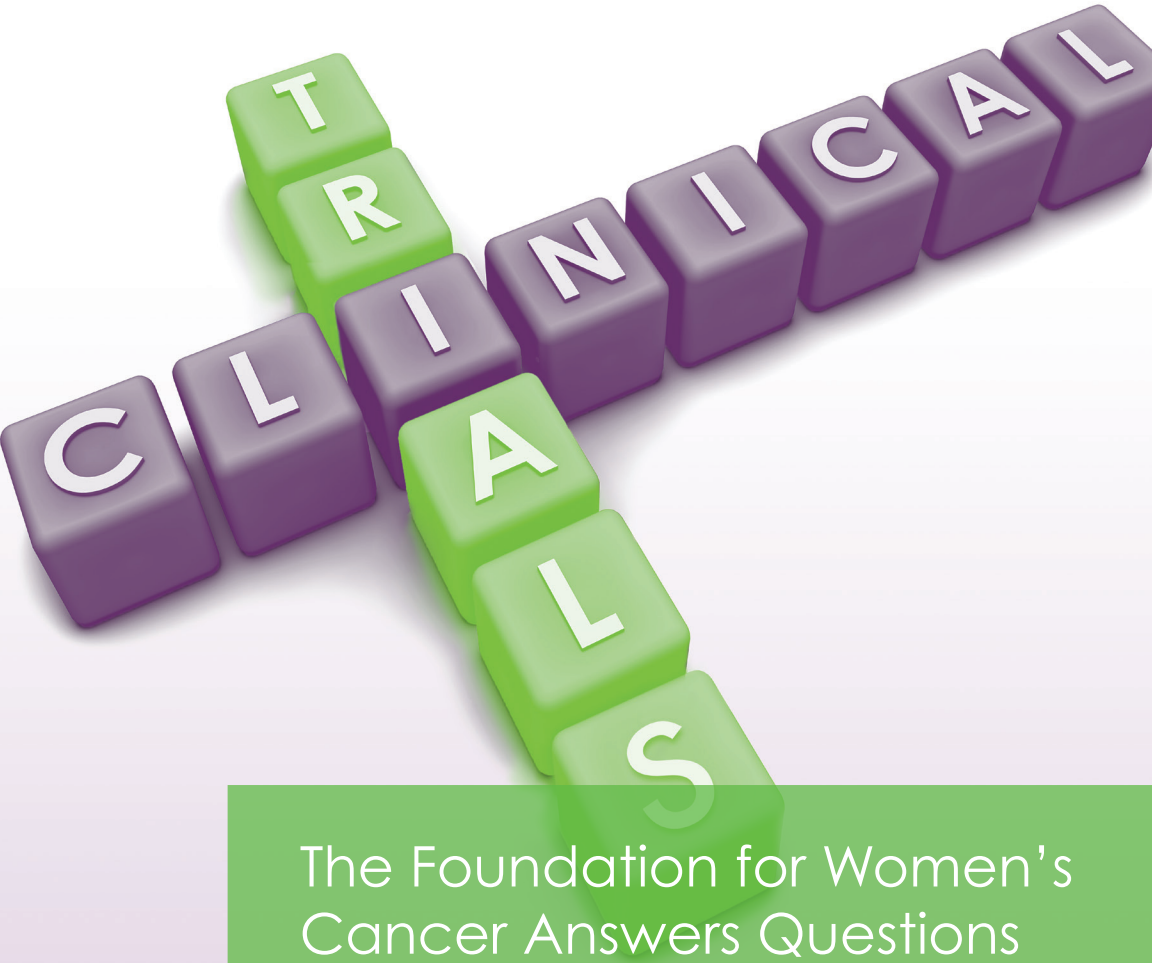
FOUNDATION FOR WOMEN'S CANCER

Gynecologic Cancer
Awareness • Research • Education



The Foundation for Women's Cancer Answers Questions about Clinical Trials

foundationforwomenscancer.org

Clinical trials are the key to improving the prevention, diagnosis, and safe and effective cancer treatment. They are the process through which standards of care are defined. The Foundation for Women's Cancer is pleased to offer answers to your questions about these trials, especially as you consider participation. It is our hope that this information will help you understand the process, and goals and objectives of clinical trials in order to broaden your general knowledge and provide a framework to help you make a decision about participating in a trial that is right for you.

WHAT ARE CLINICAL TRIALS?

Clinical trials are research studies that investigate treatments and observe patient performance with new treatments. They play an important role in developing new treatment options for a variety of diseases, including gynecologic cancers. Before any treatment can be tested in humans, it must show positive results in the laboratory and/or in animal studies.

Gynecologic cancer clinical trials are necessary to determine whether new treatments developed in the laboratory are beneficial to women living with a gynecologic cancer. There are two primary entities devoted to ensuring that clinical trials are conducted in an ethical and scientific manner.

The United States Food and Drug Administration (FDA) monitors clinical trials to protect participants and the general public. In addition, institutions conducting clinical trials must establish an Institutional Review Board (IRB) which is a committee that has been formally designated to approve, monitor and review biomedical and behavioral research involving humans.

A clinical trial is one of the final stages of a long and careful gynecologic cancer research process. The research usually includes new drugs, new treatment combinations, or new medical devices or technologies. Most clinical trials are classified as a Phase I, Phase II or Phase III trial. In addition, after a treatment has been approved and is being offered to patients, the drug's maker may study it further in a Phase IV trial.

PHASE I TRIALS

Phase I is the first step in testing a new therapy in humans. At this point, the therapy has already shown effectiveness in the laboratory. In Phase I studies, a small group of patients, usually between 20 and 40 women, are tested with the new treatment. The goal of Phase I studies is to determine safety, the appropriate dose and how the treatment is processed inside the body. Generally the best way to administer the drug (by mouth or injection) has already been determined. Participants are closely monitored for side effects and doses are adjusted as needed.

PHASE II TRIALS

Phase II trials involve a larger number of participants, usually between 25 and 100 women. These trials continue to test the safety of the drug, or a combination of drugs, and begin to evaluate how well the new drugs(s) work. Phase II trials usually focus on a particular type of cancer, such as ovarian cancer, and are designed to learn more about side effects of the drug(s).

PHASE III TRIALS

Phase III trials test how a new drug or combination of drugs, or a new surgical procedure, compares with the currently approved standard treatment. Phase III trials are randomized, meaning that women have an equal chance of being assigned to either the new therapy group or the approved treatment group. In order to prevent bias, the participant and the doctor administering the treatment may not know to which treatment group the woman has been assigned.

Phase III trials often enroll large number of women (between 100 and 1,000 patients) and are used to determine if the new treatment is more effective than the standard of care. These trials may be conducted in doctors' offices, clinics and cancer centers nationwide, or even worldwide.

If the new therapy is found to be effective and meets safety requirements, an application will be submitted for FDA approval.

PHASE IV

Phase IV trials take place after a therapy has been approved by the FDA. The drug manufacturer may continue, or be required by the FDA, to continue to test the drug over a longer period of time with a larger number of participants to determine long-term safety and cost effectiveness, and to improve the management of side effects.

IMPORTANCE OF CLINICAL TRIALS PARTICIPATION

Only about 5% of women with a gynecologic cancer participate in the dozens of clinical trials available for gynecologic cancer. The primary hope for improving the treatment options for women diagnosed with a gynecologic cancer is through the conduct of clinical trials.

The Foundation for Women's Cancer actively works with NRG Oncology, formerly the Gynecologic Oncology Group (GOG), to encourage women to participate in clinical trials. This is one of the five clinical research organizations funded by the National Institutes of Health.

Clinical trials are a crucial step in finding new and promising ways to improve treatment for women diagnosed with a gynecologic cancer.

Three examples of the important advances in the care of women as a result of clinical trials include:

- Chemotherapy added to radiation improve cure rate in locally advanced cervical cancer (GOG 120, 109)
- Platinum based chemotherapy plus paclitaxel is superior to platinum based chemotherapy plus cyclophosphamide (GOG 111)
- IP therapy improves survival in subsets of women with newly diagnosed advanced ovarian cancer (GOG 172)

The patients who participated in the Phase III clinical trials that led to these discoveries were among the first to benefit from these scientific advancements.

What are the potential benefits to participating in a clinical trial?

- Health care provided by leading physicians in the field of gynecologic cancer research
- Access to new drugs and interventions before they are widely available
- Close monitoring of your health and side effects
- A more active role in your health care
- If the approach being studied is found to be helpful, you may be among the first to benefit
- An opportunity to make a valuable contribution to gynecologic cancer research, helping other women diagnosed in the future

Are there potential risks in participating in a clinical trial?

- New drugs and procedures may have side effects or risks unknown to the doctors
- New drugs and procedures may be ineffective, or less effective, than current approaches
- Even if the new approach has benefits, it may not work for you personally

How do I know if I am eligible to participate in a clinical trial?

Each study has its own eligibility criteria for participation. To ensure the strongest results, researchers want study participants to be alike in key ways. For example, a treatment trial might be for a particular type and stage of a gynecologic cancer, and other factors, like the woman's age or previous treatments, might also be included in the eligibility criteria.

How can I find out what clinical trial might be right for me?

The Foundation for Women's Cancer works closely with NRG Oncology to make information about active clinical trials readily available. To access this information, visit:

foundationforwomenscancer.org/clinicaltrials/NRGgrouptrials.

Each gynecologic cancer trial being conducted by NRG Oncology is listed with a link to learn more about the eligibility requirements for the trial. In most cases, contact information is listed for an individual who can answer your questions about the particular trial.

Once you find a clinical trial that you are considering, you will need to talk to your doctor or clinical trials staff who can answer questions as they relate to your particular case. Here are some questions to ask when talking to them:

1. What kinds of therapies, procedures and/or tests will I have during the trial?
2. How will the trial affect my current treatment plan and daily life?
3. Will I be taken off my current treatment plan or will I continue to take my regular medications while in the trial?
4. Where will I receive my cancer care and who will be in charge of my care?
5. If the person in charge of my cancer care during the trial is different from the doctor from whom I receive my current care, what will be the communication/interaction between the two?
6. What are the benefits to my treatment offered by this particular trial?
7. Are there any potential side effects or risks connected to this particular trial?
8. Who do I call if I have questions about the trial once I am enrolled?
9. How can I drop out of the trial if I don't like it or change my mind?
10. Will my insurance cover the costs of my participation?
11. Will I have any out-of-pocket expenses?
12. How long will the trial last?

Additional information you might have questions about includes:

1. What is the purpose of the study — is it to determine the effectiveness of a new drug or a new combination of drugs/treatment?
2. Who is the sponsor of the study?
3. Who has reviewed and approved the study?
4. How are study results and participant safety being checked while the study is underway?

What is a randomized clinical trial?

A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized.

What is a treatment arm?

A treatment arm is any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more.

What is a placebo?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

If I enroll in a clinical trial, will I get a placebo rather than my regular treatment?

No. Obviously, a cancer patient who is in need of treatment would not be given a placebo. However, there are situations where patients have received treatment for their cancer and it is not known whether additional treatment would improve the outcome. In these situations, a portion of a study population may receive a placebo while others are given additional treatment. Such patients are always made aware that they might be receiving a placebo. The potential advantage for the placebo group is they may avoid the toxicity of additional treatment that may offer no better outcome than simple observation.

Can I be in more than one clinical trial?

Yes. Whether you are eligible depends on the criteria set for each trial. In some cases, the treatment you had in a prior trial may exclude you from being in a later one using the same or a related treatment. However, being in one clinical trial will not necessarily keep you from being in another one later.

Are the costs covered when participating in a clinical trial?

The federal health care reform law — the Patient Protection and Affordable Care Act (ACA) — includes the requirement that private insurers cover the routine patient costs associated with participation in approved clinical trials starting in January 2014. In addition, 38 states and the District of Columbia have laws or cooperative agreements requiring insurers to cover the routine patient costs associated with clinical trials. The American Society of Clinical Oncology is an excellent resource regarding this requirement. For more information, go to **asco.org/insurance-coverage-clinical-trial-participants**.

The cost of the research itself is paid for by the sponsoring organization or governmental entity.

We advise you to check with your individual insurance company to verify what is covered based upon your particular plan.

SAFETY AND INFORMED CONSENT

The federal government requires a system to protect individuals who participate in clinical trials. The protocol, or plan for the trial, must be approved by a Institutional Review Board (IRB) before the trial can begin.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of individuals participating in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of those who volunteer to participate in a research study.

The clinical trial doctors and staff have special training in the design and conduct of clinical trials. As referenced above, all clinical trials are locally reviewed by an IRB to ensure both the scientific value and safety of the trial. Several layers of safety evaluations and protection exist both at the local institution and the sponsoring organization, including the federal government.

This includes the requirement that the researchers thoroughly inform patients about the study's treatments and tests, and possible benefits and risks. This process must be undertaken before the patient decides whether or not to participate in any study. This process is called informed consent, and you will be required to sign a document(s) that states that you have been fully informed about the trial as part of the enrollment process.

We hope that this information is helpful to you as you consider participating in a gynecologic cancer clinical trial. As referenced earlier, the primary hope for improving the treatment options for women diagnosed with a gynecologic cancer is through the conduct of clinical trials. Thank you for your consideration of being part of this effort to improve treatment options for women diagnosed with a gynecologic cancer.

OTHER RESOURCES

- Cancer.gov/clinicaltrials
- ClinicalTrials.gov
- Emergingmed.com

About the Foundation for Women's Cancer

The Foundation for Women's Cancer is a 501(c)(3) not-for-profit organization whose mission is to ensure public awareness of gynecologic cancer prevention early detection and optimal treatment. In addition, the Foundation supports research and training related to gynecologic cancers. The Foundation advances this mission by increasing public and private funds to aid in the development and implementation of mission-driven programs to meet these goals.

For more information about the Foundation, its educational materials and research grants, please visit foundationforwomenscancer.org or contact the Foundation Headquarters Office by phone at 312.578.1439, or by email at info@foundationforwomenscancer.org.

FOUNDATION FOR WOMEN'S CANCER

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Awareness • Research • Education

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