

## Fact Sheet:

### Understanding Clinical Trials

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- ✧ A clinical trial is a health-related research study in human beings that follows a pre-defined protocol. Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.
- ✧ All **clinical trials have guidelines** about who can participate. The factors that allow someone to participate in a trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria." These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.
- ✧ You can **learn about applicable clinical trials** by going to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and searching for a particular medical condition.
- ✧ Clinical trials are **conducted in phases**. The trials at each phase have a different purpose and help scientists answer different questions:
  - In **Phase I** or "First in Man" trials, researchers test an experimental treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
  - In **Phase II** or "Pivotal trials," the experimental study treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
  - In **Phase III trials**, the experimental study treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental treatment to be used safely.
  - In **Phase IV trials**, post-marketing studies describe additional information, including the risks, benefits and optimal use for treatments.
- ✧ There are different types of clinical trials.
  - **Treatment trials** test experimental treatments or devices, new combinations of drugs or new approaches to procedures, surgery or radiation therapy.
  - **Prevention trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from progressing or returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
  - **Diagnostic trials** are conducted to find better tests or procedures for diagnosing a particular disease or condition.
  - **Screening trials** test the best way to detect certain diseases or health conditions.
  - **Quality of Life trials** explore ways to improve comfort and the quality of life for individuals with a chronic illness.
- ✧ A **control group** is the standard by which clinical trials are evaluated. In many trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo (an inactive pill, liquid or powder that has no treatment value).

- ✧ The **clinical trial team** includes doctors and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.
- ✧ Clinical **trials are funded** by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and companies, in addition to federal agencies such as the National Institutes of Health (NIH).
- ✧ The **benefits of participating in a clinical trial** include:
  - Playing an active role in one's own health care.
  - Gaining access to new research treatments before they are widely available.
  - Obtaining expert medical care at leading health care facilities during the trial.
  - Helping others by contributing to medical research.
- ✧ The **risks of participating in a clinical trial** include:
  - There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
  - The experimental treatment may not be effective for the participant.
  - The protocol may require more time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

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