

Phase IV 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 don't necessarily end with a product's approval by regulators. It's only after a medicine has been approved for use that late phase trials begin.

Phase IV trials may be used to address the safety and efficacy of a drug when it's used for diseases or durations of time beyond those described in its original application to the regulatory authority. Or they may test different dosage strengths and formulations, such as a sustained-release capsule or a flavored solution for children, or confirm extra-clinical benefits such as cost-effectiveness or improved quality of life. Phase IV trials also collect and analyze long-term safety data from patients treated in normal practice.

Compared to the other trial phases, Phase IV trials are more 'real world' projects. They tend to be community based and involve doctors on an international scale. Because of this huge patient population, Phase IV expands the database to help identify rare events: for example, an adverse event that occurs at rate of 1 in 1,000.

During Phase IV, researchers have the opportunity to observe the effects of a drug on many thousands of people and so improve understanding of how the treatment performs in actual use. Phase IV also gives prescribing physicians practical experience with the new medicine.



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Sometimes regulators will approve a drug, with the proviso that it undergoes further testing. For example, if a newly approved medication is in the same class as other drugs with certain known side effects, regulators may want to review additional data reporting on the drug's long term effect on a large population. Phase IV trials may identify, or confirm side effects that were not readily apparent in earlier trials but have become clearer over time.

In other cases, the pharmaceutical or biotechnology company that originally developed a drug may want to learn whether the product has uses beyond the indication for which it was approved, or whether it offers benefits that weren't identified in its original clinical trials. For example, recent studies have examined the benefits of statins beyond their principal use of lowering cholesterol in the bloodstream. Their aim is to determine whether these drugs might be able to play a more direct role in preventing heart attacks.

Regardless of the objective of these trials, Clinical Research Organizations or CROs are at the forefront of managing Phase IV investigations. CROs provide the expertise to recruit the right patients and physicians for each trial, accurately monitor their participation and collect the data necessary for analysis – all in a timely and efficient manner.

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.

