

Quick Guide to Clinical Trials

A **clinical trial** is a research study that “prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” Practically speaking, clinical trials are research studies that find and test new treatments or procedures. Without clinical trials, we would not have the medical and scientific advances that we have today.

There is a great deal of confusion about clinical trials. This Quick Guide provides resources to help you learn more about participating in a clinical trial, to dispel myths about clinical trials, and to help you find clinical trials that might be available to you.

Finding a Clinical Trial

Work with your health care team to identify a clinical trial that might be a good fit for you. There are many resources available to help you find a clinical trial:

- National Cancer Institute: www.cancer.gov/about-cancer/treatment/clinical-trials/search
- National Institutes of Health: <https://clinicaltrials.gov>
- To find other clinical trials databases and matching services: TriageCancer.org/Clinical-Trials

Qualifying for a Clinical Trial

Just because you are eligible for a trial does not mean that you will be accepted. Some clinical trials only accept a certain number of patients. Or, you may want to participate in a trial that you are not eligible for because you have already had different treatments. In that case, you can ask your doctor to request a special exception to access the trial, but if approved, your results will not be included in the research study. The Food and Drug Administration (FDA) also has an Expanded Access program that allows people access to drugs or devices that have not yet been approved by the FDA:

www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

ACT: About Clinical Trials

The American Cancer Society (ACS) and Genentech have partnered together to provide information about participating in clinical trials. Triage Cancer participated in this series of videos providing useful information to help you understand clinical trials and make choices about what is best for you.

At TriageCancer.org/Clinical-Trials, you will find six, free informational videos:

- Why Should I Consider a Cancer Clinical Trial?
- How Will I Know if a Trial is Right for Me?
- How Should I Prepare for Discussions With My Doctor?
- What Standards Safeguard Trial Participants?
- What Is Informed Consent?
- Where Can I Turn for Information and Support?



Insurance Coverage for Clinical Trials

- It is important to talk with your health care team and your insurance company to find out what insurance coverage you have for participating in a clinical trial and what out-of-pocket costs you might expect to pay. The Patient Protection & Affordable Care Act (ACA) requires most private insurance companies to cover the routine costs of your health care when you participate in a clinical trial. Routine costs include office visits, blood tests, and imaging scans that you would receive if you were getting the standard of care. Insurance companies cannot drop your coverage or refuse to let you take part in the clinical trial.
- Insurance companies are not required to cover the research costs that are specific to the clinical trial, such as extra blood tests or imaging scans. However, most clinical trials will cover those costs. Insurance companies are also not required to cover care that you receive from doctors or hospitals that are outside the insurance companies network, if your plan does not normally cover out-of-network providers. Some insurance companies will cover out-of-network providers, but at a lower rate, meaning that you will have higher out-of-pocket costs when getting care from those providers.
- Some states may have laws that offer additional protections for consumers: <https://trriagecancer.org/health-insurance-state-laws#hinav>
- Different rules apply for government programs such as Medicare, military, and VA plans: www.cancer.gov/about-cancer/treatment/clinical-trials/paying/federal-programs
- After 1/1/22, Medicaid will cover routine patient costs associated with clinical trials. Medicaid cannot deny coverage based on the state where the clinical trial is conducted, or whether the provider is in-network for Medicaid. For details: www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf.

Other Things to Consider When Participating in a Clinical Trial

When deciding to participate in a clinical trial, you should also consider other factors that might impact your decision, such as:

- Where is the trial located?
 - Will you have additional transportation expenses (ground/air, parking, tolls, lodging, etc.)?
- What is the time commitment?
 - Will it impact your ability to work or care for your family (minor children, aging parents, etc.)?

Here are other questions to help you make a decision about whether or not to participate in a clinical trial: www.cancer.gov/about-cancer/treatment/clinical-trials/questions.

When an Insurance Company Says No

For information on appealing an insurance company denial of coverage: TriageCancer.org/cancer-finances-appeals.

For More Information About Clinical Trials

- Triage Cancer: TriageCancer.org/Clinical-Trials
- Triage Cancer Animated Video - How to Find & Pay For Clinical Trials: TriageCancer.org/Video-ClinicalTrials

