

## Phase I Clinical Trials

The discovery of a potential new medicine or device is an important and exciting event. But before it is finally introduced – and although many patients and doctors may be eager to actually use it – the treatment has to pass through a well-defined procedure which may take many years. This is known as a clinical trial or clinical study.

Clinical trials are divided into phases. The first three phases take place before approval for broader use in the general population, and are designed to show the regulators exactly how effective the drug is and to ensure that it is safe to use. These may be followed by late phase studies, which are often used after approval to identify additional applications of the drug.

Phase I clinical trials will be the first time an investigational drug is tested on humans which means that the welfare of study volunteers is of vital importance. That's why, before the start of the trial, it is imperative to ensure that patients fully understand what is involved, so that they can give 'informed consent'. It is the responsibility of the healthcare professionals running the study to ensure this happens. They need to explain the benefits and risks, advantages and inconveniences of the research in everyday language, so that volunteers are comfortable with all aspects of the trial before agreeing to take part.

The actual number taking part is usually between 20 to 200. Most often, these participants aren't patients with illnesses, but healthy volunteers who consent to be given the new medications for the simple, vital purpose of testing their safety and gathering basic data. This phase of a trial seeks to determine suitability for further development and will document how a drug is metabolized and excreted, and will identify any side effects.



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All clinical trials have a written protocol or 'Study Plan' which is approved by the appropriate ethics committee and meets legal, ethical, practical regulatory and statistical requirements.

Clinical Research Organizations or CROs, manage trials on behalf of the pharmaceutical, biotechnology or medical device company developing the medicine. As experts who specialize in such clinical trials, CROs are responsible for recruiting and selecting trial participants, overseeing administration of the test medicine and the collection of accurate data about patient reactions. Throughout all phases of research, CROs help sponsor companies navigate through the regulatory maze.

During a trial, it is very important that patients are closely monitored to assure their safety and to ensure they are not exposed to unnecessary risk. Because of this, CROs often have their own specialized facilities for use as controlled environments in which to conduct medical trials. Every effort is made to make volunteers as comfortable as possible during their stay, providing facilities such as television, DVDs and the internet.

Only after results are collected and analyzed from these Phase I trials can a decision be made about whether to proceed to the next trial phase.

*Trials managed by CROs are conducted in accordance with all applicable laws and regulations, as well as recognized principles of Good Clinical Practice (GCP) wherever in the world they are conducted.*

*The Association of Clinical Research Organizations (ACRO) represents the world's leading CROs.*