care is provided. These facilities include more than 2,000 sites throughout the United States, such as military hospitals, clinics, cancer centers, community hospitals, and doctors' offices.

7. Who is eligible to participate in the DoD/NCI clinical trials agreement?

TRICARE beneficiaries, including retired service members and their families, and family members of active duty personnel are eligible. Medical care costs are covered when participating in both phase II and phase III NCI-sponsored clinical trials in civilian health care facilities and in military treatment facilities. Active duty members can participate in clinical trials at military treatment facilities.

8. What is covered?

Costs for screening tests to determine clinical trial eligibility, as well as the related costs of participating in the trial, are covered under this demonstration project. All usual TRICARE rules, cost shares, and deductibles apply, and eligible patients may receive care out of the TRICARE network.

9. How can patients and health care providers learn more?

Patients and providers can learn more about patient participation in the DoD/NCI clinical trials demonstration project through the resources listed below.

- **Over the phone:** Call the NCI's Cancer Information Service (CIS) at 1-800-4-CANCER (1-800-422-6237), Monday through Friday, 9:00 a.m. to 4:30 p.m., local time. The CIS is a national information and education network that provides up-to-date cancer information to patients, their families, health professionals, and the general public. CIS information specialists have

access to PDQ®, NCI's comprehensive computer database of cancer information, and can share information from PDQ about clinical trials covered by the demonstration project. The CIS responds to calls in English and Spanish. Deaf and hard of hearing callers may use the toll-free TTY number at 1-800-332-8615.

Also, the DoD cancer trials demonstration project coordinator may be contacted at 1-800-395-7821 in regions 6, 9, 10, 11, 12 and the Central region, or 1-800-779-3060 in all other regions. Patients and health care providers can call for more information about using and authorizing this benefit, or they may contact a case manager. Pre-authorization is required only when patients are treated in a clinical trial outside of a military treatment facility.

- **On the Internet:** The NCI has many online resources to help people locate cancer clinical trials and cancer information.

The NCI's Web site (<http://cancer.gov>) provides up-to-date PDQ cancer information summaries on prevention, screening, treatment, supportive care, and complementary and alternative medicine for many types of cancer.

The clinical trials page of NCI's Web site (http://cancer.gov/clinical_trials/) provides the latest news in cancer research and general information about clinical trials. This page also has a feature that allows users to search for trials using specific criteria, including the trial's location. Instructions for finding trials being conducted at military treatment facilities are available on the Veterans Affairs and Department of Defense Beneficiaries Digest Page at <http://cancer.gov/clinicaltrials/digestpage/VA-DOD> on the Internet.

For assistance in navigating Cancer.gov and other NCI Web sites, Internet users can chat online with an information specialist using the NCI's *LiveHelp* service. Through *LiveHelp*, information specialists provide Internet users with help in navigating NCI Web sites, searching for clinical trials, and finding answers to questions about cancer. The service is available from 9:00 a.m. to 10:00 p.m. Eastern time, Monday through Friday.

TRICARE's guide to the cancer clinical trials demonstration project is available at <http://tricare.osd.mil/cancertrials/> on the Internet.

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

NCI Online

Internet

Use <http://cancer.gov> to reach the NCI's Web site.

LiveHelp

Cancer Information Specialists offer online assistance through the *LiveHelp* link on the NCI's Web site.

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