About Clinical Trials [1]

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Key Messages:

- Clinical trials enroll people in studies to help make progress in preventing, diagnosing, and treating cancer.
- Each clinical trial follows a set of rules called a protocol that describes who can participate in the study and how the treatment will be given and monitored.
- Governmental and non-governmental organizations may sponsor clinical trials, and people may participate in a clinical trial at a variety of hospitals and doctors? offices.
- The sponsor pays for many of the costs of participating in a clinical trial, but it is important to talk with your doctor about the possible costs you?ll need to pay.

To make scientific advances, doctors create research studies involving volunteers, called clinical trials. Many clinical trials evaluate new treatments to find out whether they are safe, effective, and possibly better than the current (standard) treatment. However, there are many different types of clinical trials. Some studies test different combinations of existing treatments, new approaches to radiation therapy or surgery, and new methods of treatment. There are also clinical trials that study new ways to ease symptoms and side effects during treatment and manage the late effects that may occur after treatment. In addition, there are ongoing studies about ways to prevent cancer.

Some clinical trials, called placebo-controlled clinical trials, compare a new treatment with a placebo (an inactive drug or treatment). The use of placebos alone in cancer clinical trials is rare; they are used when there is no effective, standard treatment available, or they are given in addition to standard treatment. They are also given along with treatment to manage any symptoms and side effects of the cancer, called supportive or palliative care [3]. The research team will let participants know when a placebo is a possible option in a study. Find out more about placebos in cancer clinical trials [4].

The importance of clinical trials

Cancer clinical trials have led to scientific advances that have increased doctors' understanding of how and why tumors develop and grow. This knowledge has helped doctors make progress [5] in preventing cancer, diagnosing cancer, slowing or stopping the development of cancer, and

finding cancers that have come back after treatment. Because clinical trials may involve hundreds or even thousands of people, it often takes a long time to find out the results. This process is also ongoing. As new information is learned and studied, new standards of care are added to or replace the old standards. Still, clinical trials remain the most reliable and only accepted scientific method to find out if a new treatment works better than the current standard of care.

Despite the promise offered by clinical trials, less than 5% of adults with cancer enroll in them. This low level of participation slows progress in the development of new, more effective therapies. By contrast, more than 60% of children with cancer receive treatment through a clinical trial. Approximately three-quarters of children with cancer survive long-term, compared with half of adults. The increased survival rate for children can be directly linked to the enrollment of patients in cancer clinical trials over many years whose experience led to better treatments and better outcomes. Read stories about patients who have participated in clinical trials [6] and find out what led them to participate.

How clinical trials are set up

All clinical trials have requirements about who can join, called inclusion and exclusion criteria. Examples of the criteria are a person's age, type of disease, medical history, and current health.

Inclusion criteria help make sure that all the people in the clinical trial are medically similar. For example, the inclusion criteria may require that each participant have the same kind of cancer or the same stage of disease (such as stage IIA colorectal cancer). If the people have too many medical differences, the doctors will have more difficulty interpreting the results.

Likewise, exclusion criteria help keep people safe. For example, it is often not safe for patients with a severe heart condition or kidney failure to receive some cancer treatments, so they may be excluded from some clinical trials. Exclusion criteria are not used to reject people personally but to protect people from potential risks and increase what doctors and researchers can learn from each study.

Each clinical trial follows a set of rules called a protocol. A protocol describes inclusion and exclusion criteria; the schedule of tests, procedures, medications, and doses; and the length of the study.

While a person is participating in a clinical trial and often for a time after the treatment has ended, the research team monitors the health of the participants to determine the safety and effectiveness of the treatment. The research team [7] includes doctors, nurses, social workers, and other health care professionals. They will check the person?s health at the beginning of the clinical trial, give specific instructions for participating in the clinical trial, monitor the person carefully during the clinical trial, and stay in touch with the person after the study. A person's participation will be most successful if they carefully follow the instructions given to them by the research team and stay in contact with the research staff.

Clinical trial sponsorship

Clinical trials are sponsored by government agencies such as the National Institutes of Health

(NIH), including the National Cancer Institute (NCI), pharmaceutical companies, individual doctors, health care centers such as health maintenance organizations (HMOs), and organizations that develop medical devices or equipment. Clinical trials can take place in hospitals, universities, doctor's offices, or community clinics.

One effective way to operate clinical trials is through an NCI-funded cooperative group. Cooperative groups are large networks of doctors and other health care professionals from many different centers that develop and coordinate clinical trials. Cooperative groups are funded by the NCI. Because so many doctors and institutions are involved, the clinical trials sponsored by cooperative groups can enroll more people than a single clinical trial at one hospital. Also, the cooperation makes it easier for people from different parts of the country to enroll in a clinical trial. Find an NCI cancer center or cooperative group [8].

More Information

ASCO Answers Fact Sheet: Clinical Trials (PDF) [9]

Finding a Clinical Trial [10]

Cancer.Net Video: What are Clinical Trials, with Richard Goldberg, MD [11]

Cancer.Net Video: Types of Cancer Clinical Trials, with Louis Weiner, MD [12]

Cancer.Net Video: Clinical Trials and Safety with Eric Singer, MD, MA [13]

Additional Resources

National Cancer Institute: Clinical Trials [14]

ClinicalTrials.gov: Learn About Clinical Studies [15]

Center for Information and Study on Clinical Research Participation [16]

Links:
[1] http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/about-clinical-trials
[2] http://www.cancer.net/about-us
[3] http://www.cancer.net/node/25282
[4] http://www.cancer.net/node/24390
[5] http://www.cancerprogress.net/
[6] http://www.cancerprogress.net/stories
[7] http://www.cancer.net/node/24957
[8] http://www.cancer.net/publications-and-resources/support-and-resource-links/general-cancer-organizations-and-resources/cancer-centers-coop-groups
[9] http://www.cancer.net/sites/cancer.net/files/asco_answers_clinical_trials.pdf
[10] http://www.cancer.net/node/24878
[11] http://www.cancer.net/node/27106
[12] http://www.cancer.net/node/27086
[13] http://www.cancer.net/node/27076
[14] http://www.cancer.gov/clinicaltrials
[15] http://www.clinicaltrials.gov/ct2/info/understand
[16] http://www.ciscrp.org/