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# About Clinical Trials

## Clinical trials are usually categorized into three phases:

- **Phase I** trials evaluate the safety of new pharmaceutical compounds in the body, as well as methods for safely administering these drugs, including dosage and delivery (such as oral, injection, and intravenous). These trials involve a small number of patients -- usually no fewer than 20 and no more than 80.
- **Phase II** trials measure a new treatment?s efficacy, or how well it works, and may also gather additional information. Phase II trials typically involve 100 to 300 patients.
- **Phase III** trials compare a new strategy to an approach that is already in use. These studies involve larger numbers of patients -- typically 1,000 to 3,000. Participants are randomly selected to either receive the new treatment or the standard one, and data from the two groups are compared.

Protocols are reviewed for approval by one or more bodies associated with the research institution. The UCSF Comprehensive Cancer Center requires approval from three groups:

- The Site Committee evaluates protocols from the standpoint of a particular cancer site, organ, or type of disease, so that available resources can be applied to the most promising new treatments.
- The Protocol Review Committee evaluates the scientific integrity of the protocol, ensuring that the study will yield useful data and that it will answer the questions it has raised.
- The Committee on Human Research considers the ethics and risks that apply to a particular study. In many institutions, this committee is called the Institutional Review Board, or IRB.

Other checks and balances include safety and data monitoring committees for Phase III trials.

For more information about clinical trials http://clinicaltrials.gov/ct2/info/understand [1]

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UCSF Main Site



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**Links**
[1] http://clinicaltrials.gov/ct2/info/understand