

Phase III 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.

Phase III trials begin after the trial's Phase II data has been reviewed and the treatment has been shown to be effective and safe enough to merit further study. As in other phases, Clinical Research Organizations (CROs) play a pivotal role in the conduct of Phase III trials. Indeed at this stage, their expertise can help get the drugs approved and delivered in good time to the patients who need them. Published data confirms this: "pharmaceutical companies reported to the Tufts Center for the Study of Drug Development that trials are more likely to stay on schedule, and data is more likely to be submitted to regulators on projected dates, when trials involve CROs."

CROs are responsible for selecting trial participants, which is more than a matter of recruiting mere numbers. They have to make sure the trial population is correctly balanced to age and race, so that results are a representative example of the eventual patient population. They will also train physicians in research techniques showing how to administer the test medicine and how to collect accurate data about patient reactions. CROs may also introduce a patient recruitment and patient retention programme to the study team.

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.

During Phase III, researchers seek to gather enough information to determine whether the drug merits regulatory approval for market use, and how it compares with other approved treatments in the same therapeutic class. CROs who can access large patient populations can really prove their worth at this stage and make considerable difference to the status of the study.



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Phase III trials are broken into two segments: Phase IIIa tests the drug with several hundred to several thousand subjects to verify its safety and efficacy on a large scale. Over a course of two to three years, Phase IIIa trials are conducted at a variety of locations with as diverse a population as possible.

While volunteers join trials for a number of reasons, Phase III trials are more likely to include patients with a particular medical condition that is not responding to currently available treatments.

Once Phase IIIa is complete, the drug's sponsor submits all pre-clinical, pharmacologic efficacy and safety data to the appropriate regulatory agencies, along with information on the drug's composition and plans for producing, packaging and labelling. Depending on the country and type of drug, the resulting regulatory review can take 30 months – or more – to complete.

During this review period, Phase IIIb trials begin. Using a large number of patients, Phase IIIb focuses on issues such as cost-effectiveness and efficacy compared with already approved drugs that are either in the same therapeutic class or are used to treat the same condition as the trial drug.

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.

