Cancer Clinical Trials

Clinical trials are used to evaluate tests or treatments that have not yet been proven to be effective. Clinical trials rely on volunteers to take part in them. The June 9, 2004, issue of JAMA includes an article about patients who participate in cancer clinical trials.

**PHASES OF TREATMENT TRIALS**

- **Phase 1 trials** are conducted to determine if a new treatment is safe and what doses can be given and to discover the main adverse effects of the new treatment. At this first phase, a small number of patients are enrolled.
- **Phase 2 trials** further evaluate the safety and potential effectiveness of a therapy and evaluate how it affects the body.
- **Phase 3 trials** provide scientific testing of the value of a new treatment. Participants are randomly (by chance, like flipping a coin) assigned to receive the new therapy, the current standard therapy, or a placebo (an inactive pill or procedure). Most new therapies move on to phase 3 trials only if they have shown promise during phase 1 and phase 2 trials.
- **Phase 4 trials** evaluate the long-term safety of the new treatment and take place after the new treatment has been approved for use.

**ELIGIBILITY TO PARTICIPATE IN A CLINICAL TRIAL**

Every clinical trial has guidelines that outline who can and cannot participate in the study. These guidelines are called eligibility criteria. Cancer clinical trials usually require that patients have a particular type or stage of cancer to participate.

**INFORMED CONSENT**

Patients who wish to enroll in a clinical trial must give informed consent before participating. Informed consent ensures that patients understand the potential risks and benefits of joining a clinical trial prior to participating. During the informed consent process, participants are told about what the trial involves and the purpose of the study. Participants sign an informed consent form to acknowledge that they understand the risks and benefits of the study, but the form is not binding, and participants can leave the study at any time for any reason.

**BENEFITS OF PARTICIPATING IN A CLINICAL TRIAL**

- Participants may receive promising new therapies that are not available to the public.
- Participants are closely monitored by researchers, doctors, and other health care professionals during the clinical trial.
- Results from the clinical trial may help other patients in the future.

**RISKS OF PARTICIPATING IN A CLINICAL TRIAL**

- New therapies are not always better than standard treatments with which they are compared.
- New treatments may have unexpected adverse effects or risks.
- Participants in randomized trials may not receive the therapy they want.
- Health insurance may not cover all of the costs associated with participating in a clinical trial. Disclosure about any costs should be part of the informed consent.

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