

Phase II 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.

Once a drug has completed its Phase I trial and the dosage level has been confirmed suitable for further development, researchers move onto Phase II, the phase of a trial which determines whether the medication has an effect on the illness it is intended to treat.

Phase II trials tend to run for a period of two years with up to 300 patients. In most cases, the trial will be managed on behalf of the pharmaceutical, biotechnology or medical device company by a Clinical Research Organization or CRO, who will be responsible for finding these volunteers as well as accessing the doctors (known as investigators) and clinical sites that will be involved in the study.

The CROs will be able to find the strongest candidates for each criteria so that, for the study, patients will be the most suitable, investigators will put on a strong performance and data results will be easy to access. CROs work to a plan (protocol) written by the medicine's developers and, because of their experience, they will be able to cope with any special issues that may arise.

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 that 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.



227 Massachusetts Avenue, NE
Suite 300
Washington, DC 20002
T 202 543 4018
F 202 543 5327
E info@acrohealth.org
www.acrohealth.org

contact details

During the trial, the CRO will gather additional safety data and preliminary evidence of the drugs beneficial effects, constantly refining the research methods that will be used during future trials. CROs will also be responsible for monitoring for significant trends in results. If Phase II trials indicate that the drug may be effective, and its risks are considered acceptable in the context of its efficacy and the severity of the disease, the trial process will move forward.

Phase II trials are more complex than Phase I and often make use of 'control' groups who provide a basis for assessing the effects of the treatment under study. Sometimes these 'control' patients are given standard, previously approved treatments for the indication being studied, or they may be given an inactive compound, known as a 'placebo.'

To determine which patients receive the trial drug and which are included in the control group, researchers use a process called randomization, which randomly assigns patients to one group or the other. Random selection prevents bias or personal preference from influencing a trial's outcome.

Another means to prevent bias from affecting the trial's conduct or how its results are interpreted is 'blinding.' Most trials are 'double-blind trials,' meaning that neither the patient nor the researchers know which type of treatment (or placebo) the patient is receiving.

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.

