



## Part one: What is a clinical trial?

A clinical trial is a research study that tests whether a new potential therapy is safe and effective for patients. It evaluates new drugs, behaviors, or devices, and reveals whether these potential therapies work for particular diseases or particular groups of patients. Clinical trials can provide the best available data for the approval of new disease treatments.

There are two main types of clinical trials: interventional studies and observational studies.

### Interventional studies

These are clinical trials testing whether a specific intervention (such as a drug, device, or behavioral change) affects health-related outcomes. Different groups of people are assigned at random to receive and not receive the intervention in a process called randomization. Typically, the group that does not receive the intervention – also known as the control arm – receives either the current standard of care or a placebo (a fake version of the intervention), depending on the condition. Interventional trials are typically blinded, meaning that the volunteer is not aware if they are in the control group or receiving the intervention, or double blinded, meaning that both the researcher and the volunteer are not aware.

### Observational studies

These studies are ones in which participants are put in groups based on their characteristics, and an intervention is tested in each of these groups. The difference is that the groups are assigned based on volunteer characteristics, rather than at random. Both types of studies follow a protocol, a detailed plan for the study written by the trial sponsor and approved by the FDA.

A **trial sponsor** is an organization which initiates, funds, and conducts a clinical trial. This is often a pharmaceutical company, but it can also be a university or another type of research organization. When selecting a clinical trial, it's important that potential volunteers are fully aware of and comfortable with who is sponsoring the trial.

Potential volunteers for trials can be anyone. While many people view clinical trials as a last resort only to be relied upon when all other options have been exhausted, this is not the case. Research studies need a variety of participants to enroll. Some trials are looking for volunteers who have been recently diagnosed, while others may only need those who have been living with a condition long-term. Certain studies may require patients who have had different treatment experiences in the past. Every trial is different, but with thousands of studies recruiting, there is likely a trial that is right for you.