

Clinical trials versus studies

Is there a difference?

A clinical trial is one of two main types of clinical studies. A clinical trial tests (or tries out) an intervention - a potential drug, medical device, activity, or procedure - in people. It's also referred to as an "interventional" clinical study.

The other main type of clinical study is an "observational" study. In an observational study, researchers keep a close eye on participants throughout their current treatment plan and track health outcomes.

Clinical studies are a major part of cystic fibrosis research. They take place at cystic fibrosis centres around Australia and enrol people with CF of all ages.

What's the Difference?

The terms "observational" and "interventional" describe the two main types of clinical studies. An interventional study refers specifically to a clinical trial in which researchers are testing a treatment method. The drug development pipeline refers mainly to clinical trials.

The treatment method can range from a potential drug to a treatment or even an exercise study. Participants receive one or more treatments (interventions) or a placebo so researchers can evaluate the effects on the participant's health.

The purpose of an observational study isn't to test potential treatments. These studies are used to develop new ideas about CF and how the disease might best be treated.

Many times, after a drug is approved, government regulation and monitoring requires that the pharmaceutical company continue to monitor the effectiveness and safety of the drug through observational studies.

Observational studies often take less time for people who participate in them and may involve questionnaires. Unlike interventional studies, a person with CF can be in more than one observational study at the same time because the studies do not involve changes to a treatment plan.

Under these two types of clinical studies, there are many sub-types. Some of these sub-types are not mutually exclusive. For example, a behavioural study could be observational or interventional.

Behavioural studies are designed to identify and understand how factors, such as self-management, mental health, and social support, are associated with health outcomes. Researchers can observe how the behaviour of people with CF affects their health in an observational study. Similarly, they can conduct an interventional behavioural trial to see if a change in behaviour can improve the health of people with CF.